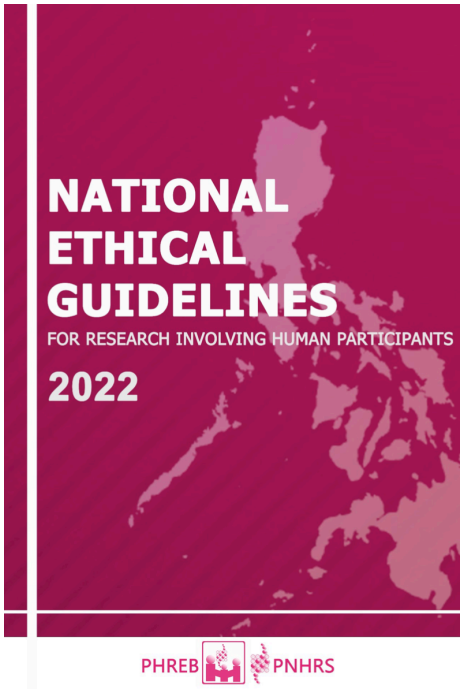
Research Ethics FAQs and answers from the 2022 NEGRIHP

This document answers some of the **F**requently **A**sked **Q**uestions regarding research ethics application and approval with the UPLB REB. Direct quotes from the **2022 National Ethical Guidelines for Research Involving Human Participants** (2022 NEGRIHP) are provided where applicable.

This resource is only a study guide. It should not replace a close reading of the 2022 NEGRIHP. As responsible researchers, we strongly recommend you become well-versed with our national guidelines.

You can download a copy of the 2022 NEGRIHP here.



This document produced by the UPLB REB was first released in **January 2024**. Modifications and additions are included as necessary and regularly.

The last edit on this document was made on **18 April 2024**.

Please check the REB website if a more recent version of the file is available.

Notes:

- The words/phrases in red are minor modifications to actual NEGRIHP statements to ensure inclusive and respectful language.
- You may interchange the term "REB/UPLB REB" (i.e. Research Ethics Board) where the NEGRIHP mentions "REC" (Research Ethics Committee)
- Some statements are in **bold and underlined** for emphasis.

The key questions addressed in this document are as follows:

1. What is research? What is research involving human participants?
2. What is a research protocol?
3. What should be included in a research protocol?
4. What does it mean for participants to have informed consent?
5. What do REB members assess when reviewing research protocols?
6. What's the difference between a "researcher" and an "investigator"?
7. Who is a "qualified" researcher?
8. Are undergraduate students "qualified researchers?
9. What are the key responsibilities of a researcher?
10. What are the responsibilities of the research adviser?
11. What is the difference between a "technical review" and an "ethics review?
12. What are the responsibilities of REB in a research ethics review process?
13. What types of reviews are done by the REB?
14. What studies may be categorized as "EXEMPT from review"?
15. What types of studies may be categorized under "DELEGATED REVIEW?
16. What is minimal risk in the context of research involving human participants?
17. Is it okay to conduct a study that has more than minimal risk?
18. Studies that involve vulnerability issues will pass through a FULL (PANEL) REVIEW. What is vulnerability, and who are the vulnerable groups?
19. Do I need to consider any vulnerability issues when researching with people?
20. Is it really necessary to consider sex and gender in designing, implementing, and reporting research involving human participants?
21. Is there a way by which I can effectively integrate sex and gender considerations into my research?

1. What is research? What is research involving human participants?

The definition of research, health, and research involving human participants, was revisited. The Ad Hoc Committee reiterated the definition of research and health as defined in the PNHRS Act (see section on Elements of Research Ethics). The Introduction to the 2017 edition, summarizes **research** "**as an activity that aims to develop or contribute to knowledge that can be generalized (including theories, principles, relationships), or any accumulation of information using scientific methods, observation, inference, and analysis."**

Health, on the other hand, as defined in the PNHRS is a state of optimal physical, mental, and social well-being and the ability to function at the individual level. This aligns with the WHO definition of health, which is the **"state of complete physical, mental, and social well- being and not merely the absence of disease or infirmity."**

Likewise, **research involving human participants,** as defined by the Declaration of Helsinki (2013), include **any social science, biomedical, behavioral, or epidemiologic activity that does not only involve direct interaction of the researcher with an individual or groups of individuals but also includes research using identifiable human materials and data**. With the broad definitions of these terms, the 2022 national guidelines make it more encompassing in scope.

The most noticeable change in the 2022 edition of the National Ethical Guidelines is in the title: from National Ethical Guidelines for Health and Health-Related Research (NEGHHR) to National Ethical Guidelines for Research Involving Human Participants (NEGRIHP). The new title makes the guidelines more **inclusive of all types of research involving human participants** and resolves the issue often raised on

whether "non-health" research needs to undergo ethics review as long as it involves human participants.

Source: 2022 NEGRIHP, pp.3-4.

2. What is a research protocol?

The protocol is the **definitive document of the research or study**. **It guides those who will conduct the research, reference for evaluators and reviewers** (e.g., REB primary reviewers)**, template for validation, substantiation for intellectual property claims, and the legacy of the proponent**. Therefore, it should be **rigorously conceptualized, carefully crafted, and elegantly formulated**.

2022 NEGRIHP, Ensuring Quality Research, p.31

For further guidance, please check **Appendix K Research Proposal Template** of the 2022 NEGRIHP, pp.334-342.

3. What should be included in a research protocol?

1. The research protocol shall be **sufficiently detailed** to serve as documentation of the study. Further, it shall:
   1.1. **Justify the need for the study**, that is, why the study shall be conducted given the current state of knowledge;
   1.2. **Establish the appropriateness of the proposed methods** for investigating the research problem;
   1.3. **Provide evidence for the feasibility of doing the study as proposed**, that is, that the study can be completed successfully in the specified time and with the available resources;
   1.4. **Describe the recruitment process** (where, who, how); and
   1.5. **Describe the dissemination plan** for research results and outcomes.
2. The **purpose of the study, the design, the population, the methods of data collection, and the planned analyses** shall be clearly described.
3. Whether invasive, intrusive, or not, **all procedures shall be satisfactorily described in detail**.
4. The research protocol shall **adequately address the elements of research ethics** as part of the Ethical Considerations section.
5. The protocol shall provide **information on how the safety and welfare of research participants shall be protected**.
6. Based on the type of study, the protocol **should be written in an inclusive language**

Source: 2022 NEGRIHP, Ensuring Quality Research, "The Research Protocol" p. 31-32

43.3. The research protocol must include the **title, significance of the study, literature review, objectives of the study, methodology and procedures, description of the study population, exclusion and inclusion criteria, data analysis, and ethical considerations.** The section **on Ethical Considerations** shall state what relevant international and national guidelines will be used as a reference in the study and include ethical issues such as **anticipated risks** (how these will be minimized) and **potential benefits; protection of confidentiality of data and privacy of the research participants; vulnerability of research participants; management of adverse events and unanticipated problems**; **and how informed consent will be obtained**.

Source: 2022 NEGRIHP, Ensuring Quality Research, "The Research Ethics Review Process" p.46

For further guidance, please check **Appendix K Research Proposal Template** of the 2022 NEGRIHP, pp.334-342.

4. What does it mean for participants to have informed consent?

6. An informed consent, to comply with these ethical guidelines, **is a competent participant's decision to take part in research after receiving and understanding complete and relevant information about the study as well as their rights, without having been subjected to coercion, undue influence, inducement, or intimidation**.

7. Obtaining informed consent is a process that **begins when initial contact is made** with a potential participant and **continues throughout the study**. By informing the potential participants of the purpose/s of the research project, repetition and explanation, answering their questions as they arise, ensuring that they understand each procedure, and obtaining agreement from them, researchers elicit their informed consent, and in doing so, manifest respect for their dignity and autonomy.

8. For most research involving humans, the researcher shall obtain the voluntary informed consent of the prospective research participant. In the case of an individual who is incapable of giving or who has diminished capacity to give informed consent, the researcher must exert effort to obtain their assent and the consent of a legally authorized representative (LAR), according to applicable laws.

9. In obtaining informed consent, sponsors, and researchers have the duty to **avoid coercion, undue influence, inducement, or intimidation**.

10. Informing the potential participant shall not be simply a ritualistic recitation of the contents of a written document. Rather**, the researcher shall convey the information**, whether orally, in writing, in other modes of communication, **in a language and manner that suit the individual's capacity and level of understanding**.

Source: 2022 NEGRIHP, Elements of Research Ethics, "Informed Consent" pp.15-16

For further guidance, you can check the following:

- 2022 NEGRHIP, Appendix O: Informed Consent Form Template for Surveys, Interviews, and Focus Group Discussions (pp.360-365)
- UPLB REB Guideline 003: Guidance on the Informed Consent Form (ICF) and Template
- University of Oxford – Informed Consent

5. What do REB members assess when reviewing research protocols?

55. Research protocols are evaluated relative to the elements of research ethics (*see Elements of Research Ethics*) and other considerations as follows:

55.1. **Social value**
- □ scientific validity,
- □ relevance to the community and national needs,
- □ suitability of the dissemination plan and
- □ beneficiaries;

55.2**. Informed consent**
- □ competence (of legal age and sound mind),
- □ mandated information to be disclosed based on the national guidelines (*see page 16*),
- □ comprehensibility of information [which means the] use of **local** and **non-technical language** (i.e. "Language used throughout form should be at the level of a Filipino local student in Grade 6 to 8" p.353),
- □ voluntariness (absence of coercion and undue influence), and
- □ articulation of consent (whether written or verbal);

55.3. **Risks, benefits, and safety**
- □ assessment of risks,
- □ Mitigation of potential and actual risks
- □ favorable risk-benefit ratio, and
- □ Safety of researchers and participants
- □ access to favorable research outcomes;

55.4. **Privacy and confidentiality of information**:
- □ respect for the right to privacy and
- □ mechanisms to protect confidentiality;

55.5. **Justice**
- □ fairness of selection process,
- □ appropriate care,

- compensation and reimbursement, and
- access to benefits,

55.6. **Transparency**

- management of COI,
- sharing of relevant information to participants,
- honesty in participation, and
- disclosure of research results;

55.7. **Qualification of researcher** specific and relevant to the research topic and population

- appropriate education,
- (appropriate) training, and
- (appropriate) experience;

55.8. **Adequacy of facilities**

- supportive of protocol procedures and
- supportive of well-being of participants;

55.9. **Community involvement:**

- respect for local traditions and culture,
- community empowerment,
- acknowledgment of participation; and

55.10. **Legal responsibility**

- for injuries in the conduct of the research,
- including insurance coverage, if any.

Source: 2022 NEGRIHP, *Ensuring Quality Research*, "The Research Ethics Review Process", pp.50-51

6. What's the difference between a "researcher" and an "investigator"?

86. For this set of guidelines, the term "**researcher**" refers to an individual or group of individuals who conceptualizes, initiates, and conducts a study.

87. In the subset of researchers that conduct clinical trials, the researcher is the "**investigator**," which refers to an individual or group of individuals responsible for conducting clinical trials involving investigational new drugs or devices, usually commissioned and sponsored by pharmaceutical companies or manufacturers.

    87.1. The "**Principal Investigator**" is the lead implementer of the clinical trial protocol. "**Co-Investigators**" (Co-Is) are a subset of key personnel with special clinical trial responsibilities.

    87.2. "**Sub-investigators**" are study team members who make critical clinical trial-related procedures and decisions. Generally, they are also study Co-Is but may also include study team members with vital and important trial-related roles.

    87.3. **All investigators have the same responsibilities pertinent to protecting human participants and ensuring the credibility of data**, but they perform their tasks based on a clear delegation of responsibility emanating from the principal investigator.

Source: 2022 NEGRIHP, *Ensuring Quality Research*, "Roles and Responsibilities of the Investigator or Researcher", pp.60-61

7. Who is a "qualified" researcher?

The researcher is **the individual who is ultimately responsible and accountable for the research**. The ethical issues in involving human participants in research are addressed, in part, by the assurance that the researcher is qualified. Such qualifications need to be provided by the researcher and vetted by the researcher, the research ethics committee (REC), the sponsors, and when applicable, other authorized bodies.

7. Persons engaged in research involving human participants shall have integrity, scientific competence, social awareness, cultural sensitivity, intellectual humility, vigilance, and preparedness for safety issues.

8. The researcher shall have **the education, training, ability, and resources** to conduct the proposed study.

9. The researcher shall be knowledgeable on updated or recent literature on the research topic.

Source: 2022 NEGRIHP, *Ensuring Quality Research*, "Qualifications of Researchers", p. 32

8. Are undergraduate students "qualified researchers"?

Not yet. The 2022 NEGRIHP, *Ensuring Quality Research*, reminds us:

88. Eligibility requirements for conducting research on human participants vary depending on the role of the researcher or investigator. Research personnel shall be appropriately qualified by training and experience to perform their research responsibilities. **Researchers-in-training, such as undergraduate students and trainees, must be supervised by a senior researcher as a designated research adviser** (see section on Responsibility of the Research Adviser)

Source: 2022 NEGRIHP, *Ensuring Quality Research*, "Roles and Responsibilities of the Investigator or Researcher", p. 61

9. What are the key responsibilities of a researcher?

89. Investigators or researchers shall be **responsible for the protocol and the conduct of the study**. These responsibilities are particularized as follows:

89.1. **Preparing the research protocol and ensuring its ethical acceptability** by submission to the REC for review;

89.2. **Obtaining ethical approval of the protocol** and cooperating with the REC in the conduct of the clinical trial;

89.3. **Bearing ultimate accountabilities for all activities associated with the protocol**, including compliance with adopted international guidelines, national and local laws, institutional policies, and ethical principles;

89.4. **Consulting or collaborating with colleagues in the scientific or academic community** to which they belong and seeking advice from authoritative bodies possessing expertise in ethical, legal, social, and other issues that the researcher may encounter throughout the research process; from the crafting of the proposal up to the disposal or archiving of data;

89.5. Performing or delegating to qualified co-investigators or research staff all the necessary tasks to carry out their studies, while **remaining ultimately responsible for the proper conduct of the study** and fulfillment of all associated obligations;

89.6. Providing members of the research team with **sufficient oversight, training, and information to facilitate appropriate safety procedures and protocol** adherence;

89.7**. Ensuring that adequate resources** (facilities, equipment, supplies, and personnel) exist to:

89.7.1. Conduct the research (e.g., through internal or external funding for staff, facilities, and equipment);

89.7.2. Protect human participants; and

89.7.3. Ensure the integrity of the research.

89.8. **Evaluating the resources available at each site** where the research will be conducted in multicenter/site studies;

89.9. **Applying for ethical review and approval before the conduct of a research/clinical tria**l. Thus, the researcher shall factor in the period for ethical review in the research timeline;

89.10. **Providing evidence of Good Clinical Practice (GCP)** training for clinical trials, Good Research Practice or Responsible Conduct of Research or equivalent, for all other types of studies, valid for three years. Training topics must include basic research ethics and Philippine regulations and guidelines.

89.11. **Obtaining informed consent from each prospective research participant** (or the participant's legally authorized representative) **before the participant begins to participate in the research** (including any related eligibility testing not conducted solely for clinical purposes) unless the appropriate REC has approved a waiver of consent, or waiver of documentation (See Informed Consent, page 21);

89.12. Having adequate time to **enlist the necessary number of participants** for the research;

89.13. **Providing a copy of the signed informed consent form to the research participant** and retaining a copy in both the research record and regular medical record (as applicable);

89.14. **Informing the REC if a researcher or investigator can no longer fulfill their duties for any reason** including, but not limited to, traveling for a prolonged period;

89.15. **Cooperating always with the REC in fulfilling its responsibilities**, and shall provide all information required by the REC as part of the review

process, such as all key personnel who contribute to the scientific development or execution of a study in a substantive, measurable way;

89.16. **Bearing accountability for the content of all submissions** (e.g., initial review, continuing review, adverse event reporting, reportable negative events or unanticipated problems, progress reports) to the REC and other review units and for ensuring that those documents are submitted promptly, as required by the REC and other review units (e.g., audit teams);

89.17. **Conducting the research as specified in the REC- approved protocol** and complying with all REC decisions pertinent to the REC-approved protocol;

89.18. **Submitting to the REC an amendment application for prospective changes in the approved protocol before the change is implemented**, unless urgently necessary to eliminate apparent immediate hazards to subjects;

89.19. **Reporting promptly to the REC any additional risks that are identified during the research project**;

89.20. **Monitoring the effective period of the ethical approval of the protocol and submitting a continuing review application in a timely manner to the REC for renewal of approval** (NOTE: If the REC approval for a study lapses for any reason, even if the researcher or investigator has submitted an application for continuing review on time and has promptly responded to any requests for clarifications or changes, the recruitment of participants shall stop until the REC issues its formal approval, or determines that it is in the best interest of individual participants to continue participating in the research interventions or interactions);

89.21. **Reporting promptly any event of ethical significance to the REC** including, but not limited to:

89.21.1. **Unanticipated problems involving risks to participants or others**, such as serious adverse events or exposure of member(s) of the research team to harm;

89.21.2 **Non-compliance with applicable laws, regulations, or REC requirements**, whether by the researcher or investigator, research staff, or others, even if the non-compliance was unintentional or was discovered during quality assurance or quality improvement activities; and

89.21.3 **Disapprovals, suspensions, or terminations of the project** by any University or non-University review units or agencies.

89.22 Cooperating with:

89.22.1 **Internal evaluations, inspections, and audits** performed by authorized internal oversight authorities, including the RECs;

89.22.2 **External reviews** (e.g., by industry sponsors or government agencies such as the FDA); and

89.22.3 **Any external investigation, inspection, or other external review** and its outcome must be reported to the REC responsible for the research in question. Researchers should consult with their administrators, the RECs, and as appropriate, the legal counsel for assistance and representation.

89.23 **Disclosing all financial and non-financial COI**;

89.24 Complying with all applicable FDA regulations and fulfilling all investigator responsibilities, and in some cases, sponsor-investigator responsibilities, as applicable when conducting research involving FDA- regulated products; and

89.25 Complying with the ICH-GCP guidelines in fulfilling all other duties in clinical trials that require FDA regulation

Source: 2022 NEGRIHP, *Ensuring Quality Research*, "Roles and Responsibilities of the Investigator or Researcher", pp. 61-66

10. What are the responsibilities of the research adviser?

73. **All research conducted in academic institutions by students/trainees**, including postdoctoral fellows, **shall be under the supervision and guidance of a senior research or faculty adviser.**

74. The senior research or faculty adviser shall:

    74.1. **Guide the student or trainee in the development of a scientifically and ethically sound research protocol**;

    74.2. **Assist the student or trainee in addressing ethical and scientific concerns** raised by reviewing bodies;

    74.3. **Serve as a model in intellectual humility** and refer the student to other persons with expertise in social, legal, and other considerations affecting the research;

    74.4. **Supervise the student or trainee in the proper collection and recording of data** including the duty to maintain the confidentiality of the information and the privacy of human participants for all the phases of the research processes, including the disposal or archival of data;

    74.5. **Review interim and final reports for accuracy and consistency**;

    74.6. **Share responsibility and accountability with the student/trainee for the ethical conduct of the research**; and

    74.7. **Ensure that the research to be undertaken by undergraduate students involves only minimal risk** (See Roles and Responsibilities of the Investigator or Researcher)

Source: 2022 NEGRIHP, *Ensuring Quality Research*, "Responsibility of the Research Adviser", pp. 57-58

11. What is the difference between a "technical review" and an "ethics review"?

A technical review is "the process of **examining, assessing or evaluating a research protocol** by technical experts, seasoned researchers, statisticians and other relevant specialists or authority, **to ensure the scientific soundness and appropriateness of the objectives and design of the study and the qualifications of the researcher(s)**" (NEGRIHP 2022, p.414).

Meanwhile, ethics refview refers to "**the evaluation of a research protocol by a REB to promote the safety and protection of the dignity of human participants.** This refers to a systematic process by which a REB evaluates a research protocol t**o determine if it follows ethical and scientific standards for carrying out research on human participants and assesses protocol compliance with the guidelines to ensure that the dignity, rights, safety, and well-being of research participants are promoted** (edited, NEGRIHP 2022, p.400).

For graduate research (i.e., MA/MS/PhD) involving human participants, technical review is done by the advisory committee before submitting to the REB for an ethics review. Please note that it is the responsibility of the research adviser to "**guide the student or trainee in the development of a scientifically and ethically sound research protocol"** (NEGRIHP 2022 Generl Guideline 71.1, p.57).

12. What are the responsibilities of the REB in a research ethics review process?

40. A REC **conducts the ethical review of research proposals involving human participants** based on an evaluation of the research activities **described in the protocol and protocol-related documents.** These are submitted to the REC for approval **before** study implementation.

Source: 2022 NEGRIHP, *Ensuring Quality Research*, "The Research Ethics Review Process", p.45

31. The REC shall **act in the full interest of potential research participants and affected communities, considering the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws** (WHO, 2000 and 2011). The REC should be updated regarding Philippine laws and policies of regulatory agencies about possible areas or groups for research.

Source: 2022 NEGRIHP, *Ensuring Quality Research*, "Guidelines for Research Ethics Committees", p.41

13. What types of reviews are done by the REB?

The research protocol you submit to the REB may be subjected to any of the three possible types of review:

- □ Exempt from review
- □ Delegated review
- □ Full (panel) review.

46. **Exempt from Review** is the term used to denote that a protocol does not need to undergo full or expedited review after a preliminary assessment by a designated member of the REC (i.e. REB Coordinator or REC Co-Chair). **"Exempt from Review" is a decision made by the REC**.

…

52 . **A full review** shall be required for protocols that **entail more than minimal risk to participants or involve vulnerability issues.**

53. In a full review, the proposal is assigned for primary review to all REC members **or at least two reviewers** (a scientific and a non- scientific/non-medical member) **before the REC meeting.** The reviewers shall present their findings during the REC meeting for discussion and final action.

54. A **delegated** [**expedited] review** can be done by the REC, **at the level of the primary reviewers** or the Chair [**or Panel Head**], for proposals that do not need a full review.

Source: 2022 NEGRIHP, *Ensuring Quality Research*, "The Research Ethics Review Process", pp. 48-50

14. What studies may be categorized as "EXEMPT FROM REVIEW"?

47. Protocols that **neither involve human participants nor identifiable human tissue, biological samples, and data** (e.g., meta-analysis protocols) shall be exempted from ethical review.

48. Provided that protocols **do not involve more than minimal risks or harms**, the following may be considered by the REC for exemption from review:

    48.1 Protocols for i**nstitutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;**

    48.2 Research that **only includes interactions involving survey procedures, interview procedures, or observation of public behavior** (including visual or auditory recording), if the following criteria are met:

        48.2.1 There will be **no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation**; and

        48.2.2 The investigator records the information obtained in such a manner that the **identity of the human participant cannot readily be ascertained directly or through identifiers linked to the participant**.

    48.3 Protocols that involve the **use of publicly available data or information**.

Source: 2022 NEGRIHP, *Ensuring Quality Research*, "The Research Ethics Review Process", pp. 48-49

15. What types of studies may be categorized under "delegated review"?

54. A delegated [expedited] review can be done by the REC, at the level of the primary reviewers or the Chair [or the Panel Head], for proposals that do not need a full review, such as the following:

54.1. Chart review

54.2. **Survey of non-sensitive nature**

54.3. Use of **anonymous or anonymized** laboratory/pathology samples or stored tissues or **data**

Source: 2022 NEGRIHP, *Ensuring Quality Research*, "The Research Ethics Review Process", p.50

16. What is "minimal risk" in the context of research?

Minimal Risk is a classification of risk in research where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Risk is the probability of discomfort or harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study.

Source: 2022 NEGRIHP, *Glossary*

17. Is it okay to conduct a study that has more than minimal risk?

23. Research can only be justified if **there is a reasonable likelihood that the participants or the population to which they belong stand to derive benefits from it**.
24. All research involving human participants shall **be preceded by careful assessment of predictable risks, burdens, and foreseeable benefits to the research participant or others**.
25. Every precaution shall be taken to **minimize the negative impact** of the study on the research participant's well-being. All efforts should be done to **maximize the potential benefits.**
26. Research shall be conducted only if **there is an acceptable positive benefit-risk ratio** and the **participants who are going to be affected give their consent** to assume research-related risks (e.g., adverse events, data sharing).
27. The researcher/funder/sponsor shall endeavor to ensure the reasonable availability and accessibility of favorable research outcomes to the community.
28. When there is ethical and scientific justification to conduct research with individuals capable of giving informed consent, the risk from research interventions that do not hold out the prospect of direct benefit for the individual participant shall be no more likely and no greater than the risk attached to routine medical or psychological examination of such persons. Slight or minor increases above such risk may be permitted when there is an overriding scientific or medical rationale for such increases and when the REC has approved them.

Source: 2022 NEGRIHP, *Elements of Research Ethics*, "Benefits, risks and safety", pp.24

18. Studies that involve vulnerability issues will pass through a full (panel) review. What is vulnerability and who are the vulnerable groups?

The 2022 NEGRHIP offers the following definitions:

Vulnerability is the state of being relatively or absolutely incapable of deciding for oneself whether or not to participate in a study, for reasons such as physical and mental disabilities, poverty, asymmetric power relations, and marginalization, among others.

Vulnerable Persons or Groups are individuals or groups which require special protection because of certain characteristics or situations that render them relatively or absolutely incapable of deciding for themselves whether or not to participate in a study.

19. **Vulnerable participants shall require special protection**, as they have certain characteristics or are in special situations that tend to magnify their vulnerabilities or expose them to risks they may otherwise be unwilling to take. Vulnerable participants are those who are relatively or absolutely incapable of deciding for themselves whether or not to participate in a study for reasons such as physical and mental disabilities, poverty, asymmetric power relations, and marginalization, and who are at greater risk for some harms.

20. **Vulnerable groups shall not be included in research <u>unless</u>** such research:

20.1. Is necessary to promote the welfare of the population represented; and

20.2. Cannot be performed on non-vulnerable persons or groups

21. Researchers, sponsors, or RECs shall not arbitrarily exclude women of reproductive age from biomedical research. The potential for becoming pregnant during a study shall not, in itself, be used as a reason for precluding or limiting women's participation in research (see section on Clinical Research).

22. Competent advice and assistance shall be provided to **participants who, due to social, economic, political, or medical disadvantages, are more likely to give consent under duress or without the benefit of adequate information**. Caution shall be exercised in obtaining informed consent for a research project if the research participant is **in a dependent relationship with the researcher** (e.g., as a research participant) to ensure that the consent is not given under duress or undue influence.

Source: 2022 NEGRIHP, *Elements of Research Ethics*, "Vulnerability of Research Participants", pp. 23-24

19. Are there any other vulnerability issues I must consider when researching with people?

13. Social researchers must recognize **the potential and actual vulnerability of their research participants**, that they care for them, and that "the personal integrity of such individuals is respected" (Universal Declaration on Bioethics and Human Rights, art. 8). Such vulnerability may prevent (prospective) participants from making a decision that is in the participants' or their community's best interests and provide voluntary informed consent. Moreover, the **contextual vulnerability of participants may more easily expose them to harm, exploitation, and manipulation**. Hence, a researcher must design a protocol that shows an awareness of and compassion for such vulnerabilities, including measures that safeguard and prioritize the well-being and safety of vulnerable human participants, such as **indigenous peoples, minors, differently abled persons, and women in poverty,** and refraining from unduly coercing and influencing their research participation.

14. The table below shows the various **categories of the potential vulnerability** of research participants that are to be considered by researchers in obtaining informed consent:

Table 1. Potential vulnerability: Research ethics taxonomy (adapted from Lahman, 2018)

Potential Vulnerability	Researcher Question	Examples
1. Cognitive	Does the participant have the capacity to deliberate about and decide whether to participate in the study?	Persons with cognitive impairment, minors
2. Judicious	Is the participant liable to the authority of others	Students, military and police personnel, persons deprived of liberty (PDL), employees
3. Deferential	Is the participant given patterns of differential behavior that may mask an underlying unwillingness to participate?	Low-in-hierarchy workers, less educated/literate
4. Medical	Has the participant been selected because they have a serious health-related condition for which there are no satisfactory remedies?	Patients – those in ICUs or terminally-ill
5. Allocational	Is the participant lacking in important social goods that will be provided because of their participation?	Economically-disadvantaged, homeless, indigenous, and other marginalized groups
6. Infrastructural	Does the political, organizational, economic, and social context of the research setting possess the integrity and resources needed to manage the study	Sites of disaster or political instability where there is lack of ethics oversight from mentors, colleagues, REC

Potential Vulnerability	Researcher Question	Examples
7. Gender	Is the potential participant in a situation where their sex category or their sexual identity is a determinant of the allocation of power, opportunities, and privileges that impacts their capacity to protect themselves from risks of harm?	Women in poverty, LGBTQI+

Source: 2022 NEGRIHP, Ethical Guidelines for Social Research, "Vulnerability in Social research", pp. 91-93

20. Is it really necessary to consider sex and gender in designing, implementing, and reporting research involving human participants?

First, one argument comes from the Canadian Institutes of Health: "**Every cell is sexed, every person is gendered." Sex and gender considerations are therefore ethical imperatives in research, especially in health and health-related research.**

"For research to be ethical, it must account for biological (sex) and social (gender) differences between women, men, boys, girls and gender-diverse people."

Source: Canada Institutes of Health (2016)

https://cihr-irsc.gc.ca/e/49932.html

Second, it is logical to consider sex and gender of participants because "different groups of people experience the same situation differently."

Third, research that is sex- and gender-blind is bad science.

"If our research designs do not take sex and gender into account, **the evidence we generate may be incomplete or simply incorrect; we risk not only doing harm** (such as extrapolating findings based on male samples to females), **but also missing critical opportunities to improve health** (for example, not detecting the benefits of an intervention in a subgroup of men). We recognize that there are

research questions where sex and gender are not relevant—but irrelevance should be determined by scientific rationale, not oversight."

Source: Canadian Institutes of Health Research. (2012). *What a difference sex and gender make: A gender, sex and health research casebook*. CIHR Institute of Gender and Health.

Fourth, **sex and gender considerations in research is a gender mainstreaming strategy which could advance the achievement of SDG Goal #5: Gender Equality.**

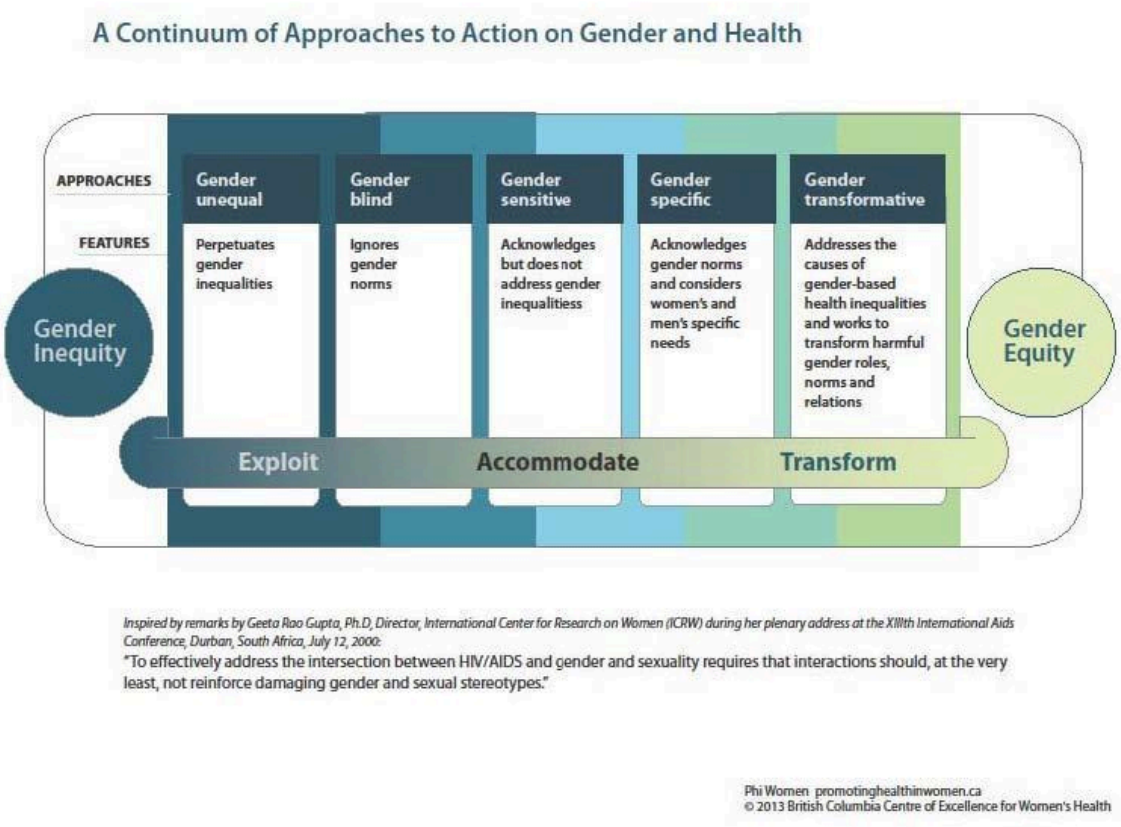
"Gender mainstreaming is the process of assessing implications for women, men, gender-diverse persons, girls and boys of any planned action including legislation, policies or programmes at all levels.

"It refers to **a strategy for making women's, men's, gender-diverse persons', girls' and boys' concerns and experiences an integral dimension of design and implementation, monitoring and evaluating policies and programmes** in all political, economic and societal spheres so that women and girls can benefit equally and inequality is not perpetuated.

The ultimate goal is to achieve gender equality."

Source: UNICEF. 2019. Gender Toolkit: Integrating gender in programming.

Fifth**, the research we do will either perpetuate or potentially transform social inequities based on sex and gender. The choice is ours.**



Source:

https://cewh.ca/webinars-and-courses/courses/gender-transformative-health-promotion-course/unit-3-approaches-to-integrating-gender-in-health-promotion/gender-blind/

Sixth, **the NEGRIHP views recruitment of participants based on sex and gender as a justice issue in research involving human participants**.

21. **Researchers, sponsors, or RECs shall not arbitrarily exclude women of reproductive age from biomedical research**. The potential for becoming pregnant during a study shall not, in itself, be used as a reason for precluding or limiting women's participation in research (see section on Clinical Research).

Source: 2022 NEGRIHP, Elements of Research Ethics, "Vulnerability of Research Participants", p.23

34. In research involving human participants, the principle of justice refers primarily to the equitable distribution of both the burdens and the benefits of participation in research. **It is unjust for one group in society to bear the costs of research while another group reaps its benefits.** Research should not worsen existing health and social inequities.

    34.1. There shall be **fair selection in the choice of population, sampling, and assignments**.

Source: 2022 NEGRIHP, Elements of Research Ethics, "Justice", p.26

14. The table below shows the various categories of the potential vulnerability of research participants that are to be considered by researchers in obtaining informed consent:

Gender (as potential source of vulnerability). **Is the potential participant in a situation where their sex category or their sexual identity is a determinant of the allocation of power, opportunities, and privileges that impacts their capacity to protect themselves from risks of harm?**

Source: 2022 NEGRIHP, *Ethical Guidelines for Social Research*, "Vulnerability in Social research", pp. 91-93

131. In identifying the research topic or question, the researcher shall ensure its relevance to the well-being of the community and the health and social challenges of the community. The researcher's agenda shall not be the primary driver. The needs of the local community shall be given priority. The health and social issues shall be determined by consultation with knowledgeable community members or based on public records. **Equitable participation of different gender identities in the community in these consultations should be ensured.**

...

136. Community volunteers, if necessary, shall be identified through a transparent and unbiased process, and such volunteers shall be properly remunerated for services rendered. **Equitable representation of gender identities in the community shall be observed.**

...

142. Research results will be validated at the end of the study through public presentation and discussion. The presentation shall be conducted in a language that is understandable and meaningful. **Representation of gender identities in the community shall be observed.**

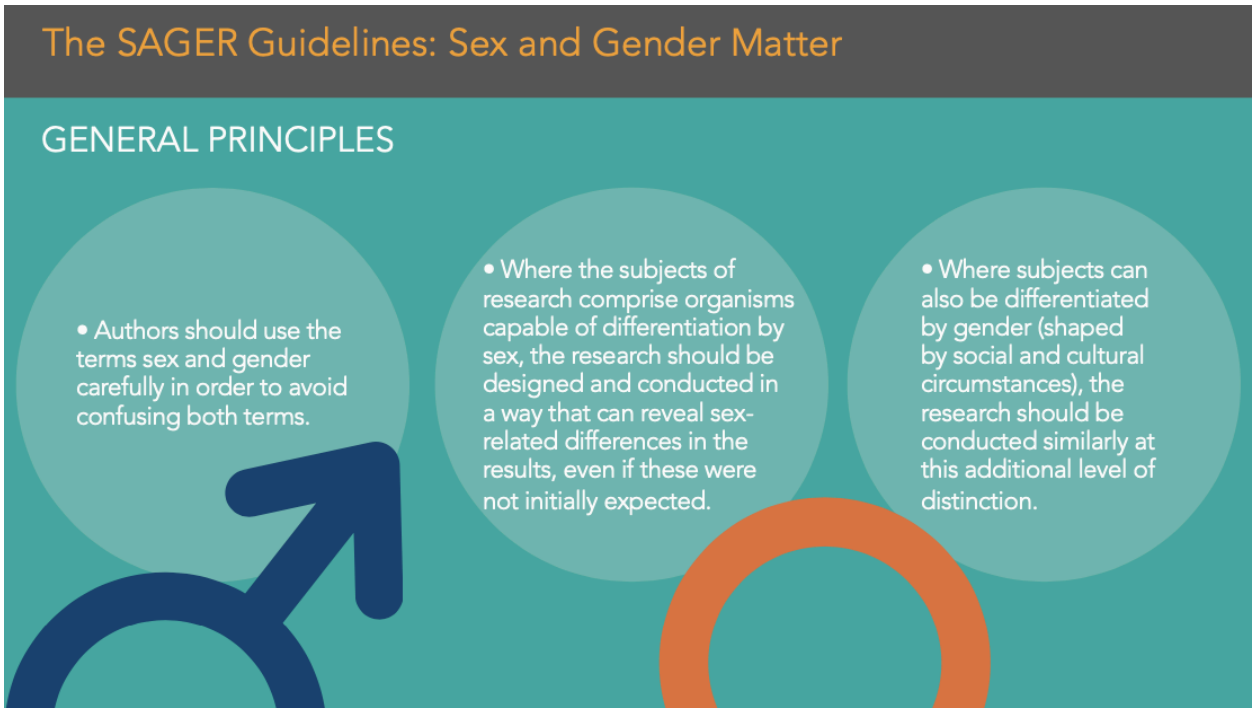
Source: 2022 NEGRIHP, Ensuring Quality Research, "Guidance on Community Engagement and Gender Inclusivity in Research", pp.78-80

21. Is there a way by which I can effectively integrate sex and gender considerations into my research?

Yes. You will find specific recommendations here:

Heidari, S., Babor, T. F., de Castro, P., Tort, S., & Curno, M. (2016). Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use. Research Integrity and Peer Review, 1(1), 1–9. https://doi.org/10.1186/s41073-016-0007-6

A quick summary of SAGER guidelines and recommendations are summarized here:




SAGER Guidelines
[1] Heidari et al. Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use. Research Integrity and Peer Review (2016) 1:2 DOI 10.1186/s41073-016-0007-6
SAGER GUIDELINES: RECOMMENDATIONS PER SECTION OF THE ARTICLE
Title and abstract
If only one sex is included in the study, or if the results of the study are to be applied to only one sex or gender, the title and the abstract should specify the sex of animals or any cells, tissues and other material derived from these and the sex and gender of human participants.
Introduction
Authors should report, where relevant, whether sex and/ or gender differences may be expected.
Methods
Authors should report how sex and gender were taken into account in the design of the study, whether they ensured adequate representation of males and females, and justify the reasons for any exclusion of males or females.
Results
Where appropriate, data should be routinely presented disaggregated by sex and gender. Sex- and gender-based analyses should be reported regardless of positive or negative outcome. In clinical trials, data on withdrawals and dropouts should also be reported disaggregated by sex.
Discussion
The potential implications of sex and gender on the study results and analyses should be discussed. If a sex and gender analysis was not conducted, the rationale should be given. Authors should further discuss the implications of the lack of such analysis on the interpretation of the results.