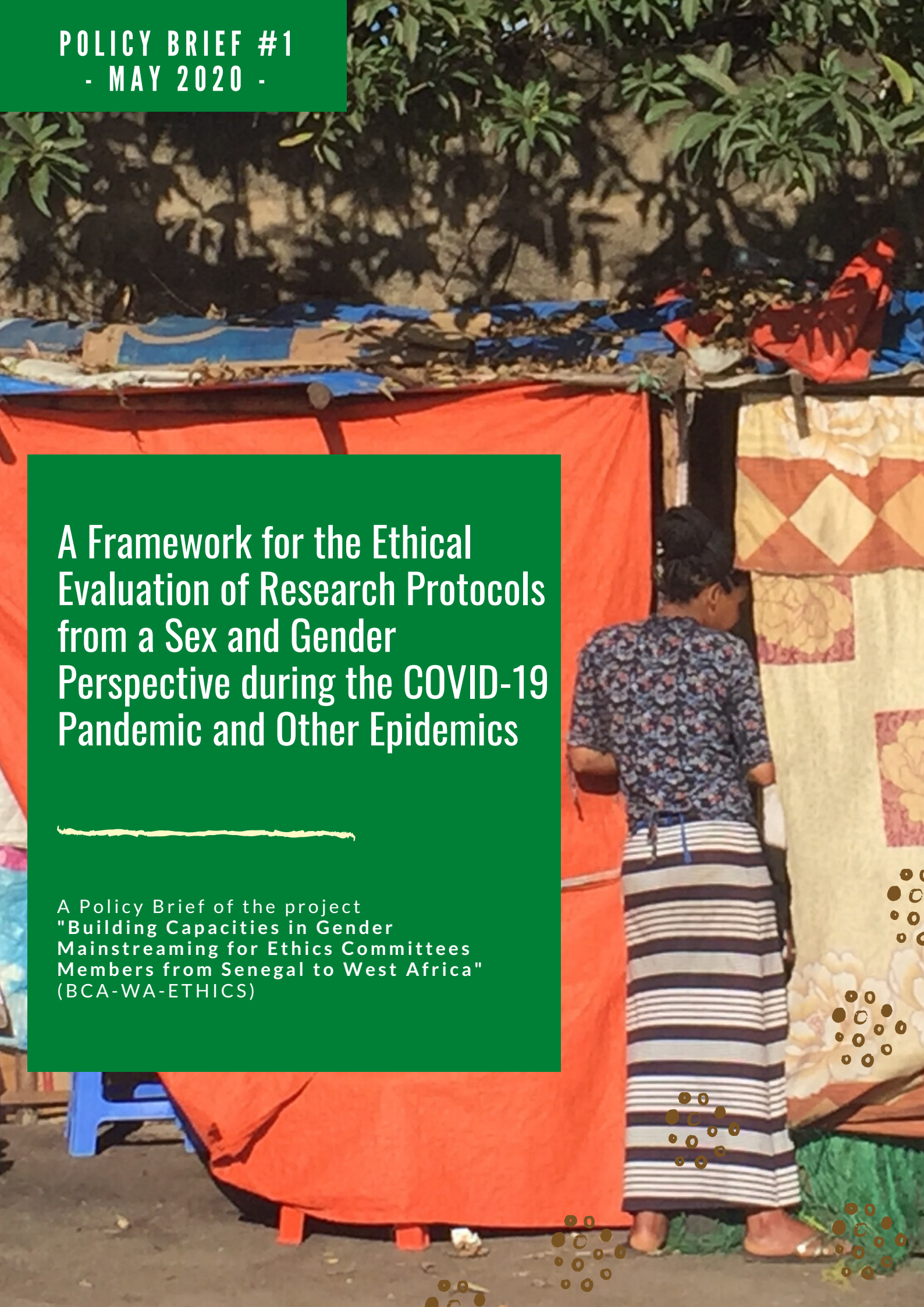


A Framework for the Ethical Evaluation of Research Protocols from a Sex and Gender Perspective during the COVID-19 Pandemic and Other Epidemics

A Policy Brief of the project
"Building Capacities in Gender
Mainstreaming for Ethics Committees
Members from Senegal to West Africa"
(BCA-WA-ETHICS)



SEX and GENDER : what do we mean?

Sex refers to a set of bio-anatomical and physiological characteristics [1]. Individuals are classified according to their biological sex into female, male or intersex. There are similarities and differences between the sexes with regard to their biological functioning, susceptibility or resistance to diseases with epidemic potential, and tolerance to certain drugs, or lack thereof.

Gender, on the other hand, refers to the behaviors, expressions and identities as well as the roles and responsibilities assigned by society to people according to their biological sex [1]. While gender is often mistakenly viewed as a female-male binary, there are non-binary individuals who do not conform to the gender roles assigned to them at birth based on their biological sex. All societies have traditional or hegemonic models of femininity and masculinity. However, the forms of gender expression by individuals are multiple and infinite, constantly evolving and changing depending on contextual and socioeconomic factors. Gender norms and roles make an important contribution to health because they influence, among other things, the exposure to environmental, infectious, and/or other types of risks, and therefore, one's susceptibility or resistance to infectious pathogens. Gender also impacts the type and effectiveness of one's responses to health interventions.

Sex and gender often interact and intersect [2], and can be involved in the transmission and acquisition of diseases with epidemic potential, and in the success or failure of treatments or interventions. Hence, it is important to take them into account in health research with the aim of reducing gender inequalities in the management of health problems and improving the wellbeing of people regardless of their sex or gender. This consideration will also encourage policy-makers to take political, legislative, budgetary and programmatic decisions with the purpose of addressing said inequalities.

Why are sex and gender important in the context of health-related issues?

1- Some diseases are sex-specific

There are diseases that exclusively or mainly affect one sex in particular [3]. **E.g.:** *breast cancer, prostate cancer, Duchenne muscular dystrophy, etc.*

2- Some physiological responses to therapy are sex-specific

Females and males have different metabolic rates and immune responses, which is why they react differently to medicine and vaccines. This can have an impact on the safety and effectiveness of preventive and therapeutic drugs in female and male individuals. **E.g.:** *data shows that females and males respond differently to antiretroviral therapy for HIV. Females showed a weaker response than males when given a combination of Darunavir and Ritonavir [4].*

3- The level of exposure to epidemics is gender-specific

Gender roles and values, and more specifically, the societal expectations that determine the distribution of family and domestic tasks, and access to professional activities influence the level of exposure to pathogens and women's and men's ability and willingness to avoid an infection. **E.g.:** *with regard to Covid-19, men are less likely to be tested if they show symptoms [5]. This is linked to hegemonic masculinities, and to society's expectation of men to show strength at all times and to not be afraid of any disease.*

4- Gender norms contribute to inequalities in health access

Reduced decision-making power, a lack of economic means, a low level of education, the prejudiced representations of certain gender identities and expressions, and an unfavourable political environment to gender approaches are all factors that create and perpetuate gender-related vulnerabilities that impede equitable access to healthcare. **E.g.:** *in numerous countries, women have less autonomy than men in terms of freedom of movement, as well as lower education rates. In addition, women bear a disproportionate burden of caregiving for children, the sick, and the elderly. The aforementioned factors can increase their lack of access to healthcare during epidemics [6].*

5- Gender inequalities in health governance

Institutionalized biases based on gender values and norms can often lead to a lack of gender-sensitive organisational cultures and work procedures, which could prevent women, men, non-binary individuals and sexual minorities from seeking and accessing healthcare. **E.g.:** *healthcare providers' gender-related biases and attitudes can influence their professional decisions, for example, when and how often they offer HIV testing to women, men, and gender and sexual minorities [7].*

[1] Canadian Institutes of Health Research. (2018). Science is better with sex and gender. Ottawa: Government of Canada. Retrieved from https://cihr-irsc.gc.ca/e/documents/igh_strategic_plan_2018-2023-e.pdf

[2] Tudiver, S, Boscoe, M, Runnels, VE, Doull, M. (2012). Challenging "dis-ease": sex, gender and systematic reviews in health in What a difference sex and gender make: A Gender, Sex and Health Research Casebook. Ottawa: Canadian Institutes of Health Research, Institute of Gender and Health.

[5] Klein, SL, Roberts, CW (Eds.). (2015). Sex and Gender Differences in Infection and Treatments for Infectious Diseases. Switzerland: Springer.

[4] Currier J, Bridge DA, Hagins D, Zorrilla CD, Feinberg J, Ryan R, Falcon R, Tennenberg A, Mrus J, Squires K. (2010). Sex-based outcomes of darunavir-ritonavir therapy: A single-group trial. *Annals of internal medicine*; 153(6): 349-57.

[5] Canadian Institutes of Health Research. (2020). Why sex and gender need to be considered in COVID-19 research - CIHR. Canadian Institutes of Health Research. Retrieved 30 April 2020, from <https://cihr-irsc.gc.ca/e/51939.html>.

[6] World Health Organization. (2007). Addressing Sex and Gender in Epidemic-Prone Infectious Diseases. France: World Health Organization.

[7] Sileo, KM, Fielding-Miller, R, Dworkin, SL, Fleming, PJ. (2019). What role do masculine norms play in men's HIV testing in sub-Saharan Africa?: A scoping review. *AIDS and Behavior*; 22(8): 2488-2479.

To sum up, considering sex and gender aspects is relevant because it allows us to:

- Detect sex- and gender-specific protective factors against diseases with epidemic potential.
- To detect the sex-related differences that explain the variability of the contagiousness of the pathogens.
- Identify sex-related differences in the toxicity, safety and efficacy of pharmacological interventions.
- To map and explain the sex-specific differences in the pathophysiology of infectious diseases.
- Identify and prevent sex- and gender-related factors that may reduce the effectiveness of preventive, diagnostic, and therapeutic interventions.
- Identify sex- and gender-sensitive indicators that target clinical and public health interventions and increase their efficiency.
- Identify and challenge gender inequalities affecting research subjects and their families, healthcare providers, researchers, and society in general.

How can I evaluate the integration of sex and gender in research?

Depending on the topic of the research, it may or may not be relevant to take sex or gender into account. Considering sex and gender may not be applicable in research on pathogens cultivated in vitro in an acellular medium, or in research on biomedical technologies tested in an acellular medium. If the study however includes cells, tissues or non-human animals, sex must be taken into account.

In the following four pages, a framework is proposed for the assessment of sex and gender integration into research protocols on epidemics. Ethics committees can use the following framework and adapt it according to their institutional needs.

Note : Even if gender aspects do not apply to the study population (for instance, cells and tissues), it should always be taken into account when considering governance, the use of resources and budgets, communication and dissemination plans, etc. Research should always ensure that its impact can help reduce gender-based social and health inequalities.

Kindly note: the recommendations found in the Sex and Gender Analysis Framework are not a basis for accepting or rejecting a protocol. They are, however, aspects that ethicists should pay attention to when evaluating sex and gender considerations.

Sex and Gender Analysis Framework for Health Research Ethics Committees

A three-step guide to help ethics committee members evaluate research protocols during epidemics.

Step 1 : Evaluating the background and justification of the research

In this step, it is important to ensure that the researchers have taken into account sex and gender aspects when introducing and justifying the topic of their research. Therefore, when evaluating a protocol, here are some of the aspects you should check:

1. Does the protocol explain if sex and gender are relevant to the study?
2. Are the terms "sex" and "gender" properly used, and without any conflation or confusion between them?
3. Are knowledge gaps and current knowledge of existing sex- and gender-specific information on the subject of the study included in the protocol?
4. Is the knowledge of the roles, responsibilities and vulnerabilities of women and men with regard to the topic of the study and the sociocultural, political and legal context of the study site included in the protocol?
5. Was the participatory engagement of women, men, and non-binary people in the study design and planning phases mentioned?
6. Are sex and gender included in the research questions and the study hypothesis?
7. Are sex and gender taken into account in the research objectives?
8. Is the inclusion of a single sex or gender justified?

Yes?	No?
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For instance, COVID-19 research could ensure that:

- Sex- and gender-specific scientific evidence from other studies on other epidemics caused by Coronaviruses (e.g. SARS-CoV-1) was used.
- A representative sample of women and men who had been confined, quarantined, or had recovered from COVID-19 was consulted on the relevance and opportunity of the research.
- Research on the incidence or aggravating factors of gender-based violence during COVID-19 confinement does not exclude men and gender minorities from the research objectives and questions.

Step 2: Evaluating the research methodology

In this step, it is important to ensure that the methodology section of the protocol is designed in a way that allows a sex- and gender-based analysis to take place and that it takes into account the sex and gender aspects identified in the background section of the protocol. Here are some things to make sure of:

1. Are women and men represented in the research team?
2. Is the research team gender-sensitive, where at least one member had received a training in sex- and gender-based analysis?
3. Does the inclusion criteria impede the participation of women, men or gender minorities due to gender barriers even when they fulfill the requirements?
4. Does the inclusion criteria exclude people because of their sex, sexual orientation, gender expression or identity?
5. Is the sample representative of females and males of all ages, all gender identities and all socioeconomic classes?
6. Are sampling procedures sensitive to existing gender-related vulnerabilities and characteristics. For example: recruitment materials, community mobilization, training of recruiters, etc.?
7. Are local gender norms taken into account in the informed consent documents? For example: taking into account power relations, decision-making actors, social distribution of tasks, etc.?
8. Do data collection tools capture variables that allow a sex- and gender-based analysis?
9. Is a detailed sex- and gender-based analysis that considers intersectionalities proposed?
10. Is a detailed plan to present results in a sex- and gender-stratified manner in all research outputs proposed?
11. Is the scientific dissemination and communication of the results at the community level, aimed at social transformation and the achievement of health equity by reducing gender inequalities, planned?
12. Is gender-sensitive budgeting (e.g. there are no gender-related wage inequalities between field agents who have the same responsibilities) mentioned and explained?

Yes? No?



For instance, COVID-19 research could make sure that:

- In biomedical studies, cells of both sexes should be included as a sample when examining how certain receptors to SARS-CoV-2 may behave differently in women and men.
- In studies on the acceptability and effectiveness of personal protective equipment, gender norms and anatomical differences between women and men should be taken into account.
- In vaccine trials, issues of access to research sites and gender-specific medical care should be taken into account, particularly in situations of confinement and quarantine.
- Socio-behavioral studies should explore how gender norms and roles affect the way people grieve their loved ones when allowed to attend their funerals or burials in the midst of a pandemic.
- In diagnostic studies, the sensitivity and specificity of the tests should be studied and presented in a sex-disaggregated manner, because, often, there are sex differences in antibodies and viral titers.
- In any research, recruitment and informed consent procedures should not perpetuate the lack of women's autonomy in situations of quarantine and confinement.

Step 3 : Evaluating the ethical impact of the research

In this step, ethicists should ensure that the research will not cause social harm or any health damage to the research participants or their communities, and will not perpetuate existing social and gender inequalities. Here are some aspects to pay attention to:

	Yes?	No?
1. Have equal benefit sharing strategies been developed?	✓	
2. Have risk mitigation strategies been proposed taking into account existing gender inequalities and intersections?	✓	
3. Have procedures been established to ensure that the reporting of adverse events to the regulatory authorities during clinical trials takes place under equal conditions regardless of the sex or gender of the affected participant?	✓	
4. How could privacy and data security breaches impact women and men differently? Has this been taken into account?		✗
5. In clinical trials, are there mechanisms to ensure that existing gender inequalities do not affect equal access to healthcare services for female and male study subjects in confinement and quarantine ?	✓	
6. Does the coverage of the clinical trial health insurance benefit any gender group over the other without adequate justification?	✓	
7. In clinical trials, do damage compensation mechanisms benefit any gender group over the other without adequate justification?	✓	
8. In socio-behavioral studies, have gender considerations influenced the proposal of mechanisms to guarantee access and use of psychosocial counseling and mental health services, if necessary?	✓	
9. Are there measures in place to ensure that protocol violations do not affect one gender group more than the other?	✓	
10. Are women, men and non-binary research team members engaged in the quality control of the research under equal conditions?		✗
11. Are women, men and non-binary research team members engaged in the dissemination and intellectual property of research under equal conditions?		✗

Research teams working on COVID-19 project could make sure that:

- The results of research on vaccines and drugs will be communicated to women, men and gender minorities using the social networks and communication platforms commonly used by the general population during COVID-19 confinement.
- The voices of women and gender minorities on the front line of the response to COVID-19 will be heard and communicated through research results.
- The anonymized data from clinical and vaccine trials will be placed in an open-access repository to allow the scientific community to reproduce relevant sex- and gender-based analyses.
- Gender-related vulnerabilities will be taken into account in all future public-private partnerships to ensure that pharmacological interventions are accessible to vulnerable populations affected by COVID-19.

Final Recommendations for Ethics Committees

Ethics committees are encouraged to adopt the following recommendations to improve their consideration of sex and gender in the ethical evaluation of research protocols on COVID-19 and other epidemics:

- Build the capacities of members of the ethics committee as well as other research actors in sex and gender mainstreaming in epidemics and infectious diseases research.
- Propose amendments to the regulatory documents of the ethics committee suggesting that the committee's composition be representative of all gender groups, that the procedures for appointing members become more sensitive to gender-related barriers, and that the distribution of responsibilities and functions be fair and balanced.
- Organize gender equality training for ethics committee members.
- Ensure that at least one member of the ethics committee is a trained gender expert.
- Develop a gender equality plan with the support of the committee's host organization.
- Ask researchers to answer the following question in their protocols: "How does your study take into account sex and gender?"
- Include tips in the 'Researcher's Guide' on how to take sex and gender into account in all phases of research.
- Develop checklists to assess the integration of sex and gender aspects into infectious diseases research protocols.
- Organize and participate in networking activities to keep abreast of evidence on sex and gender aspects that are relevant in epidemic research.
- Communicate and disseminate the lessons learned of integrating sex and gender dimensions in research protocol evaluation as part of the committee's sensitization and educational activities on research ethics.
- Monitor and evaluate the implementation of the aforementioned recommendations for strengthening the capacity of ethics committees to assess the integration of sex and gender in research projects.

Here are some indicators to help you self-evaluate the your application of the recommendations:

	6 months	12 months	Target
The percentage of ethics committee members who have received a gender equality training in the past year.			100%
Number of meetings conducted to review and integrate a sex and gender perspective in the ethics committee's guidelines and standard operating procedures			Once a month
The percentage of protocols evaluated using the Analysis Framework proposed in this Policy Brief during each evaluation meeting in the past year.			100%
Percentage of members of the ethics committee who participated in networking activities such as conferences or forums on sex and gender mainstreaming in epidemic research in the past year.			100%
The percentage of protocols that applied sex and gender approaches according to instructions and tips included in the committee's 'Researcher's Guide' in the past year.			100%
The percentage of actions included in the gender equality plan of the ethics committee that have been implemented in the past year.			100%
The number of communication outputs such as advocacy papers produced by the ethics committee to disseminate their experiences in sex and gender mainstreaming, and to promote its application.			Once every 6 months

This Policy Brief is a product of the BCA-WA-ETHICS Gender Mainstreaming Secretariat

The Gender Mainstreaming Secretariat is a virtual help desk at the service of all National Ethics Committees (NECs) and Institutional Review Boards (IRBs) in West Africa. Its purpose is to promote that all NECs and IRBs develop or improve their regulations, guidelines and standard operating procedures to:

- Consider gender-representation in their composition.
- Establish gender-sensitive recruitment, budgeting, procurement and administrative procedures.
- Incorporate a gender lens in protocol evaluation activities.
- Support incorporation of gendered perspectives in health and social research.
- Promote sex and gender approaches in data collection and analysis.
- Develop gender-sensitive educational and professional development programs.
- Develop and facilitate gender equality training programs.
- Design and implement gender equality plans.



Any NEC or IRB representative may contact the Gender Mainstreaming Secretariat at any time to request advice and technical support in any of the areas listed above. Technical services are provided **free of charge**.



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