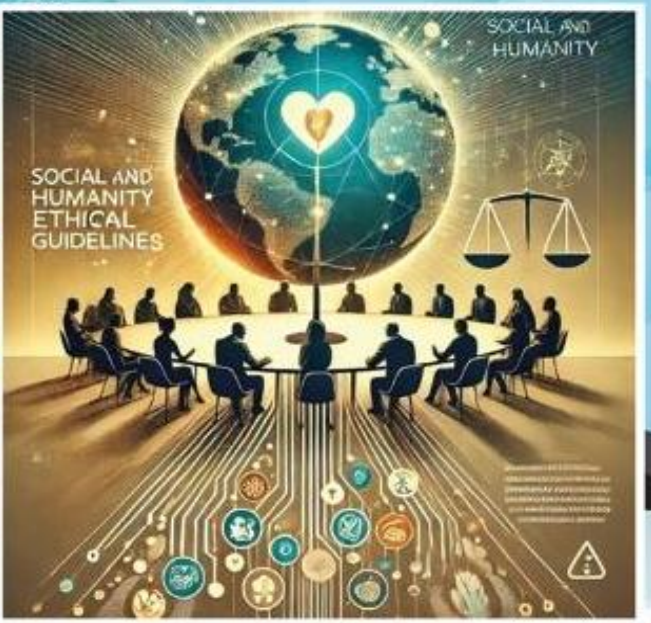
Health Systems Research Institute

Ethical Guidelines for Human Research in Social Sciences and Humanities



Working Group on the Development of Human Research Ethics Committee Project in Thailand

2024

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“The ethical justification for undertaking health-related research involving humans is its scientific and social value: the prospect of generating the knowledge and the means necessary to protect and promote people’s health.”

- CIOMS Guideline 1-

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Preface

The definition of “health” in the World Health Organization Charter states that “Health is a complete state of physical, mental, and social well-being, not merely the absence of disease or infirmity.” And the world recognizes that the factors determining good health are no less important than the “social determinants of health.” In addition, many studies, especially studies of single-egg twins, found that genetic factors are only 25 percent important for health while the rest is a matter of environment and behavior. In order to improve human health and medical development, it is necessary to conduct a lot of research and development in the social sciences and humanities.

Conducting research correctly, in terms of scientific merit and ethical principles, is necessary to ensure that research studies have reliable data and are accepted in various civilized countries. Adhering to ethical guidelines for human research is essential when the research involves or is related to humans.

In medical research, there are international guidelines that have been developed for quite some time, starting from the Nuremberg Rules, the Declaration of Helsinki, the International Council on Medical Sciences (CIOMS) International Ethical Guidelines, and the International Council on Harmonization Good Clinical Research Guidelines (ICH GCP). As for research guidelines in the social sciences and humanities, they have been developed in many countries, but there are currently no guidelines that are widely accepted in Thailand.

The Health Systems Research Institute (HSRI) has a role and duty to support research related to the public health system. Many research projects are in the social sciences and humanities; therefore, it is essential to have ethical guidelines for human research in the social sciences and humanities for researchers and ethics committees in these fields to use. Consequently, a project to develop such guidelines has been initiated, supported by several experts in research ethics in Thailand, led by Professor Dr. Juntra Karbwang and her team, who have extensive experience in this field both within the World Health Organization and in Thailand.

This project has received excellent cooperation from many leading scholars in the social sciences and humanities. The guidelines were developed after a review of various international and national frameworks, drafted, reviewed, and modified by scholars in the social sciences and humanities until an acceptable version was achieved for all stakeholders involved.

These guidelines will be used for social sciences and humanities research, specifically for projects supported by the Health Systems Research Institute (HSRI). If any agency or institution wishes to adopt these guidelines, HSRI welcomes and appreciates any feedback for future improvements.

Dr. Suphakit Siriluk
Director, HSRI

Statement

This edition of the “Ethical Guidelines for Human Research in the Social Sciences and Humanities” was developed by the Working Group on the Development of Human Research Ethics Committee Project in Thailand, focusing on social sciences, behavioral sciences, and humanities. The development process is outlined as follows:

1. The group thoroughly reviewed ethical guidelines for human research from educational institutions and research organizations across various countries to ensure a broad perspective.
2. Ethical issues pertinent to human research within Thai society were identified and collected to provide a contextual foundation for the guidelines.
3. The Working Group engaged in collaborative discussions to address ethical issues surrounding human research. They drafted guidelines that aligned with international ethical standards while also considering the unique research context and the protection of participants' rights in diverse aspects of Thai society. The draft guidelines were scrutinized, and feedback was received from social sciences and humanities experts. Multiple public hearings and meetings were held to gather further opinions and suggestions, allowing for thorough revisions and enhancements. This extensive process resulted in the current edition of the “Ethical Guidelines for Human Research in the Social Sciences and Humanities.”

The Working Group envisions these guidelines as a foundational platform for the ongoing development of human research ethics in the social sciences and humanities. The aim is to foster broad participation from scholars and relevant stakeholders, enabling continuous enhancement of these guidelines to ensure they are closely aligned with the specific research context and the challenges faced in Thai society while meeting international standards.

The successful creation of these research ethics guidelines is a testament to the collaborative efforts of researchers and experts in the social sciences and humanities, who have provided invaluable insights and feedback during the drafting process. We extend our heartfelt gratitude to everyone involved.

We acknowledge that there may be areas for improvement, and we welcome any constructive feedback or corrections. The Working Group is committed to refining these guidelines further to ensure their comprehensiveness in the future.

Vichai Chokevivat

Chair, the working group

Chapter 1

Glossary

Glossary

This guideline offers specific definitions of terminology relevant to research in social science and humanities, as follows:

1. Informed Consent Process

The informed consent process entails the procedure utilized to request consent from individuals interested in participating in research. It includes the consent requester, timing, location, and method of seeking consent. Its purpose is to ensure that prospective research participants can make decisions freely regarding their involvement in the research, without coercion, pressure, or circumstances hindering refusal. Appropriate timing is crucial to ensure that potential participants are not preoccupied with daily activities or experiencing stress or anxiety, which may affect decision-making. The ideal location for seeking consent should be quiet, comfortable, and private, conducive to providing information and addressing any confidential concerns. Prospective participants should be adequately informed about the research and given sufficient time to decide. Consent may be documented through written signatures, verbal agreement, or actions indicating consent.

2. Protocol Deviation

Any actions that deviate from the approved research protocol endorsed by the research ethics committee or the Ethics Committee (EC), encompassing deviations in research procedures, consent documentation, and associated tools such as questionnaires and data collection instruments.

3. Protocol Amendment

A formal description of changes or official clarifications to the research protocol subsequent to its approval.

4. Noncompliance

Instances where researchers or affiliated individuals fail to adhere to relevant laws, regulations, and requirements associated with the research endeavor.

5. Research Integrity

Research integrity entails conducting research in a manner that others can trust and have confidence in, both in terms of research methodology and the findings obtained from the research. Key components of research integrity include: (1) Honesty and integrity in presenting research proposals, conducting research, and reporting research findings; (2) Disclosure or declaration of conflicts of interest; (3) Accuracy and fairness in participation in research proposals, research conduct, and result reporting; (4) Protection of research participants according to the ethical principles of research involving human; (5) Humane care and treatment of animals according to ethical standards for the use of animals in scientific research; (6) Good association among research groups in academic terms, communication, and sharing of data or resources; (7) Commitment to shared responsibility among researchers, consultants, or mentors with research trainees; and (8) Expertise and fairness in research review.

6. Confidentiality

Safeguarding the privacy of research participants by not disclosing or divulging personal data of participants to individuals or organizations without proper authorization, except when required by law or with appropriate consent from the research participants.

7. Protocol Violation

Any deviations from the approved research protocol that significantly impact the rights, safety, and well-being of research participants, as well as the integrity of the research.

8. Research

A systematic scientific inquiry process designed to develop or generate generalizable knowledge. This knowledge encompasses theories, principles, relationships, or relevant data collected. It is knowledge that can be tested and confirmed using accepted scientific methods, including observation and inference.

9. Cross-cultural Research

Cross-cultural research involves collecting data from individuals originating from two or more distinct cultural backgrounds to compare them directly or indirectly. This type of research may involve comparing cultures in which the researcher is a part of one culture with the cultures of ethnic groups within the same country or abroad. Researchers conducting this type of research must be mindful of unequal economic and political power between

researchers and research participants stemming from past injustices and continuing into the present.

10. Ethnography

Ethnography is a research method used to study social group behaviors or even individual behavior in areas such as language, culture, value systems, organizational structures, and social systems. Its objective is to elucidate the meaning of actions in real-life situations. It is a research method aimed at describing the way of life and culture of people in a particular society, allowing for both macro-level cultural studies and micro-level studies focused on specific subgroups.

11. Community-Based Research (CBR)

Community-Based Research (CBR) is driven by the pressing issues within local communities. It emphasizes the process of learning and active involvement of stakeholders.

12. Research in Humanities

Research in humanities encompasses studies related to both living and non-living aspects of humanity, including tangible and intangible cultural heritage. It covers data concerning language, literature, history, archaeology, culture, religion, philosophy, art, and more.

13. Social Science Research

Social science research pertains to the study of human societies, encompassing all dimensions of human life, activities, and behaviors. This includes populations, institutions, social phenomena, and also extends to the field of primatology within physical anthropology.

14. School-Based Research

School-based research involves investigations concerning students and/or teachers, as well as school personnel. The objective of such research is to seek systematic and reliable knowledge to address educational variables and outcomes resulting from educational administration. The findings contribute to understanding various phenomena related to education, improving educational management effectiveness, and fostering educational innovations and reforms. Researchers may include teachers, school administrators, or external researchers, while participants may consist of students, teachers, and/or school personnel.

15. Community-Based Participatory Research (CBPR) or Participatory Action Research (PAR)

Community-Based Participatory Research (CBPR) aims to enhance the community's capacity to address its own issues by actively involving community members throughout the entire research process. This includes identifying significant community problems, drafting research proposals, analyzing results, and implementing actions for community development or improvement. Sometimes referred to as Participatory Action Research (PAR), this approach emphasizes collaborative engagement with the community.

16. Research in Psychology, Psychiatry, and Behavioral Science

Research on behavior, cognition, emotions, learning, and memory, including the behaviors of individuals, encompasses the impacts of mental states and mental health. It focuses on studying and testing psychological hypotheses related to emotions, learning, social systems, diverse behaviors, and processes that lead to behavior formation, as well as targeting behavior modification.

17. Archaeological Research

This refers to research on humans, culture, and the environment in ancient times. In the United States, this is considered a part of anthropology. In Europe, it is regarded as a specialized branch closely related to physical anthropology, including bioarchaeology and forensic archaeology, which are sub-disciplines of archaeology. This is because human skeletal remains are often discovered through archaeological excavations.

18. Research in Physical Anthropology

Physical anthropology is a branch of anthropology closely related to subfields of archaeology, including bioarchaeology and forensic archaeology. It involves studying skeletal remains, ancient human skeletons, current human skeletons, bodies that are proven to be related to specific individuals, groups, and contemporary races, as well as the study of primates.

19. Criminological Research

The study of law-breaking behavior or legal violations. It encompasses factors influencing criminal behavior, criminal acts, coping mechanisms for crime, social factors, psychology, mental health, offending, and rehabilitation of offenders. Additionally, it examines the various impacts arising from criminality and alternative justice processes.

20. Research Involving Humans

It comprises systematic scientific inquiries that affect the physical, mental, or social aspects of human beings. It encompasses the study of personal data, living or deceased human bodies, and body parts. Research involving humans can be categorized into three main types: (1) biomedical research, (2) social science research (including psychology, economics, and humanities-related research concerning individuals), and (3) epidemiological research. Research methodologies include data collection through actions or direct interactions with individuals, such as surveys, interviews, focus group discussions, and observation of behavior, including community populations.

21. Internet Research

It involves utilizing data within the internet network. This encompasses data obtained from the fundamental technological infrastructure based on IP addresses (Internet Protocol addresses—unique identifiers assigned to each device connected to the computer network system using the Internet Protocol for communication). It also includes other communication network systems such as GSM, 4G, wireless LAN systems, and other wireless telephony systems, area-specific service systems, biometric identity verification technology, and behaviorally unique or non-replicable physical characteristics (biometrics). This involves equipment sets, circuits, or systems for detecting changes in properties or features of objects (sensors) surrounding the target object, as well as digital data repositories (data storage).

22. Hospital-based Research

Hospital-based research involves investigations concerning hospital personnel, such as physicians, nurses, pharmacists, physical therapists, social workers, nutritionists, staff from various departments, patients, and their relatives. It encompasses general research aimed at acquiring knowledge or transitioning from routine to research (R2R) with the objective of utilizing research findings to enhance or improve the quality of routine work or service. Research problems stem from routine tasks requiring improvement, and researchers must be regular employees or primarily engaged in the subject matter under study. Outcome measurement involves direct assessment by service recipients or patients.

23. Covert Research

It refers to situations where researchers do not inform participants that they are being observed, as participants may alter their behavior if they become aware of being observed and recorded.

24. Deception Research

Deception research involves researchers intentionally deceiving or misleading research participants within the research context to obscure the true purpose of the study.

25. Ethics Committee

An institutional, organizational, or agency committee is established to oversee and ensure the protection of the rights, dignity, safety, and well-being of research participants. This committee reviews and approves research projects both scientifically and ethically, ensures continuous monitoring of research activities, reviews amendments to approved research projects, and oversees the process of obtaining informed consent and the documentation used for obtaining consent from potential research participants.

26. Cultural Sensitivity

The awareness, knowledge, and acceptance of cultural differences, beliefs, values, customs, and traditions. Researchers can adapt their behavior or communication patterns to be appropriate when interacting within culturally diverse environments. This involves respecting cultural norms, customs, language, behavior, traditions, cultural history, community values, and social norms within the context of specific local or regional settings.

27. Assent

The agreement of minors or individuals with impaired or reduced decision-making capacity must be accompanied by valid informed consent, obtained with genuine understanding from their parents, guardians, or legally authorized representatives.

28. Privacy

The condition in which individuals, groups, or organizations are not disturbed or intruded upon by others and the public, both physically and in terms of personal information.

29. Valid Informed Consent

Valid informed consent involves obtaining consent entails receiving complete and relevant information crucial for informed decision-making, ensuring genuine comprehension, and voluntary decision-making free from coercion, deception, pressure, or situations that make it difficult to refuse, especially in relation to individuals in positions of authority.

30. Broad Consent

Broad consent for future research involves consenting to participate in unspecified future research within certain boundaries and/or processes, where participants can control the use of identifiable data to some extent. Broad consent is less specific than study-specific consent but narrower than open-ended consent without any restrictions, such as blanket consent. Broad consent is an alternative to specific consent rather than a waiver of consent rights. It can be beneficial as it allows researchers to request relevant information for current studies that may be used in future research without needing additional consent from research participants.

31. Risk

The probability of undesirable events or outcomes occurring as a result of participation in research within a specified timeframe, which may affect individuals, families, groups, communities, organizations, or societies involved.

32. Minimal Risk

The probability and magnitude of potential harm or inconvenience expected to occur to research participants. It should not exceed the risks associated with everyday activities or routine physical and psychological health examinations.

33. Protocol

A document describing the rationale, objectives, research design, methodology, statistical considerations, and research management procedures. Research protocols encompass considerations of ethics, risk, and anticipated benefits for research participants, as well as the informed consent process.

34. Vulnerable Participant

Individuals or groups with certain characteristics or combinations thereof that render them lacking or diminished in their ability to make independent decisions regarding participation or refusal to participate in research, or to express their true desires. They may be subject to coercion, undue inducement, or undue influence in research participation decisions, increasing the possibility of physical, mental, and social harm, as well as the risk of deception, breach of privacy and confidentiality, or limited capacity to provide or refuse informed consent to research participation.

35. Conflict of Interest (COI)

Conflict of interest occurs when personal or organizational interests conflict with the public interest. Such conflicts may influence and impact research, starting from the selection of research questions, research design, participant selection, and retention, to data interpretation, publication, as well as ethical considerations in research.

36. Research Participant

Individuals who meet the eligibility criteria to participate in research, receive sufficient information to make an informed decision about joining the research, and voluntarily consent to participate in the research.

37. Principal Investigator

The individual with the role and responsibility for designing the research, conducting the research, collecting and analyzing data, drawing conclusions, making recommendations, and coordinating the dissemination of academic work.

38. Gatekeeper

An entity or individual who can communicate with potential research participants to inform them about the project and obtain permission for researchers to contact them for potential participation in the study.

39. Researcher

A researcher systematically conducts inquiries to seek knowledge, addressing issues of interest. They adhere to accepted methodologies within their respective fields, covering conceptual frameworks, paradigms, and methods used in data collection and analysis. Researchers interpret and summarize research findings, engage in discussions about results, and compile research reports for dissemination, whether for public disclosure or exclusive to funding sources.

40. Key Informant

Individuals or target groups who play a pivotal role in providing crucial information for research. They possess qualities specified by the researcher as having broad, deep, and relevant knowledge suitable for the research objectives.

41. Humanities

The study of human values and arts, including disciplines such as art, literature, fine art, history, archaeology, linguistics, religion, and philosophy.

42. Research Design

The framework, methods, and techniques selected by researchers to suitably collect data within the field of study. Selecting an appropriate research methodology enables the study to obtain accurate and comprehensive data. In the social sciences and humanities, research methodologies include quantitative research, qualitative research, and mixed methods research.

43. Research Methods with Potential Ethical Risks

According to ethical principles, researchers must carefully consider whether the research methods they employ can achieve the research objectives. The benefits derived from the research must outweigh the risks to research participants. Researchers must articulate the research objectives, the research process, the risks, the benefits that may accrue to research participants and/or the community, and the society as a whole. This is to enable prospective research participants to make informed decisions to consent or refuse to participate in the research voluntarily. However, in some cases, if researchers assess that the benefits to the community and/or society outweigh the benefits and risks that may accrue to research participants, and obtaining informed consent from prospective research participants would not lead to undue benefits from the research, researchers must provide strong reasoning and evidence to the Ethics Committee (EC) to consider. Once approved, research can proceed. Research methods described in sections 23. Covert Research, 24. Deception Research, and 21. Internet Research are considered research methods with potential ethical risks in human research.

44. Research Institution

State or private organizations, educational institutions, or institutions that support research conducted by personnel within the organization have a responsibility to protect research participants conducted within the institution or conducted by institution personnel within their scope of responsibility. Research institutions with established Ethics Committee (EC) should support the effective functioning of these boards, free from interference from the institution's management or external parties. They should also have policies to ensure transparency and accountability of the Ethics Committee (EC).

45. Social Sciences

Social sciences encompass knowledge about society. Within this field, it can be further categorized into various sub-disciplines, such as history (related to society), anthropology, sociology, economics, social psychology, political science, law, judicial processes, communication studies, demography, and geography.

Chapter 2

Basic Ethical Principles

Basic Ethical Principles

The fundamental ethical principles outlined in this document pertain to protecting research participants' rights, welfare, and safety. It is imperative that research participants be treated fairly and with respect for their inherent human dignity.

This document consolidates ethical guidelines for human research, reflecting broadly accepted standards derived from key historical documents, including the Nuremberg Code (1947), the Declaration of Helsinki, the Belmont Report, and the Council for International Organizations and Medical Sciences (CIOMS) guidelines on ethical conduct in biomedical research involving humans.

These established rules and guidelines encompass core ethical principles that govern research involving human subjects, which are articulated as follows:

1. Respect for human rights and human dignity

Research at every stage must be conducted to respect human rights, honor participants' dignity, and uphold their inherent values. Research institutions are required to mandate that all human research undergoes thorough review and approval by a research ethics committee prior to initiation. Furthermore, institutions must ensure that the Research Ethics Committee (REC) has the authority to provide ongoing oversight of research activities, thereby safeguarding research participants' rights, safety, and well-being throughout the study.

2. Honesty and transparency

Researchers must be honest and transparent in their interactions with research participants. The REC should implement transparent processes to review and approve research projects and appropriately manage potential conflicts of interest. Research institutions should establish accessible channels for complaints from researchers, research participants, and other stakeholders involved in human research. These institutions must also establish clear and transparent procedures for investigating any complaints that arise.

3. Respect for individual autonomy

Researchers must treat research participants as autonomous individuals, recognizing their capacity to reflect on their own goals and take action to achieve them. Respecting each participant's autonomy involves providing opportunities for individuals to express their opinions, make choices, and act according to their judgment unless those actions clearly harm others.

Researchers' actions should demonstrate their commitment to respecting participants' autonomy. Disrespecting the autonomy of research participants can manifest in various forms, such as failing to acknowledge participants' decisions or withholding essential information necessary for informed decision-making without valid justifications. Researchers are obligated to ensure that participants are fully informed and supported in their decision-making processes.

4. Informed consent (ICF)

Researchers must obtain informed consent from research participants before initiating any research activities. Researchers have a fundamental duty to provide relevant information about the research and clearly explain it to potential research participants. It is essential that participants possess sufficient information and comprehend the research project to make well-informed decisions.

The informed consent process and the information shared should be designed to enable potential research participants to evaluate the benefits and risks of participation and make informed choices about their involvement in the research. The design of the ICF should consider the aspects of the study, the perspectives of potential research participants, and the appropriate use of technology to enhance comprehension.

The provided information must be clear, concise, and comprehensive, ensuring that potential participants or their legally authorized representatives can fully comprehend the research details.

5. Specific protection for vulnerable participants

Vulnerable individuals should only be recruited into research if there is a direct benefit to them or if the research is essential to address issues specific to their group. When involving vulnerable populations, researchers must implement specific protective measures to address their particular vulnerabilities.

Research involving these participants can be ethical only when it genuinely responds to their needs and when the research cannot be conducted with non-vulnerable groups.

Furthermore, it is imperative that vulnerable populations stand to benefit from the knowledge, practices, or interventions that emerge from the research.

6. Consideration of benefits and rights

Research must prioritize the benefits and rights of participants. While the primary aim of research is to generate new knowledge, this objective cannot supersede the rights and interests of individual research participants.

7. Minimizing risk and harm

Researchers must minimize potential risks and harms to participants while maximizing the benefits to participants. Continuous assessment and evaluation of the risks to participants should be conducted. Researchers should carefully weigh the foreseeable risks and discomfort against the anticipated benefits for each participant and society. Research should only be initiated and continued when it is determined that the anticipated benefits outweigh the known and foreseeable risks.

8. Privacy and confidentiality protection

Privacy entails individuals having control over the content, timing, and circumstances of sharing their personal data (such as physical attributes, behaviors, thoughts, and feelings) with others.

Researchers must not invade the privacy of research participants by avoiding unnecessary data collection, such as age, which could be collected within a range instead. This includes omitting data (speech, observed behaviors) without permission, refraining from observing behaviors, recording images, or recording sound during periods when participants desire privacy. In the process of selecting research participants through snowball sampling, individuals who provide referrals should seek consent from the person they intend to refer before providing their name and contact information to the researcher.

Researchers have a duty and responsibility to maintain confidentiality, including the personal data of research participants. Confidentiality is an agreement communicated to research participants during the consent process, outlining who can access research data, the methods and duration of data retention, procedures for withdrawing consent, reporting research results, utilizing research findings, and destroying data after the research conclusion.

9. Benefit sharing with disadvantaged populations

Disadvantaged populations should have the right to participate in research if there are potential benefits for that population. Additionally, they should receive equitable benefits from activities or research outcomes.

10. Adherence to the Justice principle in the distribution of benefits and burdens in research

In the context of human research, justice refers to the fair distribution of the risks associated with participation and the anticipated benefits derived from research outcomes. The risks of participation can range from minimal discomfort to significant physical or psychological harm. No individual or group should bear more risks from research participation than others without receiving anticipated benefits in a fair manner.

11. Respect and protect the environment and future generations

Future generations refer to individuals, groups, and nations that will inhabit the planet in the future. Researchers have a responsibility to respect these future human beings and safeguard their rights to protection, which encompass political and civil rights, economic, social, and cultural rights, the right to a clean and sustainable environment, the right to self-development without discrimination, and the right to live in peace.

To uphold these principles, any research conducted must adhere to the following guidelines:

1. It must not cause or lead to the loss, destruction, or depletion of essential resources necessary for human life without considering the potential future impacts.
2. It must not transfer the responsibility for addressing current crises onto future generations.
3. It must not assign lesser value to the lives and rights of future generations compared to those of current generations.

By committing to these principles, researchers can ensure that their work promotes sustainability and equity for both present and future populations.

Future generations refer to those who do not currently exist but will be born and live on this planet in the future. It includes individuals, groups, and nations that researchers must respect as human beings and respect their rights to have and receive protection as human beings. This includes political and civil rights, economic, social, and cultural rights, the right to a clean and sustainable environment, the right to self-development without discrimination or derogation, and the right to live in peace.

Any research conducted by researchers must:

1. Not cause or lead to the loss, destruction, or use of necessary resources for human life without considering the future impact;
2. Not shift responsibility for managing current crises onto future generations; and
3. Not undervalue the lives and rights of future generations less than the lives and rights of current generations.

Chapter 3

Ethical Dimension of Research Methodology

Ethical Dimension of Research Methodology

Chapter 3 addresses ten guidelines, classified according to commonly encountered social science and humanities research in Thailand. Each guideline comprises specific details of the respective research, finer details relevant to other organizations or units, researchers' obligations, and considerations for the Ethics Committee (EC), as follows:

Guideline 1: Research in Physical Anthropology and Archaeological Research

Guideline 2: Criminological Research

Guideline 3: Cross-cultural Research

Guideline 4: School-based Research

Guideline 5: Community-based Participatory Research (CBPR)

Guideline 6: Ethnographic Research

Guideline 7: Hospital-based Research

Guideline 8: Research in Psychology, Psychiatry, and Behavioral Science

Guideline 9: Deception and Covert Research

Guideline 10: Internet Research

Guideline 1
Research in Physical Anthropology and Archaeological Research

Researchers must rigorously comply with government regulations and secure approvals from relevant organizations and individuals, including the Research Ethics Committee (REC) for Human or Animal Research, when utilizing human biological materials or in studies involving animals. Researchers should respect local beliefs and cultural practices while actively engaging with affected communities or ethnic groups throughout the research process to ensure respectful and inclusive collaboration.

Consideration for Guideline 1

1. In research involving physical anthropology, key considerations include:
   1.1 Authorization from relevant authorities and permissions for skeletal, DNA, and physiological studies.
   1.2 Detailed plans to minimize harm to remains and specimens.
   1.3 Ethics committee approval and participant consent for studies collecting living human samples.
   1.4 The individuals or ethnic groups being studied should be involved throughout the study process. Respect and consideration should be given to the perspectives of the stakeholders.
   1.5 In studies involving DNA of living humans, approval from the ethics committee must be obtained before conducting any procedures involving the individuals or ethnic groups being studied.

2. In research involving primates that aim to understand human-animal behavior and evolutionary development, key considerations include:
   2.1 Compliance with regulations from relevant agencies and local communities, with necessary permissions for experimentation.

2.2 Ethical data collection to minimize harm, stress, and disruption to animals.

2.3 Avoiding direct contact to prevent disease transmission.

2.4 Where local cultures hunt primates for food, researchers should respect local customs but should not encourage killing, harming, or causing suffering to animals for the sake of obtaining research data.

3. In archaeological research involving human remains and skeletal studies, key considerations include:

3.1 Obtaining permission and complying with local or national regulations.

3.2 Ensuring research quality to minimize harm to remains.

3.3 Involving and respecting stakeholder perspectives from the start.

3.4 Informing the local community before beginning research.

3.5 Respect local beliefs regarding archaeological sites, with necessary consultations.

3.6 Consulting and obtaining stakeholder permission for sites with religious, political, or cultural conflicts.

3.7 Intellectual property that is the cultural heritage of indigenous people, ethnic groups, and local people, such as food, art, handicrafts, and music, which are used in the design to create added value in commercial uses, must cite and acknowledge the originators of cultural heritage in that work.

Guideline 2
Criminological Research

Research involving incarcerated individuals, individuals under legal control, children and adolescents in conflict with the law, and individuals within alternative justice systems should focus exclusively on studying the conditions impacting these populations.

Researchers must provide strong justification for selecting these groups and ensure fair selection processes.

Informed consent procedures should empower participants to make autonomous decisions. Researchers must effectively communicate the study's objectives, risks, and potential benefits, emphasizing voluntary participation, the right to refuse participation, and the right to withdraw from research at any time.

When reviewing research proposals involving these populations, the research ethics committee should include at least one member or consultant with expertise in incarceration, legal control, or juvenile justice issues. The research ethics committee should assess research projects against the minimum standards outlined by the United Nations organizations concerning various offenses and alternative justice processes. These standards include the United Nations Standard Minimum Rules for the Treatment of Prisoners (the Mandela Rules 1955 and 2015), the United Nations Standard Minimum Rules for the Administration of Juvenile Justice (the Beijing Rules, 1984), and the United Nations Rules for the Treatment of Women Prisoners and Non-Custodial Measures for Women Offenders (the Bangkok Rules, 2010).

Consideration for Guideline 2

The Corrections Act B.E. 2560 (2017) defines "prisoner" to include all categories of incarcerated individuals—convicts, detained persons, and entrusted persons—experiencing a deprivation of freedom. This inherent vulnerability may lead to coercion or threats to participate in research. Researchers must respect the human dignity of these individuals.

The Belmont Report emphasizes the principles of respect for persons and justice, requiring special protection to ensure voluntary, coercion-free participation. The necessary level of protection depends on the risks and benefits the research presents. Researchers must justify the involvement of the particular population group to the ethics committee. If no direct or

indirect benefit exists, this protection may involve the exclusion of the population from the research.

Researchers must weigh the anticipated burdens and benefits of research, addressing participants' responsibilities, obligations, requirements, and associated risks. Benefits should primarily benefit those represented by the participants and be achievable through collaborative responsibility. Involving stakeholders—such as prisoners, behavioral control individuals, juvenile offenders, alternative justice system participants, prison staff, medical personnel, and administrators—throughout the research process ensures the study is relevant and respects the specific characteristics of correctional facilities.

This involvement enhances informed and voluntary consent, protects participant privacy, and fosters cooperation from correctional facility staff, leading to more accurate outcomes and greater benefits for all involved.

Researchers should fairly select eligible prisoners, individuals under behavioral control, juvenile offenders, or alternative justice system participants without interference. Random sampling is recommended unless an alternative method has been justified to the Ethics Committee. Informed consent must be obtained freely, without coercion, and in private, without the involvement of staff or other groups.

Security constraints in correctional facilities may limit researchers' ability to collect data directly from prisoners, affecting participant selection and the research process. A significant concern is the potential conflict of interest for researchers who are also prison staff. These researchers must be cautious about offering incentives, as prisoners might view participation as a way to gain privileges in prison facilities.

Researchers must address privacy and confidentiality concerns when involving prisoners, individuals under behavioral control, juvenile offenders, or participants in alternative justice systems. These participants might fear repercussions if information is disclosed. To protect everyone involved, researchers should implement measures to ensure the well-being of participants and secure their data.

For research involving prisoners, individuals under behavioral control, juvenile offenders, or participants in alternative justice systems, the research ethics committee must thoroughly review the study to ensure it does not exploit this vulnerable population. Such research should only be conducted if it specifically aims to study aspects affecting this group. Participant selection must also be fair.

Guideline 3

Cross-cultural Research

Cross-cultural research presents ethical challenges due to cultural differences, including cultural biases, power imbalances, and the necessity of respecting the values and beliefs of the studied communities.

Researchers should undergo comprehensive cultural sensitivity training and work closely with local experts and community members. They should conduct thorough literature reviews relevant to the culture or pilot studies to identify potential cultural challenges, ensuring that research design and implementation are accurate and culturally appropriate. Researchers must be vigilant in avoiding cultural biases and stereotypes.

Informed consent is a critical ethical requirement; researchers must adapt their approach to align with diverse cultural norms and practices. This involves obtaining permission from communities as well as consent from individuals. Since research activities may inadvertently disrupt cultural practices or pose risks to individuals or communities, researchers should comprehensively assess potential psychological, social, and cultural risks.

Researchers should be aware of power imbalances between researchers and participants, taking steps to prevent coercion and exploitation.

Including at least one ethics committee member or an independent consultant with expertise in cross-cultural issues is advisable as part of the Research Ethics Committee deliberations. This inclusion will help ensure a thorough review and adherence to ethical standards across diverse cultures.

Considerations for Guideline 3

Cross-cultural research compares individuals from at least two different cultural backgrounds, including the researcher's culture and ethnic groups domestically or internationally. It is often referred to as ethnically or culturally comparative research. Researchers must be aware of economic and political power imbalances stemming from past and present injustices. Ethical considerations include carefully defining cultural groups (e.g., by nationality, ethnicity, or religion), which is crucial for scientific and ethical validity.

When defining population groups for study, researchers must consider diverse individual identities and subgroups to avoid perpetuating prejudices or biases. Acknowledging that past cross-cultural research has, at times, supported discriminatory policies, researchers should critically examine the assumptions behind their definitions and methodologies. Ensuring scientific integrity and ethical principles requires designing research to encourage diverse interpretations, reviewing relevant literature on cultural differences, and seeking guidance from knowledgeable community members, avoiding preconceived cultural categorizations for more appropriate research practices.

In cross-cultural research, data collection often requires an extended period during which researchers act as guests within the community. Prior authorization is necessary, as the presence of external individuals can create stress and impact the community. Researchers' actions, whether intentional or unintentional, may violate community norms and affect dignity and power dynamics, leading to feelings of stigma or marginalization. Researchers must respect community norms, refrain from rushing participants, and consider the significance of participants' own projects. They should not monopolize time or resources and must remain patient and flexible. Researchers can minimize negative impacts and foster a respectful research environment by conducting themselves as welcomed guests and integrating into the community.

Researchers must avoid becoming overly involved in the community to prevent perceptions of financial dependence or overreliance on their expertise, which could lead to unrealistic expectations. Balancing the community's benefits with the risk of dependency is crucial. As researchers often rely on community members as informants or translators, careful selection is essential to prevent perceptions of favoritism.

To avoid ethical issues in human research, researchers must refrain from romantic or sexual relationships with participants and community members due to potential power imbalances and exploitation. Such relationships should only be pursued after the research is concluded.

Informed consent is essential in cross-cultural research. Researchers must ensure participants genuinely understand the research and voluntarily consent. Understanding of consent may vary across cultures; in some cultures, community or tribal consent is paramount over individual consent, and signed forms may be uncommon. Researchers should respect and navigate community decision-making processes, but community consent cannot replace individual consent.

Guideline 4
School-based Research

Researchers must provide a clear rationale for conducting studies involving children and adolescents in educational settings. They should follow established procedures for obtaining permission from the educational institution and relevant stakeholders, including teachers and school administrators and securing parental or guardian informed consent and assent from each child.

The informed consent process must be tailored to the developmental levels of the children and adolescent participants. Researchers must respect the decision of any child or adolescent who chooses not to participate.

Researchers should identify the circumstances or specific characteristics that render children and adolescents vulnerable, such as vulnerabilities arising from their dependent relationships with teachers (refer to Guideline 11) and provide appropriate protection accordingly.

Researchers should possess adequate experience or training in working with children and adolescents and conducting research involving this population. They must also complete training in research ethics.

Schools should implement policies that support researchers in conducting research according to human research standards and relevant regulations.

The research ethics committee should consist of members with relevant expertise, such as developmental psychologists, curriculum specialists, educational psychologists, and legal experts, to ensure thorough review and ethical oversight of research projects.

Considerations for Guidelines 4

In the research context, children and adolescents are considered as one of the populations with limited decision-making opportunities. However, respect for their right to free expression is essential.

Researchers must recognize children's vulnerability, not just due to age but also research-specific circumstances. Children often lack the qualifications to fully understand research, so researchers should use age-appropriate methods to facilitate genuine comprehension.

Obtaining meaningful assent from children should mirror the informed consent process in adults while securing consent from parents or guardians.

1. Basic ethical guidelines for research involving children/ adolescents in schools

Researchers must prioritize the trust children and adolescents place in their parents, guardians, teachers, and school principals in educational settings. This trust must not be compromised, especially in environments where parents or guardians are absent, such as schools, kindergartens, educational institutions, or activity/sports clubs. Researchers should proactively communicate with parents or guardians about the research project to maintain this trust. They must ensure that parents are informed about the research being conducted, regardless of whether their children are directly involved or if parental consent is needed. Researchers should discuss with school authorities how to conduct this communication effectively and respectfully, deciding on the most appropriate timing and circumstances for engaging with families.

When conducting research involving children/adolescents in schools:

1.1 Researchers should have strong scientific reasons for involving this population, such as the relevance of the research to their educational activities and learning outcomes.

1.2 Researchers must complete training in human research ethics and have the necessary experience or qualifications to work with children and adolescents.

1.3 Researchers should foster positive relationships and provide counseling and support to children, parents, guardians, teachers, and school principals to ensure participants' well-being.

1.4 Researchers must obtain permission from school authorities (principals, teachers, or club advisors) and secure consent from parents or guardians of the children and adolescents involved.

1.5 Research involving children and adolescents in activities outside of their routine can increase risks. Therefore, researchers should design studies while taking into consideration the participants' daily lives by ensuring: 1). Activities align with what is normal in the school setting; 2). Relationships between researcher and student reflect typical school interactions; and 3). The activities are the ones that children and adolescents usually participate in. For instance, classroom observations of students

working on projects are normal activities. However, interviews in separate rooms introduce new environments and relationships, which may not feel normal. Researchers must have the experience and skills for these activities and provide necessary counseling and support.

1.6 When children and adolescents are indirectly involved in research, such as studies focusing on teachers and knowledge transfer that relies on children's participation, researchers must obtain voluntary consent from both the teachers and the school principal, who acts as the guardian in place of the parents or guardians.

1.7 An ethics committee should review and evaluate school-based research to ensure scientific integrity, adherence to ethical standards, and proper informed consent. If a school lacks its own ethics committee, it should use a qualified external ethics committee. This ensures research quality and safeguards the well-being of child participants.

2. Researcher who serves both as a researcher and a teacher in an educational institution

When researchers are also teachers, they must consider:

2.1 Conflict of Interest (COI):

COI occurs when researchers cannot balance students' learning objectives with research goals for researchers' professional advancement. A researcher's personal knowledge of various aspects of their students might influence participant selection, research measurements, and research outcomes. This imbalance can affect teacher-student relationships and attitudes. Researchers should recognize, evaluate, and disclose potential COI to the ethics committee for appropriate management.

2.2 Researcher Bias:

Teacher-researcher relationships and personal teaching beliefs may introduce biases, affecting research integrity and measurement accuracy. The teacher-researchers might seek positive outcomes to validate their teaching methods, potentially compromising the study. It's crucial to adhere to ethical standards by reporting all findings honestly, regardless of alignment with initial hypotheses.

2.3 Vulnerable Student Populations:

Students with special needs, disabilities, or in care facilities may be particularly vulnerable during research. Teacher researchers must ensure these students are not unduly burdened and implement safeguards to protect their well-being, reduce stress, and support academic progress during research involvement.

2.4 Power Imbalance and Participation Willingness:

The power imbalance between teacher researchers and students together with students' dependency on teachers for evaluations can affect students' willingness to participate. Parents and students may fear that declining participation could negatively impact the student's academic standing or well-being. To mitigate this, a co-researcher or research assistant without a dependent relationship with the students should handle the consent process from parents and the student assent process.

2.5 Privacy Issues:

Reporting or publishing research findings may inadvertently disclose sensitive information about the school or student participants, especially in small communities. Researchers should avoid linking individual students or the school to published results. To protect student and school privacy, use pseudonyms and omit geographical identifiers, ID numbers, and other identifying information.

3. Researchers from external institutions

When external researchers are involved, the researchers should respect the school's culture and regulations, obtain permission from the principal, prioritize building trust with stakeholders, including parents and students, and ensure the research design aligns with the school's conditions and regulations. They should also consider the school's and staff's unique characteristics in data analysis and interpretation.

Being an external researcher presents several limitations as follows:

(1) Time constraints can restrict full participation in essential activities, affecting the comprehensiveness of the findings.

(2) Research activities may disrupt school routines, affecting student, teacher, and parent relationships. Researchers are required to implement measures to mitigate these disruptions.

4. Considerations for research involving children/adolescents in schools

The Research Ethics Committee should include members with diverse expertise, such as those in curriculum design, educational planning, educational psychology, developmental psychology, special education, legal advisory, and linguistic and cultural specialists for cross-cultural studies. The committee should comprehensively evaluate the research's appropriateness and assess the age of participants, specific groups involved, the necessity of the research, and variability among students, including those with special needs.

The research ethics committee should exercise extra caution in:

4.1 Assessing the appropriateness of methodologies, especially for sensitive data or direct interactions with students,

4.2 Evaluating the appropriateness of the research topic for the age group of the children/adolescents.

4.3 Evaluating potential conflicts of interest or overlapping benefits among researchers, teachers, and other involved parties.

4.4 Reviewing the consent process to ensure that the language is age-appropriate, culturally sensitive, and comprehensible. The informed consent form should be clear and concise, and illustrations or other media should be considered to aid understanding.

4.5 Considering alternatives for students who do not consent to participate.

4.6 Reassessing the consent process for voluntary participation whenever there are changes to the research details and adjusting research processes as necessary to align with school schedules and activities.

Guideline 5

Community-based Participatory Research (CBPR)

Researchers should initiate authentic community engagement from the outset and maintain ongoing collaboration throughout the research process. This engagement begins with identifying key community issues, formulating research proposals, and designing methodologies as well as informed consent processes. The same level of engagement should also be applied throughout the result analysis and findings dissemination processes, with the ultimate aim of implementing research outcomes that may improve the community.

Researchers should conduct research collaboratively with the community and research participants, focusing on stakeholder learning and participation processes. The goal is to foster the development of community capacities in addressing community issues and enhancing the community's capability to identify and address their challenges independently.

Researchers should possess culturally appropriate competencies relevant to the research context and be sensitive to the needs, values, preferences, and unique beliefs of the local community being studied.

Considerations for Guideline 5

Community-based participatory research (CBPR) is a collaborative social science methodology that addresses societal issues and improves community well-being. It emphasizes equity, involves researchers and community members at every research stage, and requires cultural sensitivity and community empowerment. Despite its potential, researchers must manage ethical issues in practice according to ethical principles as follows:

1. Genuine community engagement

Researchers should ensure genuine community engagement from all stakeholders throughout the research process, starting from the preparation and planning stages. Researchers should seek community input through meetings, focus groups, or consultations to understand their needs and priorities. It is important to discuss the research's linkage with the community, potential risks and benefits, risk management methods, and expectations among stakeholders, including advisory boards and diverse community representatives.

Researchers should conduct consultations openly, ensuring public participation and transparency, and encourage stakeholders and community members to disclose conflicts of interest, incorporate diverse perspectives, seek advice from those with similar research experience. With respect to data collection, researchers should obtain permission from community leaders or representatives for their help to clearly communicate the research status, objectives, and methodology to the community. Furthermore, they can help to ensure that community members do not feel pressured to participate, especially when researchers hold esteemed positions that could influence participation.

Active community involvement builds trust and ensures the research addresses important issues and gains acceptance. It helps researchers understand the community's culture and perspectives, reducing biases, especially in minority or marginalized groups. Conversely, communities will gain an understanding of the research processes, alleviating concerns and fostering mutual trust, benefiting the research progress at all stages.

The researchers should ensure ongoing community involvement and sustainable relationships beyond the project. They should also provide a communication platform for researchers and community members to learn and solve problems together. This will empower the community to identify and address issues autonomously, build community confidence and trust, and enhance its capacity for development.

The research ethics committee should assess community involvement and review the roles and responsibilities assigned to the community by researchers. The plan should demonstrate that the communities actively participate in discussions, formulate research questions, design the research, and plan data collection methods. The proposal should be culturally sensitive and responsive to community needs, values, and customs.

The ethics committee should review the process for developing community capacity and ensure that community members have the necessary skills and resources for genuine participation and examine plans to promote sustainable empowerment and involvement beyond the research project.

Researchers must clearly outline these processes, activities, and measures in detail so that the committee can assess and evaluate community involvement.

2. Power balance

Community-based participatory research (CBPR) aims for equal stakeholder involvement, but issues of power imbalances between researchers and community members often persist,

especially with marginalized or disadvantaged groups. Researchers should avoid exploiting or deriving unfair benefits from these groups. The researcher must ensure all stakeholders have equal decision-making rights. Researchers can empower community members by voluntarily sharing their power and resources, promoting equality during the collaboration, and implementing an open, inclusive process that values and amplifies community voices alongside researchers.

3. Informed consent

Obtaining consent can be challenging with marginalized or at-risk groups. Researchers must ensure community members understand research objectives, risks, benefits, and data use. Participation must be voluntary and based on informed consent, requiring clear information for decision-making.

Researchers should obtain individual consent even with prior gatekeeper approval. Broad informed consent may be needed for future data use or sharing (see Guideline 15).

Researchers should involve the community in developing the informed consent process and information sheet, ensuring they are culturally appropriate and easily understood. They should use clear, non-coercive language to uphold independent decision-making. Researchers and ethics committees should also ensure that community involvement does not unduly pressure participants into deciding to participate in the study.

4. Privacy and confidentiality

Maintaining privacy and confidentiality in community-based research is complex and requires careful protocols. Researchers should establish clear protocols for managing and storing data to protect sensitive information. This may involve segregating personally identifiable information from other collected data to reduce data breach risks and implementing measures to protect individuals with criminal records, under legal supervision, or juveniles with prior offenses to prevent stigmatization within the community.

5. Cultural sensitivity

Community engagement involves collaborating with culturally diverse communities. Researchers must be culturally sensitive and respectful to avoid misunderstandings. Communities can provide valuable insights into research procedures, ensuring they are respectful and minimally disruptive.

6. Ownership and control of research data

Determining data ownership and control in community-based research is complex. Researchers should discuss and agree with the community on details regarding data ownership, access, and sharing. Researchers should also define who has the right to use the data and whether permission is required from all parties to ensure the genuine sharing of research findings and benefits with the community. Finally, researchers should consider the community's perspective on disseminating research findings.

7. Compensating data providers or communities for their participation in research

Researchers should exercise caution when compensating data providers or communities. Compensation is reimbursement for time, not payment for information, and may cover travel expenses or lost wages. It should not be used as an incentive for data acquisition, which could affect data integrity and sample selection. Compensation can also include knowledge sharing, healthcare advice, coordination with organizations, or other community benefits, focusing on collective welfare over individual gain.

8. Researcher's legal risks

Researchers may be at risk of legal repercussions during participatory observation, so they must meticulously plan and inform relevant authorities about the project beforehand.

The ethics committee must review community-based participatory research (CBPR) to ensure credibility and ethical compliance. The top priority should be to ensure community benefits. The review process should be flexible, tailored to each community's unique needs, and conducted by members knowledgeable about CBPR principles, methodologies, and ethical issues.

Guideline 6

Ethnographic Research

Ethnographers frequently gather sensitive and private data about individuals and communities. Researchers must implement measures to protect the privacy and confidentiality of participants, such as anonymizing data, using pseudonyms, or obtaining a waiver of the signed consent document requirement from the ethics committee. Research reports should not disclose any personally identifiable information, and researchers must consider appropriate methods for disseminating research findings to minimize the risk of harm to participants or communities.

Researchers should be culturally sensitive and respectful toward the studied communities, understanding and respecting their customs, beliefs, and traditions. It is essential to avoid imposing personal values and judgments on research participants.

Researchers should obtain permission from both the community and the participants prior to conducting the research, ensuring that the research is conducted in a manner that is not harmful or exploitative to research participants.

Considerations for Guideline 6

Ethnographic research is a qualitative method aimed at understanding cultural behaviors and social interactions. Ethnographers use multiple data collection methods, including surveys, recordings, photography, document analysis, and digital communication. Fieldwork involves participant observation, structured and informal interviews, and spontaneous conversations in a natural context. The goal is to explore language, culture, value systems, organizational structures, and social orders to uncover the meaning behind practices in real-life situations.

In ethnographic research, researchers immerse themselves in communities, often for extended periods ranging from months to years. Building trust with primary informants is crucial as this will lead to interviews with relevant community members. Researchers should adapt their behaviors to respect social norms, avoid taking sides in conflicts, and maintain professional relationships without creating dependency or bias.

Results are reported using narrative and qualitative analysis, which are suitable for studying community groups and cross-cultural comparisons. Fewer participants are involved, as the aim is for data to emerge naturally. Researchers should refrain from using methods of persuasion or deception. Clear communication of research objectives is essential, and consent may be obtained without requiring a signature.

Ethical principles involved in field research include creating benefits for and avoiding harmful impacts on research participants. Researchers should ensure participants' physical and mental well-being, safety, and dignity as well as safeguard the participants' autonomy in their decision-making.

Researchers should maintain professional boundaries with participants and avoid deception or creating misunderstandings. To protect the identities and privacy of the participants, pseudonyms should be used in research reports. Research findings should be disclosed while taking into consideration the benefits and potential risks to participants, such as avoiding reinforcement, stereotyping, bias, or stigmatization. Researchers should exercise special caution in research involving illegal activities of individuals, groups, or communities.

Guideline 7

Hospital-based Research

Researchers must thoroughly assess participants' potential vulnerabilities when conducting studies in hospital settings. This includes considering the perspectives of hospital personnel, such as physicians, nurses, pharmacists, physiotherapists, social workers, nutritionists, and other departmental staff, as well as patients and their relatives. Appropriate protections must be tailored to address the specific vulnerabilities identified.

Researchers must implement robust measures to access and handle the personal and confidential information of both hospital staff and patients. Maintaining this data's integrity and privacy is essential throughout the research process.

The transition from routine work to research (Routine to Research [R2R]) requires the submission of a project proposal for ethical review or exemption. This applies even when the research aims to improve routine operations. Researchers should be aware that this process extends beyond standard practice, and its efficiency and effectiveness are yet to be established.

Considerations for Guideline 7

Hospital-based research has different considerations between researchers who are hospital personnel and researchers from outside the hospital as follows:

1. The researchers are hospital personnel.

1.1 Hospital personnel researchers should assess if participants belong to vulnerable groups and outline appropriate protective measures (see Guideline 11).

1.2 Hospital administrators or department heads should avoid conducting research within their units. If necessary, they should ensure participant autonomy and implement measures to minimize the impact on their rights and work performance evaluations (see Guideline 11).

1.3 Researchers with access to personal information must avoid using data without consent to protect participants' privacy (see Guideline 13).

1.4 Research on psychiatric and behaviorally sensitive topics necessitates careful planning and ongoing support. Researchers must monitor the long-term psychological effects on participants and be skilled in interviewing, counseling, and helping distressed research subjects. Collaborating with relevant organizations and grasping the ethical standards of social science and humanities research is crucial. (see guideline 8).

1.5 Transitioning Routine Work into Research: Researchers should conduct research following the scientific principles relevant to the research type and apply the appropriate research ethics guidelines. As with other research types, the researcher should propose research projects for ethical review and seek informed consent or collaboration agreements as required.

2. External researchers

2.1 The research has clear direct or indirect benefits to participants

2.2 Researchers must secure ethical approval from the ethics committee and obtain permission from the hospital director prior to data collection. If the hospital does not have an ethics committee, approval should be sought from the affiliated institution's ethics committee.

2.3 Researchers must be cautious when collecting data to protect participants' privacy and confidentiality.

Guideline 8
Research in Psychology, Psychiatry, and Behavioral Science

Researchers must carefully evaluate participants' capacity to make independent decisions regarding research participation, especially taking into consideration whether the participants have any vulnerabilities or health conditions, both physical and mental. Researchers must also implement stringent measures to safeguard the privacy and confidentiality of research participants. This is especially critical in research involving sensitive issues or those that may lead to stigmatization.

Researchers should strive to minimize the use of deception in their studies. Deception should only be employed when necessary to achieve the research objectives, and research should involve no more than minimal risk to participants.

In research that utilizes artistic processes for participatory therapy, special care must be taken when research involves sensitive topics such as psychological trauma, substance abuse, and suicide. Researchers should thoroughly assess the potential long-term impacts on participants' mental health and overall well-being.

Researchers conducting these types of research, especially those addressing sensitive issues, should possess relevant skills in conducting interviews, providing counseling, and supporting participants who have experienced psychological trauma. This expertise is crucial for creating a safe and supportive research environment.

Researchers should collaborate with legal authorities and support organizations to ensure participants have access to necessary assistance, particularly in cases involving family violence or other critical issues. This partnership enhances participant safety and well-being.

Researchers must be well-versed in research ethics relevant to social science and humanities. This foundational knowledge will guide ethical decision-making and reinforce the commitment to protect vulnerable populations throughout the research process.

Consideration for Guideline 8

Studying human behavior involves emotions, thoughts, and actions in various contexts. Ethical concerns depend on research methods and participant vulnerability. Additional safeguards are crucial for sensitive or high-risk topics prone to stigmatization.

1. Evaluating Decision-Making Capacity in Psychiatric Research Participants

Decision-making capacity varies depending on the symptoms and severity of psychiatric illnesses. Evaluating each individual's cognitive capacity and determining the informed consent process is important. For patients in stable conditions whose cognitive functions are deemed sufficient, informed consent can be obtained from the patient. For those with limited capacity, informed consent should be obtained from a legally acceptable representative with the patient's assent. Joint consent from the patient and a legally authorized representative is more appropriate for patients at risk of deterioration.

2. Participatory observational research in psychological, psychiatric, and behavioral studies.

Participatory observation involves interaction, not just observing public behaviors, and typically requires consent. However, informing participants about the study may alter their behavior and affect outcomes. In studies where certain aspects of research activities must be concealed from the participants, researchers must clarify the reasons for the concealment and provide detailed information regarding the informed consent process for ethics committee consideration. Additionally, they should disclose study details to participants at the end of their observation and seek permission to use observed or recorded data. If patients do not consent, the data cannot be used. (see Guideline 9)

3. Research involving participatory art processes with vulnerable groups

Research using participatory art processes for vulnerable groups, such as refugees displaced by violence or war (especially children and adolescents) and diagnosed patients, involves activities like photography, drawing, designing, acting, singing, and composing poetry for emotional and psychological healing.

Researchers must consider deep psychological impacts, linguistic contexts, religious and cultural backgrounds, trust, and communication issues. Chosen art forms may evoke sensitive emotions or intense reactions, requiring researchers to monitor and promptly address any

emotional changes in participants. Immediate care and referrals for additional assistance may be necessary.

Researchers should obtain ethics committee approval and genuine informed consent from participants. For child participants, legally acceptable representatives and their assent are required.

Researchers must rigorously ensure participant privacy, keeping all personal data and created artwork confidential unless they receive explicit written consent from participants and approval from the ethics committee.

Upon research completion, researchers should establish a mutual agreement on artwork ownership. Publicly presenting participants' artwork may depict traumatic events, pose mental health risks, and open opportunities for misuse. Researchers should collaborate with experts in psychology to ensure a clear representation of reality, interpretation, or symbolism.

Researchers should obtain consent from participants before publicly displaying or publishing artwork. For child participants, this should include consent from parents or guardians and the child's assent.

4. Research that is sensitive or potentially stigmatization

Researchers must ensure the confidentiality of participants in studies involving sensitive topics such as substance abuse, illegal activities, or socially stigmatized actions such as drug use, abortion, or prostitution. Identifiable participant information must be protected to prevent legal, psychological, or other risks. Minimizing such risks includes obtaining verbal consent from participants instead of signatures or using voice conversion technology during data recording.

Studies involving vulnerable groups, such as children or adolescents experiencing abuse, require careful planning. Questions about traumatic experiences may trigger negative feelings or psychological risks. Precautionary measures include establishing clear protocols for preventing and managing potential risks, providing assistance through state agencies if child abuse is discovered, and coordinating immediately with mental health experts to support participants experiencing distress or severe emotional turmoil during data collection.

When conducting home visits as part of the research, researchers may uncover histories of misconduct or encounter the perpetrators of misconduct against the participants. If the perpetrator is a parent or community member, researchers should coordinate with organizations capable of assisting the participants in every area where data collection occurs. Researchers should also inform officials responsible for child protection, as researchers cannot

remove children from their homes; only legally authorized individuals can intervene. Researchers should obtain consent from community leaders and permission from relevant government agencies, especially the provincial Office of Social Development and Human Security, responsible for protecting children from violence.

5. Consideration for Informing Research Participants of Psychological Assessment Results

Researchers typically do not disclose interviews, psychological assessments, or evaluation results to participants, as it is research rather than treatment. However, the decision to inform participants of such information should take into consideration the potential risks and benefits to the participants. If an assessment reveals a treatable mental health condition and the participant seeks help, sharing the results may offer additional benefits. If the assessment identifies untreatable issues, such as genetic predispositions to mental illness, disclosing the results may pose psychological risks. Researchers should have guidelines to utilize study findings for providing ongoing support and assistance where necessary.

Guideline 9

Deception and Covert Research

The use of deception research or partially concealed information research may be justified when the study offers significant societal benefits and requires withholding certain information to ensure its integrity. However, such research must involve minimal risk to participants.

The researcher should provide potential research participants with sufficient relevant research information to fully understand their involvement, even if some details remain omitted.

After completing data collection and prior to data analysis, researchers must seek re-consent from research participants. This process involves notifying research participants and disclosing all previously omitted information about the research. This allows participants to make an informed decision about the use of their data or withdraw their consent based on a comprehensive understanding of the study (*see guideline 14*)

In cases of covert research, researchers must always respect the privacy of participants. Informed consent should be sought immediately whenever possible. If consent cannot be obtained, researchers are prohibited from using any data previously collected as part of the study.

Considerations for Guidelines 9

Researchers must choose methodologies suitable to their objectives, ensuring the benefits outweigh any risks to participants. Participants should be well informed and comprehend the information to make independent decisions about their involvement without pressure or coercion. In some behavioral and human sciences research, methodologies may fulfill scientific requirements but conflict with the ethical principles of respect for persons.

1. Deception Research

When disclosing research objectives may alter participants' behavior and distort results, researchers may use deception. However, they should never withhold information that could cause physical or psychological harm. Although deception is employed, researchers must

ensure that participants are not demeaned and that their decision-making abilities are not compromised. Once each participant's involvement is completed, or at the end of the study, the exact objectives must be disclosed, and re-consent must be obtained. Participants should be informed of their right to withdraw their data without consequences if they revoke consent after learning the concealed information, and such data must not be used (see guideline 14).

Deception in research undermines the informed consent principle and can negatively impact research participants, researchers, social and humanities professionals, and society as a whole. If no alternative methods can address the critical societal and scientific questions, researchers must justify deception as the only viable approach. However, they must never use deception if it poses physical or psychological risks. Measures must be in place to minimize risks, ensuring they remain no more than the minimal risk threshold.

2. Covert research

When conducting covert research, it is vital to ensure that risks remain no more than the minimal risk threshold. This research method violates informed consent and may infringe on privacy. Researchers must clearly justify the necessity of this method based on scientific principles and processes. They should avoid collecting personally identifiable information, using methods that compromise participants' dignity, and invading the participants' privacy. Informed consent must be sought as soon as feasible; without consent, previously collected data should not be used (see Guideline 14).

For studies involving unlawful activities, researchers must be aware that authorities could investigate them. They may be called upon as witnesses, face allegations of complicity, or be guilty of failing to report illegal acts to the responsible authorities. Before starting the research, researchers should seek legal advice, assess their risks versus the potential benefits, develop risk management plans, and disclose necessary information to relevant authorities (see Guideline 16).

Guideline 10

Internet Research

Researchers must evaluate the publicity of the data available on the internet, recognizing the varying levels of accessibility and privacy associated with different types of data. This assessment is crucial to prevent privacy infringements of data publishers.

When utilizing data from public websites without directly interacting with the individuals who own or publish the data, researchers must strictly adhere to the website's terms of use. Additionally, researchers should seek permission from website owners and post an ethical declaration regarding their research activities.

Researchers should thoroughly evaluate the privacy risks faced by individuals who own or publish data online and take steps to minimize these risks as much as possible. Protective measures must be implemented to safeguard against the inadvertent disclosure of personal information, whether directly or indirectly inferred from the data.

Researchers should obtain informed consent from data publishers, clearly informing them about the research objectives, the context of data usage, and the privacy and data security protection measures. This includes outlining any limitations related to privacy and data handling.

Researchers must respect the decisions of data owners or publishers who decline to grant permission to use their data in research. If consent is not given, researchers must refrain from using the data.

Considerations for Guideline 10

Data shared publicly on the internet is not always intended for broad dissemination. Social media platforms may facilitate communication within specific groups, whereas original data publishers may not have intended wide-spread distribution. Using or disclosing such data can raise ethical issues, especially concerning children, youth, or vulnerable individuals.

Before using internet-sourced data, researchers must consider the following:

1. Differentiation considerations in research

When accessing data from public spaces, researchers must differentiate between the nature of the space and the sensitivity of the information shared. Individuals may discuss topics publicly or privately, but the content might still have privacy concerns. Researchers should assess whether individuals sharing information over the internet understand or expect their content to be public. Ethical dilemmas can occur if it's unclear whether information disseminators comprehend the public nature of their shared content. In such cases, researchers should establish criteria to assess this understanding and expectations of publicity to guide the research ethics committee appropriately.

2. Considerations on the context of data communication/dissemination on the internet

In this guideline, "context" refers to how communication formats and technology design, especially blogs and social media platforms, impact users' understanding and expectations about public data, privacy, and location information. These platforms can lead to varied perceptions among users about the public nature of their data. Researchers must consider the context of communication, including the service's openness, technology format, age restrictions, number of users accessing the information, and whether the service is intended for public information dissemination.

Researchers must decide if informed consent should be obtained from data owners or publishers. For example, data from private, password-protected social media groups require a consent process for research use. Even when using covert research methods, researchers must seek informed consent from data owners, publishers, or controllers, regardless of the research's potential societal benefits.

3. Considerations when dealing with information disseminators on the internet who belong to vulnerable groups

Researchers must adhere to ethical guidelines for human research. This involves obtaining informed consent in accordance with international standards and respecting the dignity, privacy, and confidentiality of data owners or disseminators. Researchers must also respect the values system of different vulnerable groups. For instance, if data owners or disseminators are minors or adults with diminished decision-making capacity, informed consent and/or joint assent must be obtained from guardians/legal representatives. If the data owners or disseminators are opposition politicians with issues against the government, researchers might consider alternative consent methods, such as verbal consent.

4. Protecting the privacy of information disseminators on the internet

Because of the public nature of the internet, maintaining privacy is challenging. At times, protecting privacy may necessitate creating a new identity for the data owner or information disseminator. However, even when using a pseudonym or new identity, complete privacy cannot be guaranteed. Therefore, when obtaining informed consent, researchers must clearly explain this limitation to potential research participants to ensure they understand the risks to their privacy.

5. Sharing research findings

Disclosing research findings and systemically organized big data is crucial for research validation and future benefits, enhancing confidence within society and the scientific community. However, it raises concerns about data protection, privacy, and confidentiality of research participants. Publishing data online, in academic networks, or in journals may require researchers to disclose datasets publicly, potentially in open data formats. This can lead to identifying individuals when linked with other supplementary datasets.

Therefore, internet-based researchers must consider future data use conditions, the research's public nature, the information's sensitivity, the vulnerability of data owners, and other necessary review aspects. Researchers should also implement measures to mitigate privacy breaches and confidentiality violations, such as anonymizing personally identifiable information from datasets throughout the data collection, analysis, and disclosure processes.

6. Additional considerations in accordance with the Personal Data Protection Act (PDPA)

Data owners have several rights, including the right to be informed, to access their data, to data portability, to object to data processing, to request erasure or anonymization (right to be forgotten), to restrict data processing, and to rectify.

Researchers must obtain clear, written, or electronic consent from data owners before or during data collection. The purpose of data collection must be stated clearly and understandably without deception. Consent must be voluntary and permit withdrawal unless legally restricted. Additionally, researchers must comply with the country's Personal Data Protection Act.

Chapter 4

Ethical Issues in Social Science and Humanities Research

Ethical Issues in Social Science and Humanities Research

Chapter 4 deals with the ethical issues of research in the humanities and social sciences that are important considerations in the development and implementation of research methods for researchers. The chapter also provides key components for the consideration of the research ethics committee. The five guidelines covered in this chapter include:

Guideline 11: Research in Vulnerable Participants

Guideline 12: Risks and Risk Assessment

Guideline 13: Respect for Privacy and Confidentiality

Guideline 14: Informed Consent

Guideline 15: Collection, Storage, and Use of Data in Social Sciences and Humanities Research

Guideline 11

Research in Vulnerable Participants

In the field of social science and humanities, research involving vulnerable human participants necessitates stringent ethical considerations and tailored protection to address their unique vulnerabilities. Researchers must provide a well-defined rationale for including or excluding these individuals from the research, prioritizing considerations of the risks and benefits to the participants.

The research ethics committee is responsible for evaluating and approving the proposed safeguards for vulnerable individuals. The committee may suggest additional strategies or modifications to better protect vulnerable participants. However, in some situations where the risks significantly outweigh the benefits or participation poses substantial harm, the committee may limit the involvement of vulnerable individuals in research as necessary.

Considerations for Guideline 11

Researchers have a responsibility to ethically engage with vulnerable individuals, ensuring measures are in place to protect their safety, security, and well-being when these individuals choose to participate in research. Researchers should consider the following issues:

1. Physical, emotional, psychological, reputational, social, and economical risks to research participants must be clearly specified.
2. If research poses risks that may lead to stigmatization or result in physical or psychological harm to participants, steps must be taken to minimize these risks to the greatest extent possible.
3. To prevent participants from having unrealistic expectations or undue apprehensions, researchers must communicate clearly and transparently about the potential benefits and risks associated with participation in the research.

To ensure appropriate protection for vulnerable research participants, vulnerability can be categorized based on its nature or characteristics, as follows:

1. Cognitive vulnerability or communicative vulnerability

1.1 The nature of the vulnerability

(1) Individuals with intellectual disabilities or cognitive impairments that affect decision-making abilities, such as patients with dementia or, psychiatric patients with uncontrolled symptoms or are at a stage of disease exacerbation.

(2) Individuals in situations that reduce their ability to make decisions, such as those with physical challenges or disabilities, patients in medical emergencies, those who are unconscious, or individuals enduring severe pain

(3) Children or minors under the age of 18.

(4) Individuals who cannot communicate effectively, those with hearing or vision impairments, or those who are illiterate.

(5) Individuals who cannot understand the language used to convey information about the research project, such as foreign workers or migrants.

1.2 Protective guidelines

Protective guidelines for vulnerable groups in 1.1(1), 1.1(2) and 1.1(3)

(1) A legally authorized representative should make decisions on behalf of the vulnerable individual in 1.1(1).

(2) In cases where individuals have reduced decision-making capacity, there should be a process of obtaining assent from the individual and consent from a legally authorized representative.

(3) Reconsent should be sought when the participant regains consciousness.

Protective guidelines for children or minors in 1.1(4)

(1) Researchers must have sufficient justification to involve children/adolescents in research.

(2) Researchers must seek assent from the children/adolescents and informed consent from the parents or legally authorized representatives. Researchers must observe both verbal and non-verbal cues to ascertain the child's assent or disagreement or desire to stop participating in the research. If the child is unwilling to participate, they cannot be included in the research.

(3) Research conducted in preschools or educational institutions may require permission from local government organizations, educational committees, or other relevant authorities that hold the jurisdiction to grant permission.

(4) Approval from the relevant agencies is required for research involving children and adolescents who have been prosecuted and are currently under the care of juvenile training and rehabilitation centers, the Department of Juvenile Observation and Protection, or the Ministry of Justice.

Protective guidelines for communicative vulnerability 1.1(5)

This group includes individuals who cannot understand the language used to convey information about the research project, such as migrant workers or displaced individuals. Consent documents and informational materials should be translated into a language that potential research participants can comprehend. For individuals with hearing or vision impairments or who are illiterate, impartial witnesses must participate in the consent process.

2. Institutional vulnerability

2.1 The nature of the vulnerability

Inmates, individuals on parole/probation, psychiatric patients, military personnel, elderly residents in care facilities, children in orphanages or under state custody, and employees subject to company orders are among those who reside in controlled environments governed by specific rules and regulations. This situation may result in decisions being easily influenced by those in power or guardians/overseers. Research participants may lack certain freedoms enjoyed by others and may have dependent relationships with caregivers or authority figures.

2.2 Protective guidelines

To ensure voluntary participation in research, potential participants must be able to make decisions independently and free from any undue influence from individuals in positions of authority who may exert control over them. Supervisors, caregivers, or authority figures should not be involved in obtaining consent. Researchers must communicate to these individuals the importance of respecting and safeguarding the autonomy of vulnerable individuals, enabling them to make their own informed decisions about whether to participate in the research.

3. Deferential vulnerability

3.1 The nature of the vulnerability

(1) Individuals in dependent situations may be susceptible to influence or persuasion from others. This includes patients with specific medical conditions who require care from researchers who are doctors or nurses, long-term care patients, or students who rely on researcher-teachers for their education. These groups of individuals can be characterized by their dependence on researchers or research teams for support or guidance.

(2) Individuals who are in an inferior position of power, such as children undergoing rehabilitation in rehabilitation centers, incarcerated youth, employees in companies, teachers in schools, or incarcerated individuals.

3.2 Protective guidelines

The process of obtaining consent should be conducted without the influence of individuals who could compromise the independent decision-making of the research participants.

(1) In research involving students, it is essential to ensure that research participants can freely choose to participate or withdraw from the research. Recruitment and obtaining informed consent from students to participate in research projects should be carried out by researchers who do not hold authority over the students. Measures should be implemented to ensure that research data can be collected anonymously and that researchers cannot identify research participants. For example, returning completed questionnaires in sealed envelopes or boxes. If participation in research is part of a course activity, researchers should offer alternative options to students. Students who opt not to participate or withdraw from the study should retain their rights and benefits and not be required to engage in other activities as compensation for declining or withdrawing participation in research.

(2) Researchers should refrain from conducting research within their own unit or department where research participants rely on them or their teams. For instance, a researcher acting as the head of a nursing home for the elderly, the director of a psychiatric facility, or a deputy dean of education should not engage in research

involving those populations. Institutional policies should prohibit individuals in positions of authority from conducting research within their own units. If such a researcher desires to conduct research, it should be carried out in other research settings with similar characteristics where the researcher is not involved in managing or making decisions regarding the benefits or preferences that research participants rely on.

4. Medical vulnerabilities

4.1 The nature of the vulnerability

Patients with severe, difficult-to-treat, or refractory illnesses, such as cancer patients who do not respond to treatment, patients with rare diseases, or critically ill patients with no alternative treatment options.

4.2 Protective guidelines

(1) Researchers provide complete information about the research project and explain the contents of the research to prospective participants, especially the potential risks involved. Researchers should be careful to avoid therapeutic misconception; potential participants should not misunderstand that participating in research will improve their health or well-being. Prospective participants should be given sufficient time to make an informed decision, and it is advisable to encourage them to consult healthcare providers or family members before making a decision.

(2) In cases where the research is complicated and involves intricate study designs and procedures, researchers may assess the participants' understanding to determine if they truly comprehend the research procedures.

5. Economic vulnerabilities

5.1 The nature of the vulnerability

Individuals facing poverty or lacking various welfare benefits, such as homeless individuals, patients without access to healthcare, or individuals burdened by debt.

5.2 Protective guidelines

Researchers should provide potential participants with accurate and complete information about the study while ensuring that no undue inducements are being offered that could affect their ability to decline participation. The research ethics committee should carefully consider the methods and amount of compensation for participation. Special privileges in healthcare treatment or hospital services should be avoided to prevent undue influence on participants' decision-making.

6. Social vulnerabilities

6.1 The nature of the vulnerability

Individuals in marginalized conditions within society, such as refugees, ethnic minorities, marginalized social groups, sex workers, individuals with non-conforming gender identities, political dissidents, socially stigmatized professions, and those affected by conflicts, crime, or violence. These groups have an increased risk of facing unjust practices or stigmatization.

6.2 Protective guidelines

Researchers must design the informed consent process to promote voluntary decision-making, limit the risk of privacy violations and confidentiality breaches, and implement other measures to protect the interests of those at increased risk of harm. Research ethics committees should not be overly discriminatory and allow vulnerable individuals to participate in research that directly benefits them. Special protections should also be implemented as follows:

(1) Information provided to potential research participants must not unduly coerce their participation.

(2) Consent may be strengthened by seeking permission from legal guardians, family members, or other appropriate representatives.

(3) Research risks must be limited to no more than minimal risk for studies that do not provide direct benefit to participants.

(4) Involvement of socially vulnerable groups in research should be limited to studies specifically designed to investigate conditions that directly affect these populations.

(5) Modifying the consent process should be considered to mitigate risks associated with research participation, including options such as waiving signatures or obtaining verbal consent when appropriate.

Guideline 12

Risks and Risk Assessment

During the research planning phase, researchers must perform a comprehensive risk assessment of the potential impacts on research participants and society. This assessment should continue throughout the research process to ensure ongoing risk management. Researchers are obligated to promptly report any serious adverse events during the study to the research ethics committee for timely evaluation of participants' rights, safety, and well-being.

Considerations for Guideline 12

Social science and humanities research is characterized by the dynamic and evolving nature of research methodologies, which can create challenges in anticipating all potential risks associated with a project during its preparation phase. Researchers must allocate adequate time to address this complexity through careful research design and comprehensive risk assessment, considering both individual and societal implications.

Risk assessment should be viewed as an ongoing process, requiring that documentation remain adaptable to changes in research methodologies and the specific environmental conditions of the research site. While social science research is typically classified as minimal risk, it is important to recognize that certain studies may involve risks beyond the minimal risk threshold.

1. Risks

The risks can be categorized into five forms as follows:

1.1 Physical harm: Ranging from minor discomfort to death.

1.2 Psychological harm: Including stress, mood changes, hallucinations, discomfort when discussing past behaviors, and embarrassment, worry and depression from the disclosure of sensitive information.

1.3 Social harms: Adverse effects on interpersonal relationships can include stigmatization and social exclusion resulting from others’ awareness of an individual's illness or having a profession that is despised by society.

1.4 Social and economic harms: Increased financial burdens resulting from research participation, such as additional expenses for transportation to research appointments and time lost without compensation.

1.5 Legal harm: Typically associated with research involving illegal behaviors, such as data breaches leading to legal repercussions during research participation.

2. Serious adverse events (SAEs) in research within the social sciences and humanities context

Adverse events (AE) refer to abnormal occurrences during research participation, which may or may not be related to the research process. Adverse events indicate the potential for physical, psychological, social, economic, and legal harm, affecting the rights, well-being, and safety of research participants. Some adverse events may be considered serious and/or unexpected.

Serious adverse events (SAE) include:

2.1 Events that endanger life, such as successful suicide, fatalities due to conflicts or disputes resulting in deaths.

2.2 Events that could be life-threatening , such as attempted suicide.

2.3 Events that pose a danger to one's social well-being, such as stigmatization, ostracism, sexual assault or harassment, expulsion from school or workplace, damage to reputation or scandals related to the research participant, or community breakdown where people cannot coexist. In children, these events can manifest as teasing, bullying, tormenting, exclusion from activities or rejection by friends.

2.4 Events that pose a risk of property/asset loss that affects one's well-being, such as rights violations or loss of support networks.

2.5 Events that pose a risk from changes in behavior, such as aggressive or harmful behavior towards others.

2.6 Events that pose legal risks, such as being accused, arrested, detained, or sued.

2.7 Events that could lead to hospitalization, such as physical injuries from conflicts, psychological problems triggered by past traumas, or depression requiring mental health treatment

3. Reporting of Adverse Events

Adverse/unexpected events that are not serious, occurring during social and behavioral research involving humans, must be reported in the research progress report and presented to the research ethics committee periodically as specified by the committee to assess any increased risks. However, in cases of serious/unexpected adverse events, researchers must report to the research ethics committee within **5 working days of becoming aware of the events**. This report should be made via mail, phone, or email, explaining the serious/unexpected events and the results of the causality assessment to determine if the events are related to the research activities. The research ethics committee should review and notify the review's outcome within **5 working days of receiving the report.**

Guideline 13

Respect for Privacy and Confidentiality

Invasions of privacy and breaches of participants' confidential information pose significant risks in social science and humanities research. Researchers must carefully assess the suitability of recruitment venues, data collection methods, and information dissemination practices while considering the potential invasion of the prospective participants' privacy. Data collection should be limited to what is essential, and all data must be securely stored to prevent unauthorized access. Researchers are responsible for implementing stringent security measures throughout the data collection and management processes to protect participants' confidentiality.

The research ethics committee should evaluate the appropriateness of recruitment strategies, data collection processes, data storage protocols, data usage or disclosure methods, data retention periods, and data destruction practices. This comprehensive review ensures confidence in the privacy of research participants and the security of the participants' data.

Considerations for Guideline 13

The invasion of the research participants' privacy, whether through data collection via observation or interviews, may result in feelings of discomfort, unease, stress, anxiety, or disruption of everyday life and work. Disclosing confidential information may entail various risks, including psychological harm from others becoming aware of the participants' behaviors that deviate from social norms, embarrassment, damage to reputation or social status, and social risks such as feelings of ostracization or bullying - especially in children/adolescents. Furthermore, participants may face economic risks, such as job loss or decreased income, and legal risks in research involving illegal activities that could lead to arrest, prosecution, or detention. Therefore, researchers must exercise special caution to prevent invasions of privacy and breaches of participants' confidential information, especially personal data. Research participants have a fundamental right to privacy, which is a legal principle designed to protect them from interference or intrusion from others that causes distress, annoyance, harm,

embarrassment, or unauthorized exploitation. Every individual is entitled to legal protection against such interference or harassment.

In social sciences and humanities research, researchers must design the studies with careful consideration of potential privacy invasions and the disclosure of participants' confidential information. This involves:

1. Participant recruitment

For research projects involving sensitive topics, the recruitment venue should be a quiet and private room. Researchers may contact organizations or individuals who can reach out to potential participants or use a gatekeeper to inform individuals about the project and request permission to contact them. Alternatively, if individuals express interest in participating, they can directly contact the researchers. Publicity about the project may be conducted through posters or business cards that display the researchers' contact information or through emails from relevant organizational units or research participant groups.

2. Data collection procedures

The location for data collection should be quiet and private, and only essential data relevant to the research should be gathered. Observation of participants' behavior or practices should occur only with explicit consent. However, if observations are made in public spaces, obtaining consent may not be necessary; nevertheless, permission from authorized individuals for access to data should be obtained. In certain research contexts, the unauthorized disclosure of images or audio recordings can present legal risks or cause harm. In such cases, it is advisable to use written documentation instead of visual or audio recordings.

2.1 When visiting research participants at their homes or workplaces, it is essential to specify which activities will be observed. If permission is given to take photographs or record video footage, it should only be done within the limits of the granted authorization.

2.2 When contacting research participants via telephone, LINE application, WhatsApp, video calls, or other communication applications/platforms, such communication should take place in a private setting. In cases where messages are sent, whether in the form of images or audio, it is important to ensure that these messages do not inadvertently link to sensitive issues in order to prevent individuals uninvolved in the research from being able to associate the issue to the participants.

2.3 When collecting data through internet-based or online networks that identify respondents as research participants, researchers must implement measures to protect the data from unauthorized access. It is advisable to avoid requesting information that could reveal the identity of the data provider, such as email addresses, phone numbers, national identification numbers, or driver's license numbers.

2.4 Interviews and group discussions should be conducted exclusively by the researchers. Questionnaires should avoid inquiring about behaviors that could inadvertently disclose sensitive information to third parties. For topics involving high risks, researchers should take precautions to prevent external individuals from participating during data collection.

2.5 When collecting document-based, video, or audio data, it should be stored securely in a locked cabinet located in a private area. If data is stored in cloud-based systems, appropriate measures must be implemented to prevent unauthorized access. Maintaining confidentiality is paramount, necessitating security measures such as locked cabinets with keys, password-protected computers, encryption for electronic communication, including email, and restricting access to only those individuals authorized to retrieve the data.

3. Presentation of research findings

Presenting research findings may reflect the truth or deeply held beliefs, which could potentially disclose the status of the data providers. Therefore, when presenting research results and/or publishing research works, it is crucial to prioritize the confidentiality of research participants. This includes:

3.1 Implementing strategies to anonymize participants' personal data such as using participant codes or pseudonyms in place of names in research records, refraining from specifying the study's location, and avoiding the use of identifiers like village names or individual names that could reveal the identity of data providers.

3.2 Data analysis should be conducted in a generalized manner, avoiding specific identification of data sources. If case studies or examples are used, pseudonyms can be substituted, or if the pseudonyms could potentially be linked to a data provider, codes should be utilized instead to safeguard their identities.

3.3 When researchers cite or reference the words or statements of data providers to support their research, they should provide only general characteristics of the data providers to give readers a broad understanding of the data source. For instance, they might mention that the individual is female, aged 25, and employed as a laborer.

3.4 When presenting maps of communities, researchers should exercise caution to avoid including identifying information, such as street names, community names, or nearby village names. This could enable readers to identify the location and access areas where research participants reside.

The research ethics committee must evaluate the research process in relation to privacy protection and confidentiality, considering alternative approaches to minimize risks as much as possible. This assessment should focus on the details of data collection, including methods of participant recruitment, locations for data collection, data collection procedures, and the specifics of informed consent documents for research participants. Emphasis should be placed on evaluating data recording methods to ensure they do not inadvertently identify data providers.

Measures should be implemented to prevent data breaches, such as specifying which personnel are authorized to access the data, defining the duration of data retention, and outlining procedures for data destruction upon the completion of the research. Additionally, the ethics committee should provide recommendations regarding the presentation of research findings that may inadvertently disclose the status of data providers and the research locations.

Guideline 14

Informed Consent

Researchers must deliver clear, comprehensive information about the study, enabling potential participants to make informed decisions. They should inform participants of their right to withdraw at any time without repercussion. Additionally, researchers should implement measures to protect against inappropriate recruitment or undue inducements and select the most suitable informed consent process.

The research ethics committee is responsible for reviewing and approving the informed consent process and the information provided to participants. The committee may consider granting a waiver of informed consent or modifying the process as appropriate.

Researchers should evaluate whether the consent document needs to be updated when the research project changes or new relevant information becomes available. They must then seek approval from the research ethics committee for the revised documents and determine whether re-consent is necessary.

Considerations for Guideline 14

Informed consent is a vital ethical foundation of research involving humans. The underlying fundamental philosophy of informed consent is individual autonomy and respect for persons. The Belmont Report has addressed the principle of respect for persons, stating that every individual should be treated as autonomous, and those lacking autonomy should be protected. Ethical requirements are divided into two parts: 1) requirements regarding respect for individual autonomy and 2) requirements for protecting individuals lacking autonomy.

A valid consent process must encompass three components: 1) completeness of relevant information for decision-making; 2) comprehension – participants must have a sufficient understanding of all relevant research information to make informed choices; and 3) voluntariness, ensuring that potential participants can make their decisions freely regarding participation without experiencing coercion, undue influence, or deception.

Researchers are responsible for the methods and processes of obtaining consent throughout the entire research project. This process does not end when research participants

agree to join the study. The initial informed consent documented at the project's outset may not be adequate, particularly in scenarios where changes in the research project occur or new information emerges that could influence participants' decisions to continue or withdraw from the study. Thus, researchers must assess when it may be necessary to modify existing consent forms or request re-consent during the research process. Should modifications be required, revised consent documents must be presented to the research ethics committee for approval before seeking re-consent from already-enrolled participants and obtaining consent from new prospective participants.

1. Obtaining informed consent in adults

The standard for obtaining informed consent requires researchers to provide clear and comprehensive information to each potential participant before seeking their consent. Consent can be expressed in various forms, including written, verbal, or implied. Generally, research participants should document their consent in writing and date the form. For individuals who lack decision-making capacity, consent must be obtained from a legally authorized representative.

1.1 Waiver of informed consent

The research ethics committee may consider waiving the requirement for informed consent if:

(1) obtaining consent is impractical, and

(2) the research has significant social values, and

(3) the research poses no more than minimal risks, and

(4) adequate measures are implemented to protect the data confidentiality.

1.2 Waiver of signature in the informed consent process

The research ethics committee may approve the waiver of signature requirement on the consent form if the researcher provides a valid justification as follows:

(1) In certain contexts and cultures, obtaining written consent may not be suitable for research participants. Researchers should detail how they will obtain consent through alternative methods, such as verbal or implied consent.

(2) In certain situations, requiring written informed consent may expose participants to social risks. Researchers should propose alternative methods for obtaining consent, such as direct discussions with participants, and provide a clear rationale for these approaches when seeking approval from the research ethics committee.

1.3 Data withholding to ensure scientific integrity in deception study

In social science and behavioral research, researchers may intentionally deceive participants to examine their attitudes and behaviors. The research ethics committee may approve such deception if:

(1) it is deemed necessary and there is no alternative method capable of producing accurate and credible results;

(2) the research possesses significant social value;

(3) the risks to participants are minimal; and

(4) the deception would not lead a reasonable person to refuse participation once informed of the true nature of the study.

Upon completion of data collection and before data analysis, research participants must be informed of any previously withheld information. They should also be given the opportunity to withdraw their data if they desire, after being made aware of the intended use of the data (*See Guideline 9)*.

1.4 Consent with an Impartial Witness

When potential participants are illiterate, blind, or have a hearing impairment, researchers must designate an impartial witness to verify that the researcher has accurately read and explained the information to the participants and confirm the witness's involvement in the consent process. While the presence of a witness may pose a risk to the volunteer's privacy and confidentiality, it is considered an acceptable exception in such circumstances.

2. Assent process for adults

Adults with reduced decision-making capacity, such as those with early-stage dementia or occasional confusion, but retain some awareness of their surroundings, should be treated with respect for their remaining capacity. As such, their assent should be obtained alongside consent from their legally authorized representative. (*See Guideline 11*).

3. Assent process for children

Children are unable to provide consent based on full understanding, but they can offer assent. Thus, obtaining assent is essential and must be accompanied by consent from a parent or legally authorized representative before the study begins. The assent process should meaningfully engage the child, mirroring the adult consent process by providing clear and necessary information. Signatures should be obtained as evidence of the assent process. If a child reaches 18 years of age while still participating in the research, researchers must seek re-consent and obtain new signatures as evidence of continued participation.

For children aged 0-6, only parental consent is generally required. For children aged 7-12, both parental consent and the child's assent are necessary. Assent documents for this age group should use age-appropriate language and may incorporate images or media to enhance understanding. For adolescents aged 13-17, consent must be obtained from parents or guardians, along with the adolescent's assent. Explanatory documents or information provided to adolescents can be the same as those given to their parents or guardians.

3.1 Refusal of assent by the child/adolescent

If a child/adolescent refuses to provide assent, their decision must be respected, and they cannot be enrolled in the research unless the research offers significant direct benefits to them as participants.

3.2 Cases in which parental consent may be waived

Certain types of research may have future impacts on children/adolescents, such as punishment from the parent or family-related challenges. In such cases, researchers may request a waiver of parental consent, subject to review and approval by the research ethics committee. Parental consent may be waived in the following situation:

(1) Research on minors/adolescents legally considered as adults, such as those married according to the law;

(2) Research related to beliefs and sexual behavior;

(3) Research on family violence or child abuse;

(4) Research related to sexually transmitted diseases, unwanted pregnancies, abortion, family planning, or drug use; and

(5) Research on children and adolescents who had engaged in criminal activities and were placed in training or rehabilitation centers. In these cases, consent must be obtained from the legally authorized person, as defined by applicable law.

4. Informed consent form

The researcher is responsible for drafting the informed consent document, while the research ethics committee is tasked with reviewing it for completeness, accuracy, and the appropriateness of the language used. This review ensures compliance with ethical obligations and regulatory requirements (*See Item 5 below*), and confirms that essential information for participants' decision-making is clearly presented. The information must be concise, age-appropriate, and tailored to the participant's knowledge and educational level. It should use short, simple sentences in clear language or a locally understood dialect, enabling potential participants to state their reasons for consenting or declining participation.

5. Writing informed consent document and consent document

The informed consent document must include details required by ethical guidelines and applicable regulations. The information to be provided should not only describe the research but also emphasize the participant's autonomy in deciding whether to participate or decline. Researchers should provide essential information to support the decision-making process of research participants. The information provided should include:

5.1 A clear explanation that participation in the research is entirely voluntary and that no position of authority will be used to influence the participants' decision to participate.

5.2 The rights of potential research participants to withdraw consent at any time without facing any negative consequences.

5.3 A clear and detailed explanation of study's rationale, objectives, study methods, study scope, and plans for data collection, storage, use, and dissemination, as well as the expectations or requirements for participation and the anticipated outcomes

5.4 The participant selection criteria.

5.5 An outline of the potential benefits, risks, burdens, and discomforts that may arise from participation in the research.

5.6 An estimated duration of participation and tasks that potential research participants must undertake.

5.7 An explanation of the safety measures for research participants and provide information on insurance (if applicable).

5.8 Information regarding any compensation for time and inconvenience, including expenses incurred from participating in the research.

5.9 The party responsible for compensation for research-related injuries.

5.10 Information regarding alternative options if the individual chooses not to participate in the research.

5.11 A disclose regarding potential unexpected findings beyond the scope of the research and how they will be managed (*See Guideline 17*).

5.12 Information regarding which data may be used in the future. If the data is identifiable and could reveal the identity of participants, it cannot be used for other projects without obtaining their explicit consent (*See Guideline 15*).

5.13 A disclose of the research sponsor and their objectives.

5.14 A disclose of who will benefit from the research.

5.15 Information regarding potential unintended, unforeseen, and accidental findings and an explanation of how they will be addressed.

5.16 An explanation of the copyright of the data and other materials used in the research and the confirmation that the data will not be used for commercial or non-academic purposes.

5.17 An explanation of confidentiality measures and limitations for protecting research participants' personal and sensitive data, including conditions or limitations for maintaining confidentiality and non-disclosure of research participants' names, privacy, and family life.

5.18 The name, address, telephone number, and/or contact information of the person to contact for research-related questions (the researcher).

5.19 The name, address, telephone number, and/or contact information of the person to contact regarding questions about the rights or potential violations of the rights of research participants (the research ethics committee).

Specific Cases

5.20 The research design must be clearly explained for studies involving comparative groups, such as randomization into experimental and control groups. Neither the researcher nor the participants can influence or choose the group to which a participant is assigned as the process is determined randomly to ensure the integrity of the study. In the case of blinded studies, participants will not be informed about their group assignment until the study is completed to maintain objectivity and prevent potential bias.

5.21 In cases involving deception or partial disclosure of information, requesting an agreement to accept incomplete information at the outset may be necessary. Researchers must ensure that complete information is disclosed to participants prior to the analysis of research results. Researchers must inform potential participants of their right to withdraw data after they are made aware of any previously undisclosed information (*See Guideline 9*). This ensures that participants maintain autonomy and have the opportunity to make an informed decision regarding their continued participation.

5.22 Researchers must clearly differentiate between research and humanitarian assistance when conducting research on disaster victims, who are often in a vulnerable state or under threat.

5.23 When conducting research in online environments and using online or digital tools that may involve vulnerable individuals, researchers must clearly explain the privacy and security controls in place to protect participant's data, as well as the limitations of the measures used and the risks that may still occur despite preventive measures *(See Guideline 10).* Transparency about these risks allows participants to make an informed decision about their involvement, especially when vulnerabilities are a concern.

Guideline 15
Collection, Storage, and Use of Data in Social Sciences and Humanities research

When storing research participants' data for future research purposes, the data owners must give either specific informed consent for a particular use or broad informed consent for unspecified future use.

Broad informed consent is ethically acceptable when a proper governance system is in place and future research aims to benefit society, particularly human well-being. This form of consent allows research participants to control the use of their identifiable data to some extent.

The storage and future use of identifiable data in research do not require additional consent from the data owner unless the scope of the future research project diverges from the broad informed consent originally obtained. However, all future research must undergo prior review and approval by an ethics committee.

Broad consent can be effectively implemented when a research institution or researcher establishes a robust system to track data from participants who have provided broad consent, including the specific conditions of that consent for monitoring purposes. This approach ensures that future research endeavors remain within the parameters of the broad consent.

Data controllers must protect the confidentiality of information linked to research participants by sharing only de-identified or encrypted data with researchers and limiting access to third-party content. The data controller must securely manage the encryption keys.

In cases where researchers intend to use data collected from past research or stored for other purposes without having obtained informed consent for future use, the research ethics committee may consider waiving individual informed consent if the following conditions are met:

(1) the research would not be feasible without the waiver of consent;

(2) the research holds significant social value;

(3) the research poses no more than minimal risk to participants; and

(4) there are appropriate measures in place to protect the confidentiality of data in accordance with the Personal Data Protection Act (PDPA) or equivalent laws on personal data protection.

The research ethics committee must review and approve the broad informed consent documents, ensuring the process and content meet international standards. This review includes, for instance, an assessment of the data collection methods, the duration of data retention, the rationale for storing data, the scope of future use, and the governance system for data storage.

Considerations for Guideline 15

The collection and storage of personally identifiable information for future research purposes must be based on the informed consent of the data owner and should involve clear communication to ensure genuine understanding before participants make decisions. Additionally, institutions or researchers responsible for data collection must have appropriate governance systems in place.

1. The collection of identifiable personal data for future research use

Researchers must clearly explain the request to collect and retain data for future use within the current research project and the informed consent documents. Additionally, there must be a separate and comprehensive informed consent document specifically addressing data collection for future use, which is distinct from the consent to participate in the current research. This document should outline the details of data collection methods, retention practices, and the intended usage of future research data. Participants in the current study have the right to refuse consent for their data to be stored for future use without affecting their current participation in the research.

The research ethics committee should review and approve the process and completeness of the content in the consent documents, ensuring adherence to the components specified by international standards.

2. The components of documentation for seeking broad consent

Documentation for seeking broad consent for participation in research should encompass the following components:

2.1 Voluntary Participation

Participants must be informed that participation in the research and consent to data collection and retention is voluntary. Refusing broad consent should not affect their participation in the current research. Although participants may have already consented to the future use of their data, they should still be able to request for the withdrawal of their data from storage at any time. However, it should be made clear that there may be limitations in withdrawing the data, especially if research is already underway.

2.2 Notification of Changes

Participants have the right to be notified of any changes to the original research objectives that may impact their involvement or data usage.

2.3 Identification of Data

The documentation should specify the types of data intended for future research, including information from interviews, academic records, personal data, and questionnaire responses.

2.4 Scope of Future Research

Clearly defining the scope of future research using stored data without the need for re-consent is essential. This includes defining the research types and data applications, such as studies on adolescent behavior or caregiving models for individuals with mental illness.

2.5 Data Storage Specifications

Outline the location and procedures for data storage, detailing storage systems, access regulations, and authorized individuals for research access.

2.6 Data Confidentiality Measures

Describe confidentiality measures, such as coding by uninvolved individuals, maintaining separation between identifiable and non-identifiable data, and restricting access to coding information. Exceptions should be noted for necessary situations.

2.7 Data Retention Period

Indicate the expected data retention period, including the termination date or noting indefinite retention if there is no termination date.

2.8 Risks of Data Retention

Explain risks associated with retaining data, including potential exposure or leakage of personal data, and specify measures to ensure confidentiality and to limit data sharing.

2.9 Anticipated Risks or Discomforts

Provide an explanation of any anticipated risks or discomforts participants may experience.

2.10 Expected Benefits

Outline potential benefits to participants or society from the research, noting that data owners may not directly benefit from their data usage.

2.11 Sharing of Commercial Benefits

Indicate if there might be commercial benefits from the research and describe any expected benefits to the participants or others.

2.12 Communication of Results

Specify whether participants will be informed about the results of future research.

2.13 Notification of Unexpected Findings

Detail the approach for notifying data owners about unexpected research findings.

3. Research Involving Personally Identifiable Information for Secondary Data Research

3.1 Approval Before Research Commencement

Before starting research that utilizes stored data, researchers must submit a research proposal to the research ethics committee for approval. If the researcher collected the data using broad consent, they must attach a certified informed consent form endorsed by the ethics committee for the ethics committee to review.

3.2 Data Requests from Other Databases

When requesting to use data from external databases or data banks, researchers must submit a research proposal approved and certified by the research ethics committee to the data custodian for consideration and approval of data access and use.

4. Governance

Utilizing data under broad consent requires appropriate governance. The data controller must have the necessary qualifications and must ensure the implementation of the appropriate governance measures, which must include the following elements:

4.1 Objectives for data storage or database creation

4.2 Nature/type of data that will be stored

4.3 Management procedures for data retention according to established timeframes.

4.4 Provisions for the regulation of data disposal and destruction

4.5 Procedures for the Documentation and monitoring of data in accordance with the consent provided

4.6 Management procedures to handle changes in database ownership or closure

4.7 Procedures to obtain appropriate consent for personal data collection based on relevant laws

4.8 Provisions for Safeguarding of dignity, autonomy, privacy, and protection against discrimination

4.9 Data access criteria and procedures, including procedures for data sharing and granting the data controller authority to permit or deny usage.

4.10 The Data Controller, whether as an individual or group of individuals who are responsible for appropriate data governance.

4.11 Security measures to prevent unauthorized access or inappropriate sharing

4.12 Confidentiality measures for linking collected data and personal information of research participants.

4.13 Contact information for participants wishing to withdraw their data from the database.

4.14 Recontact procedures for recontacting relevant research participants

4.15 Inquiry response procedures for receiving and responding to inquiries and complaints.

Chapter 5

Other Ethical Issues related to Research Conduct

Other Ethical Issues related to Research Conduct

This section consists of four guidelines on various other ethical issues related to research conduct. These guidelines are intended to support the planning and implementation of research activities for both researchers and research ethics committees. They are as follows:

Guideline 16: Research Setting

Guideline 17: Unintended, Unexpected, and Incidental findings

Guideline 18: Misuse of Research

Guideline 19: Protocol Deviation and Noncompliance

Guideline 16

Research Setting

In the social sciences and humanities, research often requires researchers to navigate areas characterized by resource inequality, cultural differences, or environmental conditions that pose risks to the research participants and researchers.

When selecting research locations in resource-limited communities, researchers must consider strategies for sharing benefits, including addressing local research needs and fostering community development. Sensitivity to local customs and practices is essential to ensuring research alignment with the community context.

In high-risk areas, researchers must devise clear strategies to ensure the safety and well-being of all involved parties. This includes conducting risk assessments and establishing security measures, such as team training and insurance coverage.

Considerations for Guideline 16

Research in this field deepens our understanding of diverse communities both nationally and internationally. It is crucial for addressing complex social issues and improving individual well-being. However, conducting research in locations marked by resource disparities, cultural diversity, and inherent risks poses safety challenges for research participants and researchers.

1. Access to Research Settings

1.1 In research settings where gatekeepers control access to the target population, researchers must secure permission from these individuals before approaching the sample group. Consent from each research participant is necessary, and the informed consent process should provide potential research participants with the information they need to make an informed decision autonomously.

1.2 When researchers immerse themselves in communities for firsthand experience, they must obtain community permission before entry. This involves presenting themselves to community leaders, explaining the research objectives, and securing consent from community members in advance (see Guidelines 5 and 6).

1.3 Researchers must obtain permission from the Department of Fine Arts prior to commencement of studies involving ancient cities, archaeological sites, or the analysis of artifacts in laboratories abroad (see Guideline 1).

1.4 Permission must be obtained in advance from the Department of National Parks, Wildlife, and Plant Conservation, or the Department of Forestry for any research conducted within protected forest areas or requiring the removal of specimens.

1.5 Researchers must obtain permission from the relevant approving authority or agency before commencing research in educational institutions (see Guideline 4).

1.6 Researchers are required to secure permission from the respective authority in advance for research settings affiliated with the Department of Juvenile Observation and Protection.

2. Issues of Conducting Research in Economically Marginalized Areas

Conducting research in economically marginalized areas necessitates thorough ethical considerations to ensure sensitivity and respect toward participants and communities. Researchers should keep the following points in mind:

2.1 Community Relevance: The research must address issues pertinent to the specific site or provide tangible benefits to the community. Collaborating with stakeholders who have vested interests is essential. Researchers should strive to contribute positively to society while maintaining transparency about research goals and potential impacts.

2.2 Avoiding Exploitation: Researchers must refrain from exploiting educationally disadvantaged or economically marginalized communities for personal or professional gain.

2.3 Cultural Sensitivity: It is critical for researchers to be sensitive to the local context, ensuring that their work aligns with the customs and practices of the area while respecting cultural values and norms.

2.4 Informed Decision-Making: Researchers must provide comprehensive information to participants to facilitate informed decision-making regarding their involvement. Even if the research is publicly disclosed within the community, it is vital to ensure that potential participants fully understand the research objectives, procedures, risks, and benefits. Special attention should be given to the informed consent process to prevent coercion among economically vulnerable individuals.

2.5 Respect for Autonomy: Researchers should respect the autonomy and self-governance of the community. It is crucial to avoid infringing on cultural beliefs and practices, as well as actions that may harm the reputation or well-being of the community. Efforts should promote positive outcomes, such as improved health and well-being for the local population.

2.6 Community Involvement: Engaging research participants from local communities throughout the research process—from planning to evaluation—is essential to incorporate their perspectives and values (see Guideline 5).

2.7 Feedback to Communities: Researchers should provide feedback on research findings to both the community and participants in an easily comprehensible manner (see Guideline 5).

2.8 Applicability of Findings: Researchers need to demonstrate the potential applicability of their findings nationwide, in areas with economically prosperous and disadvantaged regions.

2.9 Publication Considerations: Researchers should seek community approval before publishing findings intended for public dissemination to avoid contentious issues. Caution must be exercised to exclude sensitive information that could damage reputations or incite controversy, including avoiding disclosing community names in the title or location of the study.

2.10 Privacy and Confidentiality: Protecting the privacy and confidentiality of participants, especially regarding sensitive economic and social issues, is paramount. Researchers should implement rigorous checks to ensure data do not lead to identity exposure and are securely stored to prevent harm to research participants (see Guideline 13).

3. Issues of Conducting Research in High-Risk Settings

Research conducted in environments that pose risks to both researchers and participants can jeopardize their safety and well-being. Areas affected by conflicts, non-democratic governance, economic instability, political unrest, environmental hazards, or health crises require special consideration. In such contexts, researchers should adhere to the following practices:

3.1 Local Collaboration: Research conducted abroad or in high-risk areas should involve a local researcher or coordinator and prior permission from the relevant authorities

should be obtained. Clear strategies must be established to ensure the safety of all involved.

3.2 Needs Assessment: Thorough examination and needs assessment should precede research in risky environments to confirm that it addresses significant issues that contribute positively to the well-being of local participants.

3.3 Neutrality in Conflict Areas: In conflict-prone areas, researchers must maintain neutrality and avoid taking sides. Adequate security measures should be implemented to protect both research participants and researchers.

3.4 Risk Management Plan: Where research may pose risks to health, safety, or well-being, researchers must establish a predetermined risk management plan in coordination with stakeholders from their affiliated institution before commencing.

3.5 Stigma and Accusations: In cases where participation may lead to stigmatization (e.g., research on sexually transmitted diseases) or disparagement (e.g., involvement with sex work or political beliefs), special measures should be implemented in collaboration with community representatives to ensure participant safety and well-being.

3.6 Safety Plans and Training: Research in high-risk environments requires detailed safety plans. Researchers must outline safety measures for participants, ensure research teams undergo training, and secure insurance coverage for protection.

When considering ethical issues in human research related to the research setting, committee members should recognize that the research setting encompasses not only the physical space but also the people, their lifestyles and associated dangers or risks within that place/area. Therefore, ethical considerations in human research necessitate that researchers possess adequate knowledge and understanding of their research setting to address ethical considerations effectively.

Guideline 17
Unintended, Unexpected, and Incidental Findings

Unexpected and unintended findings in social science and humanities research can present ethical and practical challenges. Researchers must approach these findings responsibly and ethically, prioritizing the safety and well-being of participants while contributing to knowledge advancement. Research institutions should create clear policies and ethical guidelines to effectively navigate and manage such situations, and researchers should diligently adhere to these established policies.

Considerations for Guideline 17

Research methods commonly used in social science and humanities, including field data collection, observation, and interviews, may lead to unexpected findings that fall outside the original research framework. In such cases, researchers face the dilemma of deciding whether to maintain confidentiality or disclose information to authorities.

Unintentional findings can present ethical challenges, particularly if they reveal criminal activities, human trafficking, misconduct, violence, or abuse within families, schools, or communities. Researchers must communicate their intentions and reasons for potential disclosures to participants, guardians, or responsible parties, ensuring that such disclosures do not harm the individuals or communities involved. If researchers discover unintended findings, they should inform the research ethics committee, as researchers' actions may extend beyond the approved research project due to unintended findings.

In some countries, the law mandates that researchers report criminal activities, even if it conflicts with confidentiality agreements. In sensitive cases, such as research involving refugees, it may be more appropriate for researchers to collaborate with non-governmental organizations or agencies with the relevant expertise rather than directly contacting authorities. Therefore, researchers should inform participants of the potential for these actions to arise during the informed consent process.

If no specific law in the country mandates that researchers report findings to authorities, research institutions should establish policies and guidelines for such situations, and researchers should be expected to adhere diligently to these policies.

Incidental findings should be managed as follows:

1. *Advance Planning*: Proactively plan for unintended and unexpected findings that may pose risks or potential harm, even if unintentional.
2. *Confidentiality Limitations*: The participant information document should clearly specify the policy regarding confidentiality and inform participants about its limitations.
3. *Legal Considerations*: Consider the legal context of the research. Consultation with the relevant regulatory bodies or legal authorities is advised to ensure compliance with the law.
4. *Discussion Structure*: Outline a structure within the research plan for discussing incidental findings within the participating organization.

Guideline 18

Misuse of Research

Misuse of research refers to the inappropriate application of findings, data, or methodologies for purposes beyond the original study objectives. Researchers must remain vigilant against potential misuse and handle such issues responsibly, aiming to prevent or minimize associated risks and damages.

When designing research, it is essential to consider the possibility of unethical objectives arising from the study. Researchers should evaluate the potential for misuse of their findings. If such risks are identified, they must promptly report them to their affiliated research institutions and funding bodies.

Considerations for Guideline 18

In some research endeavors, the materials, methods, or technologies used may create the opportunity for unethical applications. Even research initiated with benign intentions can pose risks to humans, animals, the environment, or society. While the risk of misuse cannot be entirely eliminated, it can be significantly minimized through timely identification and acknowledgment of these risks.

Researchers must consider both the immediate objectives and whether their work could be used for unethical purposes when designing studies. For example, research involving vulnerable or marginalized groups, or aimed at developing technology, social histories, behaviors, or genetics, may inadvertently lead to misuse such as stigmatization, incitement of hatred, harassment, or intimidation of participants.

1. Research Design

During the research design phase, researchers should consider the following questions to evaluate potential misuse:

1.1 Risk Assessment: Could the materials, methods, technologies, or knowledge used in the research pose risks to humans, animals, or the environment if altered?

1.2 Malicious Use: What are the potential consequences if these elements are accessed by individuals with malicious intent, such as criminals or aggressors, or if they are used to undermine human rights or civil liberties?

1.3 Unethical Usage: Could these elements be applied for purposes beyond those intended, and would such usage be unethical?

1.4 Human Rights Impact: Does the research impact human rights? Examples of this include studies on surveillance technologies and emerging technologies for data collection and merging, such as those involving big data. Social research that could lead to discrimination or stigmatization is also included in this category.

2. Measures to Mitigate Risks

2.1 Expert Involvement: Include a committee or independent consultant with expertise in human rights in meetings to evaluate research projects with potential for misuse.

2.2 Staff Training: Ensure staff are trained and equipped to protect technology with technical safeguards. Implement policies and procedures to protect and control access to personal data.

2.3 Cautious Data Dissemination: Exercise caution in publishing and disseminating data. Adopt a "privacy by design" (PbD) approach to data protection, focusing on prevention rather than correction, to prevent incidents or risks of personal data breaches (before-the-fact, not after). For example, browsers like Google Chrome warn users about high-risk websites, enabling informed decisions.

2.4 Research Design Adaptation: Adjust the research design by obtaining permission to use confidential data beforehand. Consider creating dummy data sets for initial system testing.

3. Planning research with concerns about potential misuse

When planning research with potential misuse concerns, the following steps should be taken:

3.1 Risk Assessment: Identify and detail various concerns regarding potential misuse and specify methods for mitigation or prevention.

3.2 Mitigation Strategies: Clearly present the strategies developed to mitigate the risks.

3.3 Ethics Approval: Submit the research project for approval from the research ethics committee.

Guideline 19

Protocol Deviation and Noncompliance

Researchers should promptly report any deviations from the research protocol and any instances of non-compliance with international guidelines or regulations set forth by the research ethics committee. Timely reporting is essential for the ethics committee to evaluate the potential impact of these deviations on the safety and well-being of research participants.

Considerations for Guideline 19

In the fields of social sciences and humanities research, issues of protocol deviation and research misconduct may arise and are defined as follows:

1. Protocol Deviation

Protocol deviation refers to the failure to adhere to the research protocol approved by the research ethics committee. This may include deviations from the details of the research project, summaries of participant information documents, consent forms, recruitment materials, questionnaires, and other relevant project-related information. Such deviations can range from minor infractions that do not impact the risk to research participants (referred to as deviations) to significant breaches that affect participant safety (violations).

2. Noncompliance with Regulations

Noncompliance refers to any action that fails to adhere to the laws, regulations, rules, or requirements established by a country, organization, institution, or research ethics committee. Examples include neglecting to submit mandated progress reports for the research project, failing to report deviations when they occur, or implementing changes to the research project without obtaining prior approval from the ethics committee.

3. Reporting Protocol Deviations and Noncompliance

When researchers become aware of protocol deviations or noncompliance issues, they should report the situation to the research ethics committee within 5 business days if the situation impacts the safety of research participants and within 10 business days for cases that have no impact on participant safety.

Upon receiving complaints or identifying instances of protocol deviation or noncompliance, the research ethics committee should conduct a thorough review. If the committee determines that the issue significantly affects participant safety, it may temporarily suspend the project's approval, withdraw approval entirely, or deny consideration of any new research projects submitted by that researcher.

Chapter 6

Conflicts of Interest and Management of Conflicts of Interest

Conflicts of Interest and Management of Conflicts of Interest

This chapter has a single guideline, Guideline 20, which addresses Conflicts of Interest and the Management of Conflicts of Interest. This guideline is crucial for effectively managing research conduct, encompassing the roles of researchers, research institutions, and research ethics committees.

Guideline 20
Conflicts of Interest and
Management of Conflicts of Interest

Conflicts of interest among researchers, research institutions, and research ethics committees can significantly impact various aspects of the research process, including selecting research questions and methodologies, participant selection, adherence to ethical standards, data interpretation, and disseminating findings. Therefore, it is essential to identify and manage these conflicts to uphold the integrity and credibility of scientific research.

To mitigate potential biases, researchers, institutions, and ethics committees should fully disclose all possible conflicts of interest—both financial and non-financial—in research proposals, funding applications, ethics reviews, and published studies. This transparency enables stakeholders to assess potential biases and facilitates effective conflict management, ultimately fostering trust in scientific findings.

Research institutions and regulatory agencies should collaborate to establish and enforce policies that promote transparency, ensure the disclosure of relevant information, and uphold ethical standards in research practices. Training staff involved in research is crucial to heighten awareness about the significance of conflicts of interest, their impact on research credibility, and the potential risks they pose. This collaborative approach will cultivate an environment of ethical integrity and accountability within the research community, ultimately strengthening public trust in scientific outcomes.

Considerations for Guideline 20

Conflicts of interest arise when the benefits of individuals involved in research inappropriately influence the decision making process and impact the primary objectives of the research. Managing conflicts of interest is crucial to safeguard the research's scientific integrity and protect research participants' rights and benefits.

1. Researchers

Researchers should develop and adhere to a mitigation plan that outlines steps to minimize the impact of conflicts of interest while maintaining research ethics and ensuring the safety of research participants.

1.1 Conflicts of Interest

Researchers may have financial interests linked to research outcomes that lead to overlapping benefits, a common issue in the field. Examples of financial conflicts include ownership of stocks, consultancy fees, or funding from independent companies or organizations that may influence the research process or its outcomes.

Non-financial conflicts of interest can also be significant. These may arise from personal, professional, or academic interests that could lead to biases in research. For instance, strong beliefs or partnerships with specific groups or ideologies may affect research objectives. Teachers conducting research on their students may face conflicts between the student's learning objectives and the research goals, which could positively influence their professional advancement (refer to Guideline 4).

Furthermore, intense competition within research and academic communities often exacerbates these conflicts. The criteria used for faculty appointments, evaluations, and promotions frequently emphasize publication outcomes, placing significant pressure on researchers. This competitive environment can lead to a desire for recognition or career advancement, which is often linked to the compensation received.

1.2 Responsibilities of Researchers

(1) Disclosure of Conflicts of Interest

Researchers should disclose any conflicts of interest and adhere to their institution's policies regarding such conflicts. It is important to note that conflicts of interest do not necessarily indicate inappropriate motivation or misconduct. Rather, they must be identified and managed appropriately. Researchers are required to disclose any conflicts of interest to the research ethics committee to facilitate proper evaluation and management.

(2) Training and Compliance

Researchers should actively participate in training programs related to their institution's policies and procedures on conflicts of interest. Ensuring compliance with these policies is essential to uphold the integrity of the research process.

2. Research Institution (University, Research Center)

Research institutions should develop and implement policies and procedures to mitigate conflicts of interest and educate their staff about such conflicts.

2.1 Conflicts of interest

The research institution (such as a university or research center) may experience conflicts of interest related to both its reputation and financial aspects. For example, universities often leverage their research reputation to attract faculty, students, and external funding. Additionally, some universities patent discoveries made by their personnel. Conflicts of interest may arise for a research center when it receives substantial financial support from a single sponsor or just a few sponsors.

2.2 Responsibility of Research Institutions

(1) Establishing and Promoting Institutional Policies

Research institutions must develop and maintain policies that clearly provide detailed guidance on each component of the procedure to disclose and manage conflicts of interest. These policies should be easily accessible to staff, researchers, stakeholders, as well as the public, and they should be regularly reviewed to incorporate new professional standards or regulatory changes. Specific elements of these policies should include:

1) Requiring researchers to disclose all relevant conflicts of interest to the research ethics committee when proposing research projects for review.

2) Providing guidance to researchers on how to appropriately disclose relevant conflicts of interest to research participants, other pertinent parties, and the public.

3) Explaining the processes related to identifying and managing conflicts of interest, including those responsible for these processes.

4) Mandating the retention of records of conflicts of interest related to current research funding.

5) Requiring documentation of the management of each type of conflicts of interest, taking into consideration the appropriate confidentiality requirements.

6) Specifying expectations for researchers and staff to comply with relevant external entities' disclosure policies and operational procedures.

(2) Training for researchers and research ethics committees

Research institutions must provide continuous training and instruction to raise awareness of conflicts of interest and the importance of managing such conflicts. This is

crucial for ensuring the effectiveness of processes and policies, promoting and supporting research activities responsibly, and assisting researchers and other relevant stakeholders in understanding and adhering to the institution's policies on disclosure of conflicts of interest.

2.3 Managing Institutional Conflicts of Interest

Managing institutional conflicts of interest that may affect the design, review, conduct, and dissemination of research conducted within research institutions is considered a best practice. Examples of institutional conflicts of interest include intellectual property rights or income from licensing agreements (existing or potential future), government funding for research projects, or individual infrastructure projects. If institutional conflicts of interest are identified, decisions must be made regarding the most appropriate measures to manage these conflicts, following principles of transparency. Institutions are encouraged to respond to reasonable requests for research support while addressing competing interests or related conflicts of interest.

3. Ethics Committee

Research ethics committees play a crucial role in upholding research ethics by carefully assessing conflicts of interest, considering both the likelihood and magnitude of their impact and providing appropriate recommendations for action. This process helps maintain trust in research institutions and ensures that suitable methods are used to mitigate the effects of conflicts of interest on ethical research standards and the well-being of research participants.

3.1 Conflicts of interest

Researchers who serve as members of research ethics committees may encounter conflicts of interest in their roles. Such conflicts can arise when researchers submit projects for review by the committee, or when committee members are tasked with reviewing research work submitted by close family members, acquaintances, or colleagues with whom they have a personal relationship. Additionally, conflicts of interest may occur when committee members evaluate research projects that they believe are crucial for the success of the research institution they are affiliated with.

3.2 Responsibility of ethics committee

(1) Members of the research ethics committee who have conflicts of interest must recuse themselves from reviewing certain research projects.

(2) The research ethics committee must assess the severity of the conflicts of interest, primarily determining whether these conflicts adversely affect the ethical conduct or scientific integrity of the research study. This process requires the committee's discretionary judgment and involves a thorough evaluation of the specific details surrounding each conflict of interest.

(3) The committee must evaluate the potential impact of conflicts of interest—such as financial gains or academic advancements—on the rights and well-being of research participants and scientific integrity.

1) The research ethics committee should evaluate the magnitude or significance of the conflicts of interest in relation to the specific situation and personal circumstances of those involved. For example, researchers with substantial financial ties to funders may experience a higher degree of conflict compared to those with minimal financial benefits.

2) The severity of conflicts of interest can vary significantly among individuals. Therefore, the committee should take personal circumstances into account. For instance, younger researchers with modest salaries may be at greater risk of experiencing conflicts of interest than the established senior researchers who are financially stable.

(4) When evaluating conflicts of interest, the research ethics committee must balance ethical considerations, including participant welfare and scientific validity. Protecting the rights of participants and ensuring the accuracy of research outcomes are of paramount importance.

(5) Depending on the severity of the conflicts, the research ethics committee may recommend or establish various measures to manage them. These measures may include disclosure, withdrawal from certain responsibilities, or other actions to mitigate bias or potential harm. Generally, severe conflicts of interest are more likely to arise when researchers' actions are influenced by professional or academic benefits or financial gains, leading to biased research outcomes, harmful to research participants, or unethical research conduct.

(6) The research ethics committee may require the researcher to disclose conflicts of interest such as personal beliefs to potential research participants during the consent process. This disclosure should enable potential research participants to evaluate the significance of the identified conflicts of interest. In instances of severe

conflicts, it is advisable that the information provider be a member of the research team who does not have conflicts of interest and that potential research participants are given adequate time to consider the information before making a decision.

(7) The research ethics committee may consider additional measures to alleviate or manage conflicts of interest beyond simply disclosing them to potential research participants. In severe conflicts of interest, researchers may be required to limit their involvement in research activities. For example, they might be restricted to roles as collaborating or consulting experts for specific tasks that require their expertise rather than serving as principal or co-investigators. If the involvement of researchers with severe conflicts of interest is necessary due to their specialized expertise, the committee may allow their full participation in research activities but only under clear and justifiable conditions. Additionally, the committee may mandate independent monitoring and review of the research, or it may choose not to approve the research study altogether.

(8) The research ethics committee must implement similar measures to identify, mitigate, and manage the conflicts of interest of its members. This may include requiring committee members with severe conflicts of interest to recuse themselves from deliberation and decision-making processes during committee meetings.

Chapter 7

Responsibility of Research Stakeholders

Responsibility of Research Stakeholders

This chapter provides guidelines related to stakeholders in ethical considerations in research involving humans, namely researchers, sponsors, and research ethics committees. This chapter is divided into three sections as follows:

Guideline 21: Research Ethics Committee

Guideline 22: Researchers

Guideline 23: Research Sponsors

Guideline 24: Research Institutions

Guideline 21

Research Ethics Committee

Researchers conducting research involving human participants must submit their research protocols to the research ethics committee to assess both scientific and ethical validity, unless the research falls under exempt categories from ethical review. Research projects involving human participants must receive approval or exemption from review by the research ethics committee before research commencement.

The research ethics committee thoroughly reviews research protocols and related documents before, during, and throughout the research process. The initial and ongoing reviews adhere to standard operating procedures (SOPs) that align with international guidelines, national regulations, and institutional policies. This ensures a systematic and comprehensive evaluation of all research protocols.

The research ethics committee must be formally established and operate independently, with the authority to make autonomous decisions. It should be duly authorized and adequately supported by the research institution to ensure timely and high-quality reviews of research protocols, while adhering to clear and transparent procedures. The committee must consist of members from diverse academic disciplines and sectors, reflecting gender balance and societal and cultural diversity, to effectively evaluate research protocols. Committee members must meet international qualification standards and participate in continuous training on ethics and best practices in research involving human participants.

The research ethics committee should have clear procedures for researchers or sponsors to appeal formally against the committee's decisions.

Considerations for Guideline 21

The research ethics committee plays a vital role in reviewing research protocols. To fulfill its responsibilities effectively, the committee must be well-acquainted with its composition, functions, procedures, and record-keeping requirements. This understanding is essential to safeguard the rights, safety, and well-being of research participants. Additionally, the committee should establish clear operational guidelines and standard operating procedures as detailed in the following sections.

1. The responsibilities of the research ethics committee

1.1 Safeguarding the rights, safety, and well-being or welfare of all research participants, with particular emphasis on research involving vulnerable populations.

1.2 Conduct an independent and knowledgeable review of the research ethics proposed by the researcher. This review should encompass various documents, including the research protocol and any amendments, information consent documents, and the latest version of consent documents presented by the researcher for the study. The committee should also examine the recruitment process (e.g. advertising documents), any documents provided to research participants, details of compensation and reimbursement for research participants, and documents related to research tools (e.g. questionnaires).

Additionally, the committee should review the documents that demonstrate the qualifications and experience of the researchers, including their curriculum vitae, proof of required training, and other relevant documents necessary for the research ethics committee's review process.

1.3 Conducting timely reviews of research protocols and provide written feedback that specifies the research title and documents reviewed, along with clear review dates.

Based on the committee’s assessment, the decision may be summarized in one of the following categories:

- Approval
- Request for revision for approval (Minor revision)
- Request for revision for consideration at a meeting (Major revision)
- Disapproval/rejection

1.4 The committee should evaluate the qualifications of the researchers for the proposed study by considering their educational background, accomplishments, and experiences. This evaluation should include training in human research ethics and good research practices, and/or other relevant documents specified by the committee.

1.5 Continuing review of ongoing research should be conducted at least once a year or more often according to the level of risk to research participants as determined by the committee. Furthermore, reports of deviations from the protocol, serious adverse events, amendments to the research project, and study closures should

also be reviewed. The decisions of the research ethics committee may be summarized according to the types of reports as follows:

1) Progress report and final report
   - Approval
   - Request for additional information
   - Recommend for further action

2) Reports of non-compliance and reports of serious adverse events
   - Acknowledgment with no further action required
   - Request for additional information
   - Recommend for further actions

3) Protocol amendment
   - Approval
   - Request for revision for approval (Minor revision)
   - Request for revision for consideration at a meeting (Major revision)
   - Disapproval/rejection

1.6 The committee should review the consent form, and any other written materials provided to research participants to ensure the researcher clearly outlines the details regarding compensation. This includes the method of payment, the amount, and the timing of payments, which should specify that payments will be prorated.

1.7 The committee should review the completeness of the information in the informed consent form and ensures its consistency with the research protocol, paying particular attention to the appropriateness of the language used. The committee must ensure that there is no exculpatory language or any language that is coercive or exerts undue influence on participants.

2. Components, roles, and duties

The research ethics committee should establish clear procedures for selecting potential committee members. This includes specifying the criteria for selection, detailing their roles and responsibilities, and outlining the selection process and appointment methods. Additionally, the committee should maintain a comprehensive record of members' names and qualifications.

2.1 The research ethics committee should consist of an appropriate number of members, ensuring a balance of female and male representation. Collectively, these members should possess adequate qualifications and experience to effectively review and evaluate proposed research protocols. To achieve a well-rounded perspective, the

committee should include individuals from various fields, such as social sciences, humanities, and research ethics. The research ethics committee should consist of:

(1) At least 9 members.
(2) At least 1 member with expertise in social sciences or humanities.
(3) At least 1 member with expertise outside of social sciences or humanities.
(4) At least 1 member not affiliated with the institution or organization appointing the committee.
(5) At least 1 member who is a layperson representing research participants.

2.2 The research ethics committee should fulfill its duties in accordance with established standard operating procedures. It must maintain comprehensive records of its activities and meeting minutes. Additionally, the committee should adhere to the principles of good research practice and comply with international guidelines and relevant local regulations.

2.3 Evaluation of research with greater than minimal risk should be deliberated and decided during a full board meeting, which must be scheduled in advance and ensure a quorum as specified in the standard operating procedures. This quorum should consist of more than half of the regular committee members, with a minimum of five members.

2.4 Only research ethics committee members who participate in reviewing and discussing the protocol under consideration should have the right to vote, provide feedback, or offer recommendations.

2.5 Only committee members without conflict of interests are entitled to vote and provide comments on the research protocols under review. (*See Guideline 20*)

2.6 The research ethics committee may invite researchers to provide additional information about the study, but researchers should not take part in the discussion, decision-making process, or voting of the committee.

2.7 The research ethics committee may invite other individuals with expertise in the relevant field to assist in the review process (independent consultants).

3. Standard Operating Procedures

The committee should establish and follow written standard operating procedures which should include the following topics:

3.1 Procedures for determining its composition (names and qualifications of committee members) and the scope of authority of the committee.

3.2 Procedures for scheduling meetings, notifying its members of meetings, conducting meetings, and writing meeting minutes.

3.3 Procedures for conducting the initial review of research protocols, categorized by risk levels. Protocols may fall under exemption, expedited, or full board review according to the criteria below:

(1) Exemption Review

1) Research projects involving humans that may be exempt from regular review must meet the following criteria:
   - The research involves data collection that cannot be linked to the participants.
   - The only risks to participants are minor inconveniences, such as time or effort.

AND

2) Research that are eligible for exemption should not have the following characteristics:
   - Research involving vulnerable groups that require special protection.
   - Research that may have psychological impact or involve sensitive personal matters.
   - Research related to legal cases or violations of regulations or laws that could lead to social or legal implications for participants in the event of a breach of confidentiality
   - Study involving situations where there is a possibility that the data collected may lead to loss of benefits, reputational damage, accusations, or loss of rights.

OR

3) Research that requires input from multiple fields and experts.

(2) Expedited Review

Research projects eligible for expedited review include those whose processes or procedures pose no more than minimal risk, meaning the risk is not greater than that encountered in daily activities or general physical or mental health check-ups under standard medical practices. The research must incorporate appropriate measures to mitigate these risks. However, it should not involve sensitive issues or studies on vulnerable groups requiring special protection.

(3) Full Board Review

Research subjected to full board review are those that may expose participants to more than minimal risk, involve sensitive topics, or include studies on vulnerable groups requiring special protective measures. These research projects may employ quantitative, qualitative, or mixed-method approaches.

3.4 Continuing Review: This includes the review of the following reports for on-going research:

(1) Progress Report

(2) Protocol amendment

(3) Protocol Deviations/non-compliance report

(4) Serious Adverse Event Report

(5) Research closure/Final report

3.5 Quorum requirements for full board meetings

The quorum must consist of more than half of the regular members, with a minimum of 5 members, including at least one layperson and one non-affiliated member.

3.6 Requirement for researchers to comply with the committee's instructions as follows:

(1) Researchers must follow the ethics committee's decisions and regulations.

(2) Researchers must avoid recruiting participants before written approval from the ethics committee.

(3) Researcher must not deviate from or change the research protocol before obtaining written approval, except when necessary to eliminate immediate hazards to participants or for minor administrative changes (e.g., changes in supervisor or contact information).

(4) Researcher must report to the committee within five working days if:

1) There is a deviation or change in the protocol to eliminate a hazard to participants.
2) There is a change that increases risk to participants or significantly impacts the study.
3) There is an occurrence of an adverse serious/unexpected event
4) New information arises that may negatively impact participant safety or the conduct of the study.

3.7 Written notification to researchers/institutions: Within 10 working days after a meeting or expedited review, the committee should provide:

(1) The decision and/or opinion of the committee regarding the research.

(2) Reasons for the decision and/or opinion.

(3) Information on the appeals process.

3.8 Oversight of approved research.

3.9 Quality assurance of committee operations.

3.10 Appeals/complaints process: Available to researchers, funders, or other research stakeholders.

4. The recording of data

The research ethics committee should maintain comprehensive records related to the entire process, including Standard Operating Procedures (SOPs) in written form, committee member list, lists of occupations/affiliation of members, submitted documents, minutes of meetings and correspondence, for a minimum period of three years after the completion of the research. Upon request from the regulatory body, the committee may be required by the researcher, research funder, or regulatory authority to provide its documented procedures and membership lists.

5. The establishment of and operational guidelines for research ethics committees

It is advisable to consider following the operational guidelines for ethics committees responsible for reviewing biomedical research studies, as outlined by the World Health Organization's (WHO) Operational Guidelines for Ethics Committees That Review Biomedical Research (A.D. 2000).

6. Operational quality improvement

It is advisable to consider the guidelines outlined in the World Health Organization's complementary document, "Surveying and Evaluating Ethical Review Practices: A Complementary Guideline to the Operational Guidelines for Ethics Committees That Review Biomedical Research."

7. Standards improvement

It is advisable to follow the standards and operational guidance for the ethical review of health-related research involving human participants, as stated in the World Health Organization's (WHO) document titled "Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011)" and the WHO Global Benchmarking Tools (2023).

Guideline 22

Researcher

Researchers should possess the qualifications and experience suitable for conducting research accurately and have sufficient time to conduct research appropriately and complete the research within the specified timeframe. A competent researcher should adhere to the research protocol approved by the research ethics committee, obtain consent from research participants before proceeding with the research, report research progress as scheduled, request approval for research project modifications and/or data to amend the informed consent form from the research ethics committee before proceeding with changes, and submit a final report to the research ethics committee upon completion of the research.

Researchers must report to the research ethics committee when research activities deviate from the research protocol (see Guideline 18), or when there are adverse events (*see Guideline 12*), or when there is non-compliance with international guidelines, such as failure to submit progress reports (*see Guideline 18*), or in case of premature termination of the research project.

Considerations for Guideline 22

Researchers should possess appropriate qualifications and a sense of responsibility for the well-being of research participants. They should conduct research according to good research standards and relevant regulations.

1. Researcher qualifications and agreements

1.1 Researchers should have appropriate qualifications through education, training, and experience to conduct research properly. They should also have all the qualifications required by relevant regulations and laws and demonstrate evidence of those qualifications through documents showing their educational background, recent work experience, evidence of training in research ethics and good research practices, and/or other relevant documents as required by the research funder, research ethics committee, and/or regulatory and legal authorities.

1.2 Researchers should be aware of and ready to adhere to the ethical principles of human research, good research practice, and the requirements of relevant regulations and laws.

(1) Researchers/research institutions should cooperate with the supervision and monitoring of research by the research sponsor, the research ethics committee, and regulatory/law enforcement agencies.

(2) Researchers should maintain a list of personnel with appropriate qualifications who are assigned key tasks related to the research, such as obtaining informed consent.

2. Adequate research resources

2.1 Researchers should have sufficient time to conduct research properly and to complete research within the timeframe specified in the research project.

2.2 Researchers should have research assistants with appropriate qualifications and adequate research support throughout the research period, enabling them to conduct research accurately and safely.

2.3 Researchers spend sufficient time in the informed consent process to ensure that all research participants have clear information about the research project and their respective responsibilities in the study.

3. Requesting approval from the research ethics committee

3.1 Before commencing research, researchers should obtain written and dated approval or favorable opinion from the research ethics committee. The documents related to the research should be submitted for review, including the research protocol, informed consent forms, research participant recruitment procedures (e.g. advertising materials), and other documents to be provided to research participants.

3.2 When submitting an application for approval to the research ethics committee, researchers should include complete documentation related to research instruments (e.g. interview questions, survey forms, or interview guidelines for in-depth interviews), if applicable.

3.3 Throughout the research process, researchers/institutions conducting the research should submit all necessary documents for continuous review by the research ethics committee.

4. Informed consent process

Researchers are responsible for providing comprehensive information to potential research participants and ensuring they have the opportunity to make independent decisions about their participation in the study (see Guideline 14) unless otherwise exempted by the research ethics committee.

The information shared with potential participants must be relevant to the research and approved by the research ethics committee. When presenting this information, researchers should use clear, concise, and easily understandable language to facilitate comprehension for research participants/or legal authorized representatives.

In cases where potential participants are visually impaired or unable to read or write, researchers must have an impartial witness assist with the informed consent process. This ensures that all participants receive the necessary information and can make informed decisions about their involvement in the research. (*see Guideline 11 and 14*).

5. Participant care and well-being

5.1 Throughout the research process and during any follow-up after its completion, researchers and research institutions must ensure that participants receive comprehensive care and support for any adverse events that may occur. Additionally, researchers/ research institutions should inform research participants that they will receive assistance in addressing any issues arising from the research.

5.2 If a research participant withdraws before the study concludes, they are not obligated to provide a reason for their decision. However, the researcher should strive to understand the underlying reason for the withdrawal, fully respecting the participant's rights. This inquiry is important, as there may be situations in which issues arise from the research requiring assistance.

6. Research conduct and compliance

6.1 Researchers should conduct research in accordance with the approved research protocols and/or the favorable opinion of the research ethics committee, and as agreed upon with the research sponsor. Researchers/institutions, along with the research sponsor, should jointly sign the research protocol or an alternative contract to confirm their mutual agreement.

6.2 Researchers should not implement any deviations from or changes to the research protocol without the sponsor's agreement and prior review and documented

approval or favorable opinion from the ethics committee regarding the amendment. Exceptions to this rule include situations where changes are necessary to eliminate an immediate hazard to research participants or when the changes pertain solely to logistical or administrative aspects of the study (e.g., a change of contact number).

6.3 Researchers or individuals delegated by the researchers should document and explain deviations from the approved research protocol as evidence of their research conduct.

6.4 Researchers may implement a deviation from the approved research protocols or make changes to the research protocols in cases where it is necessary to eliminate particular risks to research participants without prior approval and/or favorable opinion from the research ethics committee. However, following such actions, researchers should promptly report deviations from the approved research protocols or changes to the research protocols, including the reasons for such actions and, if appropriate, the proposed protocol amendment(s) should be submitted to the following entities:

(1) The research ethics committee for review and approval/favorable opinion;

(2) The research sponsor for agreement; and/or

(3) Regulatory and legal agencies for approval, where required.

7. Research progress report

7.1 Researchers should submit periodic written summaries of the research status to the research ethics committee annually, or more frequently, if requested by the research ethics committee.

7.2 Researchers should promptly provide written reports to the sponsor, the ethics committee, and, where applicable, the institution on any changes significantly affecting the conduct of the study, and/or increasing the risk to participants.

8. Safety report

8.1 Serious adverse events should be immediately reported in writing to the research sponsor and research ethics committee within 5 days of occurrence or awareness, except events deemed unnecessary by the research protocols or other documents. In the report, participants should be identified using participant codes, avoiding the use of names, citizen identification numbers, and/or addresses.

8.2 Adverse events should be reported to the research sponsor and research ethics committee according to reporting requirements and within the timeframe specified by the research sponsor and research ethics committee.

8.3 For death reports, researchers should provide additional information as required by the research sponsor and research ethics committee (e.g., autopsy reports, final medical reports).

9. Termination of research prior to scheduled completion or suspension of research

If research is prematurely terminated or suspended for any reason, the researcher/institution should promptly inform the research participants appropriately.

9.1 In cases where researchers terminate or suspend research without prior approval from the research sponsor, researchers should notify the research institution accordingly. Researchers/institutions should also inform the research sponsor and the research ethics committee promptly, along with a detailed written explanation of the reasons for the termination or suspension of the research.

9.2 If the research sponsor terminates or suspends the research, researchers should promptly inform the research institution, and researchers/ research institutions should promptly inform the research ethics committee, along with a detailed written explanation of the reasons for the termination or suspension of the research.

9.3 If the research ethics committee terminates or suspends approval and/or favorable opinion of the research activities, researchers should promptly inform the research sponsor, along with a detailed written explanation of the reasons for the termination or suspension of the research.

10. Final report upon completion of research by the researcher

Upon completion of the research, the researchers should notify the research institution. The researcher/ research institution should submit a summary of the research findings and/or a comprehensive research report to the research ethics committee, as well as other reports as required by the regulatory authorities.

Guideline 23

Sponsor

The sponsor or funder of research—whether from public sector agencies, private entities, companies, or non-profit organizations—holds significant responsibilities throughout the research process. Their duties include establishing a quality assurance system for research, which encompasses design, execution, documentation, evaluation, reporting, and data retention. Research sponsors should prioritize critical research activities to ensure the protection of research participants and credibility of research outcomes.

Quality management should integrate well-designed research methodologies, effective data collection tools and processes, and the necessary data to address research questions. Methods aimed at ensuring and controlling research quality must address potential risks while emphasizing the importance of the collected data. It is essential to eliminate unnecessary and overly complex procedures, ensuring clarity, conciseness, and consistency in data collection, operational procedures, reporting forms, and other documentation.

The primary role of research funders is financial support, oversight of research data quality, and the well-being of research participants. This involves selecting suitable researchers, designing research according to scientific and research ethics principles, managing research quality, overseeing data management, and maintaining accurate records.

Considerations for Guideline 23

In research involving humans, sponsors play a crucial role in initiating, managing, funding, and assuring the quality of research activities. They have the following responsibilities:

1. Quality assurance and quality control

1.1 Research sponsors are responsible for implementing and ensuring a quality assurance and control system according to the written standard operating procedure. This ensures confidence that the research conduct and the collection, recording, and reporting of data, adhere to good research practices as well as relevant regulations and laws.

1.2 Sponsors are responsible for maintaining agreements with all involved parties to ensure direct access to research site data and original documents/reports. This

facilitates oversight and audit of research activities by sponsors, as well as inspections by regulatory bodies both domestically and internationally.

1.3 Research sponsors should ensure quality control at every stage of research data management to ensure the reliability and accuracy of all processed data.

1.4 Agreements between research sponsors and researchers/research institutions involved in the research, including other relevant individuals, should be documented in writing and considered integral parts of the research project or separate agreements.

2. Research design and planning

In designing research, research sponsors should employ personnel with suitable qualifications at every stage of the research process, from planning the research framework and data recording to planning data analysis and preparing reports during and upon completion of the research.

3. Research management, data management, and record keeping

3.1 Research sponsors should employ personnel with suitable qualifications to oversee all aspects of research operations, including data management, data verification, statistical analysis, and preparation of research reports.

3.2 Research sponsors may consider appointing an independent Data Safety Monitoring Board (DSMB) to periodically evaluate the progress of the research and provide recommendations to the research sponsor on whether to continue, modify, or terminate the research. The DSMB should have written operating procedures and should maintain records of all meeting reports.

3.3 When using electronic data management systems and/or remote electronic data systems, research sponsors should ensure and document confidence that the electronic data processing system complies with the research sponsor's requirements regarding completeness, accuracy, reliability, and consistent operation. Validation of accuracy should be regularly performed.

4. Selection of researcher

4.1 Research sponsors are responsible for selecting researchers/research institutions for the study. Each researcher should possess suitable qualifications, undergo training, and have adequate experience. They should have sufficient resources to conduct the

research accurately. In cases of multiple-site studies, research sponsors are also responsible for appointing coordinating committees and/or selecting researchers to coordinate research activities.

4.2 Research sponsors should receive agreements from researchers/research institutions regarding the following:

(1) To conduct research in accordance with good research practices, relevant regulations, and the research protocol agreed upon with the research sponsor, as well as obtain approval and/or ethical clearance from the research ethics committee.

(2) To adhere to standard procedures for recording and/or reporting data.

(3) To allow oversight, auditing, and monitoring of the research.

(4) To retain important research documents until the research sponsor notifies that keeping them is no longer necessary.

Research sponsors and researchers/research institutions should jointly sign research protocols or other documents to confirm agreement to these terms.

5. The assignment of responsibilities

Before commencing research, research sponsors should clearly define, appoint, and delegate all responsibilities and obligations related to the research.

6. Compensation for research participants and researchers

6.1 When relevant regulations mandate it, research sponsors are responsible for providing insurance or agreeing to indemnify damages, covering both legal and financial aspects. Should researchers or research institutions face lawsuits related to damages resulting from the research – excluding claims arising from malpractice or negligence – the research sponsor should assume responsibility for compensation.

6.2 The policies and procedures of research sponsors should explicitly outline the expenses associated with caring for and addressing issues faced by research participants who experience harm due to their involvement in the study.

6.3 When compensating research participants, the method and nature of compensation should comply with the requirements of relevant regulations.

7. Financial support

Financial support provided for research should be documented as evidence in the agreement between the research sponsor and the researchers/research institutions conducting the research.

8. Confirmation of research review by the research ethics committee (REC)

8.1 Research sponsors should receive the following details from the researchers/research institutions conducting the research:

(1) The name and address of the research ethics committee of the researcher/ research institution conducting the research.

(2) Statement from the research ethics committee confirming the committee's establishment and that it is fulfilling its duties in accordance with good research practices and relevant laws and regulations.

(3) The research ethics committee's written approval/favorable opinion to conduct the research.

8.2 When the research ethics committee sets conditions for the approval and/or favorable opinion of changes related to the research – such as amendments, modification to consent form and other documents provided to research participants, and/or changes to procedures - research sponsors should receive copies of the modified documents from the researchers/institutions. These copies should include the date of approval/favorable opinion from the research ethics committee.

8.3 Research sponsors should receive investigator/institution documentation and dates of any research ethics committee re-approvals/re-evaluations with favorable opinion, and any withdrawals or suspensions of approval/favorable opinion.

9. Record access

9.1 Research sponsors should ensure that research protocols or written agreements explicitly specify that researchers/research institutions provide direct access to source data/documents for oversight, monitoring, audits, research ethics committee review, and regulatory oversight by governing bodies.

9.2 Research sponsors should verify that each research participant provides written consent allowing direct access to their data for monitoring and verification by the

sponsor, review by the research ethics committee, and oversight by regulatory governing bodies to ensure compliance with ethical standards.

10. Monitoring

10.1 Research monitoring aims to ensure that the rights and well-being of research participants are protected, and that research data are accurate, complete, and verifiable from the original documents. Research activities should adhere to the latest approved research protocol, comply with good research practices, and meet the requirements of relevant laws and regulations.

10.2 The research sponsor is responsible for establishing the qualifications, selecting research monitors, and officially appointing them. Research monitors should receive appropriate training and possess sufficient knowledge and capability to conduct research monitoring. Evidence of the qualifications of research monitors should be documented.

10.3 Research monitors should thoroughly understand the research protocols, informed consent documents, research sponsor's standard operating procedures, good research practices, and relevant legal requirements.

10.4 Research sponsors should specify the scope and nature of appropriate research monitoring. Generally, research monitoring is necessary at the research site before, during, and after the completion of the research.

10.5 The responsibilities of research monitors include ensuring that research is conducted and documented accurately, in compliance with the requirements set forth by the research sponsor. Research monitors should adhere to the standardized procedures specified by the research sponsor, including any additional guidelines established, if applicable, to oversee the research activities.

10.6 Upon completion of site visits or relevant communication regarding the research, research monitors should provide written reports to the research sponsor. These reports should include the date, location of the research site, the name of the research monitor, and the names of any researchers or other relevant individuals contacted. The monitoring reports should comprise summaries of the considerations made by the research monitor, as well as records of significant findings, deviations from the research protocol, identified shortcomings, conclusions, actions taken or

recommended, and any proposed measures for future compliance with the specified requirements.

11. The establishment and development of data and safety monitoring systems

It is advisable to follow the operational guidelines for establishing and functioning Data and Safety Monitoring Boards (DSMB), as outlined by the World Health Organization (WHO).

12. Audit

In the case where the research sponsor conducts research audits, which are a part of quality assurance, the research sponsor should consider the following:

12.1 The purpose of research audits conducted by the research sponsor, independent from routine oversight or quality control functions, is to evaluate research operations and assess compliance with various requirements, including research protocols, standard operating procedures, good research practices, and relevant regulatory requirements.

12.2 Selection and qualifications of research auditors

(1) The research sponsor should appoint individuals who are not directly involved in the research and/or research management systems to conduct research audits.

(2) The research sponsor should ensure that research auditors possess suitable qualifications, including training and experience in conducting accurate research audits. The qualifications of research auditors should be documented as evidence. Audits should be conducted in accordance with standard operating procedure specified by the research sponsor regarding what will be audited, how it will be audited, frequency of audits, audit formats, and the content of audit reports.

13. Non-compliance

13.1 In the event that researchers/research institutions conducting the research or members of the research team funded by the research sponsor, fail to comply with the requirements of the research protocol, standard operating procedure, good research practices, and/or relevant regulatory requirements, the research sponsor should take immediate action to ensure that proper compliance with various requirements is maintained in the future.

13.2 In cases where research oversight and/or research audits identify serious and/or persistent non-compliance with various requirements by the researchers/research institutions conducting the research, the research sponsor should terminate the participation of those researchers/institutions in the research project. The research sponsor should promptly notify the research institution and regulatory authorities of non-compliance.

14. The termination of a research project before its scheduled completion or the temporary suspension of a research project

If a research project is terminated prematurely or temporarily suspended, the research sponsor should promptly notify the researchers/research institutions involved, as well as the regulatory authorities, providing reasons for the termination or suspension. The research ethics committee should also be promptly notified, along with the rationale provided by the research sponsor or the researchers/research institutions involved, as stipulated in the relevant regulatory requirements.

15. Research conducted at multiple sites

For research conducted simultaneously at multiple sites, the research sponsor should ensure that:

15.1 All researchers diligently adhere to the research protocol agreed to by the sponsor and regulatory authorities (if applicable), and given approvals and/or favorable opinion by the research ethics committee.

15.2 Data collection forms (case report forms – CRFs) are designed to capture required data from all research sites. Researchers collecting additional data will receive supplementary CRFs designed for such additional data.

15.3 Responsibilities of the coordinating researcher and other collaborating researchers are documented as evidence prior to commencing the research.

15.4 All researchers are provided with instruction on adhering to the research protocol, on complying with a uniform set of standards for the data collection and on completing data entry in CRFs.

15.5 Communication among all researchers is facilitated for ease of coordination.

Guideline 24

Research Institute

Research institutions should be committed to protecting research participants under their authority and ensuring that research involving human subjects complies with international research ethical principles, laws, and national policies. Institutions that establish research ethics committees (RECs) must adequately support them with the necessary resources—including personnel, facilities, and funding—for the committees to operate effectively and efficiently.

It is crucial for research institutions to implement mechanisms that ensure the independence of research ethics committee when reviewing research proposals. This independence is vital to prevent any interference from the institution's administration that could compromise the integrity of the ethical review process.

The research institute should have policies to ensure that the research ethics committee is transparent, can be regularly audited, and meets the quality standards according to its standard operating procedures and international research ethics standards.

Considerations for Guideline 24

Research institutions should have a role in safeguarding the dignity, rights, safety, and well-being of research participants who fall within the institution's scope of responsibility by establishing policies to oversee research ethics relevant to human subjects, as follows:

1. Adherence to international standards, laws, and regulations

1.1 Research institutions mandate that research involving human participants undergo a thorough review and receive approval from the research ethics committee. In addition, mechanisms should be established to verify that all such research has been reviewed and approved by the research ethics committee.

1.2 Research institutions require research ethics committees to evaluate research proposals according to established international standards.

1.3 Research institutions grant research ethics committees the authority to continuously oversee research conduct throughout its duration. This includes the power to

suspend or permanently terminate a study if necessary to protect the rights and welfare of research participants.

1.4 Research institutions require both researchers and research ethics committee members to disclose any potential conflicts of interest. Furthermore, institutions should establish policies and procedures to effectively manage any conflicts of interest involving researchers and members of the research ethics committee.

1.5 Research institutions require that the research ethics committee members (including the chairperson) recuse themselves from reviewing any research proposals in which they or a close family member have conflicting interests.

1.6 The research institution requires all researchers to complete training in research ethics and responsibilities to ensure that research is conducted ethically. Furthermore, researchers must provide evidence of their training to the research ethics committee when applying for research ethics committee approval.

1.7 The research institution requires that all research ethics committee members receive research ethics training before conducting research reviews. Furthermore, continuous training is mandated, covering relevant national laws, regulations, and standards appropriate to the research protocols under consideration.

1.8 The research institution has measures to ensure that research participants can access medical treatment for research-related injuries.

1.9 The research institution should offer sufficient legal support to the research ethics committee to carry out its various activities. This includes ensuring that research ethics committee has adequate representation if its actions are challenged in a judicial process related to its operation.

2. Operational practices of the research ethics committee (for institutions with established committees)

2.1 The research institution should provide sufficient staff to support the research ethics committee's work, enabling the committee to carry out its technical reviews and administrative functions effectively and with high quality.

2.2 The research institution provides sufficient resources for staff assigned to their duties, which should include office space, equipment, and consumables. This encompasses items such as computers, software programs, stationery, telephones, document

scanners, shredders, electronic data storage, internet, servers, or cloud services. These resources are essential for facilitating administrative tasks, organizing committee files, and ensuring secure storage and maintaining confidential documents.

2.3 The research institution should allocate appropriate office space for the research ethics committee to hold meetings. Sufficient communication channels must be available for committee members to engage effectively during these meetings. Additionally, the institution should provide secure and confidential storage for documents.

2.4 The research institution allocates adequate financial resources to ensure the research ethics committee can conduct high-quality reviews of research protocols and establishes processes to verify that these resources are adequately provided.

2.5 The research institution establishes standards for document retention by the research committee, including requirements for retention periods and specifications for ensuring data security and confidentiality.

3. Independence of the research ethics committee

The research institution ensures that the decisions of the research ethics committee are free from influence by the institution administrators by making the following provisions:

3.1 The research institution stipulates that the research ethics committee must include at least one non-affiliated member.

3.2 The research institution stipulates that senior management **shall not** serve as the chairperson of the research ethics committee.

3.3 The research institution grants the research ethics committee the authority to review research projects independently. If the ethics committee decides not to approve a research project, the institution cannot override this decision, except in cases where the regulatory body determines that the ethics committee acted inappropriately.

3.4 The research institution stipulates that members of the research ethics committee and chairperson should not be removed from their position prior to the completion of their term, except in cases where significant violations of their duties are established.

4. Transparency and quality of the research ethics committee

4.1 The research institution mandates that the research ethics committee's current or latest funding sources be disclosed on its website, annual reports, or other public documents.

4.2 The research institution requires disclosing the names of research ethics committee members to the public through various channels, including websites.

4.3 The research institution mandates that the decisions made by the research ethics committee, including the approved research protocols (excluding confidential information), be publicly disclosed through various channels such as websites, newsletters, or notice boards.

4.4 The research institution mandates both internal and external assessments of the research ethics committee. Additionally, the institution's administration should be committed to continuously monitoring the feedback from these evaluations to improve the quality of the research ethics committee.

4.5 The research institution establishes a complaint system to facilitate the submission of complaints by researchers, research participants, and stakeholders regarding research conducted under the institution's oversight.

4.6 The research institution mandates a structured process for reviewing, investigating, and responding to complaints, whether related to ongoing research issues or concerning the research ethics review process. Any investigations conducted must safeguard the rights of researchers or members of the research ethics committee who are accused. This includes providing adequate notification of the allegations and allowing them the opportunity to explain or address the claims before any final decision is reached.

4.7 The research institution mandates the implementation of measures for handling researchers in cases where researchers engage in misconduct related to ongoing research projects and/or do not comply with rules and regulations intended to prevent research misconduct, academic integrity, and research ethics.

Health Systems Research Institute

Comments and suggestions on all aspects of these guidelines are welcome for consideration in future revision of this document. Please correspond with

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Health Systems Research Institute

SIDCER

Globalizing Ethics for Health Research