WHO tool for benchmarking ethics oversight of health-related research involving human participants



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The draft tool was pilot-tested in workshops between October 2022 and February 2023, as follows: Nairobi, Kenya, 10–14 October 2022; Lagos, Nigeria, 17–21 October 2022; Kathmandu, Nepal, 14–16 November 2022; Bengaluru, India, 6–7 December 2022; Cairo, Egypt, 22 January 2023; and Karachi, Pakistan, 3–4 March 2023. The workshops brought together members of more than 100 research ethics committees, national ethics committees, national regulatory agencies and other government authorities, and researchers.

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Introduction

Objectives The tool is intended to assist WHO Member States in evaluating their capacity to provide appropriate ethical oversight of health-related research involving humans[1] by identifying strengths and limitations in their laws and in the organizational structures, policies, and practices of the bodies responsible for research ethics oversight. It is also intended to guide the development of recommendations to address the identified gaps and to facilitate the assessment of countries' progress in implementing those recommendations. In addition to capacity-building, the tool is intended to promote policy convergence and best practices in research ethics oversight, to enhance public trust in health research, and to ensure that the rights and safety of humans involved in health-related research are adequately protected, both in ordinary times and during public health emergencies.

Methodology In early 2021, building on previous work by WHO staff, collaborating centres, and international consultants, WHO convened an international expert advisory group to develop a tool for benchmarking the ethics oversight of health-related research involving human participants. The group held weekly online meetings over several months. The draft tool produced by this group was published on the WHO website for public comment between January and March 2022, and the comments received were incorporated into a subsequent version.

The tool was pilot-tested in workshops between October 2022 and February 2023, as follows: Nairobi, Kenya, 10–14 October 2022; Lagos, Nigeria, 17–21 October 2022; Kathmandu, Nepal, 14–16 November 2022; Bengaluru, India, 6–7 December 2022; Cairo, Egypt, 22 January 2023; and Karachi, Pakistan, 3–4 March 2023. The workshops brought together members of more than 100 research ethics committees, national ethics committees, national regulatory agencies and other government authorities, and researchers. This version of the tool incorporates comments received during the pilot testing workshops.

Scope This tool is designed for use by all entities involved in the ethics oversight of health-related research involving humans, including government agencies, research ethics committees (RECs) and institutions whose employees or agents conduct health-related research involving humans. The tool covers all such research, including studies with biospecimens or data derived from humans. The tool is intended to be adaptable to systems in which there are a few RECs nationally or regionally (either public or private) as well as systems in which many RECs operate throughout the country, often, but not exclusively, within research institutions.

Use of the indicators The first category in this document is intended to be assessed at national level, whereas the others are designed to be measured by individual RECs or research institutions. In countries with many RECs and/or research institutions, national assessors should consider obtaining assessments of a representative sample and then aggregating the information to obtain national results. Further information on the assessment process is provided in the accompanying user guide.

1 WHO defines "research involving human participants" as "any social science, biomedical, behavioural or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge; in which human beings (i) are exposed to manipulation, intervention, observation or other interaction with investigators either directly or through alteration of their environment, or (ii) become individually identifiable through investigators' collection, preparation or use of biological material or medical or other records" (https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review).

Indicators for assessment of the legal and regulatory context (category 1)

Category:	**01: LEGAL PROVISIONS[2] AND REGULATORY FRAMEWORK**
Objective:	To determine whether the legal and regulatory framework is adequate to support ethical oversight of health-related research involving humans.
Indicator:	**01.01: Legal provisions that require health-related research involving humans to be reviewed and approved by RECs.**
Description:	Consistent with the ethical principles in WHO guidance,[3] countries should have legal provisions that explicitly require ethical review and approval of health-related research involving humans before recruitment of participants begins (or, in studies of previously collected biological specimens or data, before the research commences). Countries may choose to exempt specified categories of low-risk studies from this requirement.
Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions that require RECs to review and approve health-related research involving humans in accordance with ethical principles in WHO guidance, as well as any national laws or policies consistent with those principles; and ▪ any relevant guidance documents that provide interpretation of those provisions.
Rating scale:	➜ **Fully implemented:** Legal provisions (1) explicitly require ethical review and approval of health-related research involving humans before recruitment of participants begins (or, in studies of previously collected biological specimens or data, before the research commences); and (2) these provisions apply to all health-related research involving humans, regardless of funding source (with the possible exception of specified categories of minimal-risk studies). ➜ **Partially implemented:** Legal provisions require ethical review and approval of health-related research involving humans but do not explicitly require review to be conducted before recruitment of participants begins (or, in studies of previously collected biological specimens or data, before the research commences), and/or the provisions do not cover all health-related research involving humans presenting more than minimal risk. ➜ **Not implemented:** There are no legal provisions that explicitly require ethical review and approval of health-related research involving humans.
Indicator:	**01.02: Legal provisions that require RECs to review proposed research to determine whether it is consistent with the ethical standards in WHO guidance.**
Description:	WHO guidance sets forth specific ethical issues that RECs should consider in their review of proposed research, including the scientific design and conduct of the study; the risks and potential benefits of the research; selection of the study population and recruitment of participants; use of payments or other inducements; protection of research participants' privacy and confidentiality; the informed consent process; and the impact of research on the communities in which studies are conducted and/or to whom the findings can be linked. Countries should have legal provisions that require RECs to consider all these issues. For issues related to the scientific design of a study, legal provisions may permit or require RECs to defer to the independent review of an appropriately constituted scientific review committee.

2 As used in this document, the term "legal provisions" refers to any any legally binding source of authority, including statutes, regulations, decrees or legally binding guidelines. Where this document calls upon countries to have legal provisions in place, this requirement can be satisfied by provisions adopted at the national level or by local authorities, provided that the provisions cover all health-related research involving humans conducted in the country.

3 International ethical guidelines for health-related research involving humans, fourth edition. Geneva: Council for International Organizations of Medical Sciences, World Health Organization; 2016 (https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf); Standards and operational guidance for ethics review of health-related research with human participants. Geneva: World Health Organization; 2011 (https://apps.who.int/iris/bitstream/handle/10665/44783/9789241502948_eng.pdf; jsessionid=90EC6DA1E51844CBAC88C60235511D7E?sequence=1).

Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions setting forth the considerations RECs must take into account in reviewing proposed health-related research involving humans; and ▪ any relevant guidance documents that provide interpretation of those provisions.
Rating scale:	➔ **Fully implemented:** Legal provisions explicitly require RECs to review (1) the scientific design and conduct of the study (or, in place of such provisions, provisions permitting or requiring RECs to defer to independent review by an appropriately constituted scientific review committee); (2) the risks and potential benefits of the study; (3) selection of the study population and recruitment of research participants; (4) use of payments or other inducements; (5) protection of research participants' privacy and confidentiality; (6) the informed consent process; and (7) the impact of research on the communities in which the study is conducted and/or to whom the findings can be linked. ➔ **Partially implemented:** Legal provisions explicitly require RECs to review some, but not all, of the considerations listed under "fully implemented". ➔ **Not implemented:** There are no legal provisions that explicitly require RECs to review any of the considerations listed under "fully implemented".
Indicator:	**01.03: Legal provisions that require RECs to conduct continuing review of ongoing research at intervals appropriate to the risk to humans.**
Description:	In addition to requiring RECs to review proposed research before it begins, legal provisions should require RECs to conduct continuing review and monitoring of ongoing studies. Continuing review is intended to ensure that an ongoing study continues to meet the criteria that justified its initial approval. Continuing review should be conducted at intervals appropriate to the degree of risk to human participants (generally, at least once a year, but more or less frequent reviews may be appropriate, depending on the level of risk). Continuing review should be conducted as long as the study remains active for long-term follow-up of participants. The category of continuing review does not include review of protocol amendments. In general, protocol amendments should be reviewed as soon as possible and should not be implemented until the REC has granted approval. In exceptional situations, amendments may be implemented before REC review if the investigators reasonably determine that doing so is necessary to protect participants' health or welfare. To enable RECs to carry out continuing review, legal provisions should require researchers to provide RECs with regular reports on their projects and to report any serious unexpected adverse events or other serious unanticipated risks to RECs as they occur.
Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions regarding continuing review and adverse event reporting; and ▪ any relevant guidance documents that provide interpretation of those provisions.
Rating scale:	➔ **Fully implemented:** The following legal provisions exist: (1) provisions that require RECs to conduct continuing review of ongoing studies at intervals appropriate to the degree of risk to humans; (2) provisions that require researchers to provide regular reports to RECs on their studies; and (3) provisions that require researchers to report any serious unexpected adverse events or other serious unanticipated risks to RECs as their occur. ➔ **Partially implemented:** Some, but not all, of the legal provisions described under "fully implemented" exist. ➔ **Not implemented:** None of the legal provisions described under "fully implemented" exists.
Indicator:	**01.04: Legal provisions that authorize RECs to suspend or terminate health-related research involving humans if they determine that the study no longer meets the criteria that justified its initial approval.**
Description:	Legal provisions should ensure that, if a REC determines that a study no longer meets the criteria that justified its initial approval, it has the authority to suspend or, in appropriate cases, terminate the research. If decisions on suspension or termination are made by other authorities (e.g. national regulatory authorities or research institutions), those authorities should be required to carry out an REC's recommendation to suspend or terminate a study.

Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions that authorize RECs to suspend or terminate health-related research involving humans if they determine that a study no longer meets the criteria that justified its initial approval; ▪ if suspension or termination decisions are made by other authorities (e.g. national regulatory authorities or research institutions), legal provisions that require those authorities to carry out an REC's recommendation to suspend or terminate a study; ▪ any relevant guidance documents that provide interpretation of those provisions; and, ▪ if applicable, evidence of situations in which an REC has suspended or terminated, or considered suspending or terminating, health-related research involving humans.
Rating scale:	➜ **Fully implemented:** Legal provisions ensure that, if a REC determines that a study no longer meets the criteria that justified its initial approval, it has the authority to suspend or, in appropriate cases, terminate the research. In situations in which suspension or termination decisions are made by other authorities (e.g. national regulatory authorities or research institutions), legal provisions require those authorities to carry out an REC's recommendation to suspend or terminate a study. ➜ **Partially implemented:** Legal provisions could be interpreted to grant RECs the authority to suspend or terminate research, but such authority is not explicitly provided and/or it is not clear whether other authorities (e.g. national regulatory authorities or research institutions) must carry out an REC's recommendation to suspend or terminate a study. ➜ **Not implemented:** None of the legal provisions described under "fully implemented" exists.
Indicator:	**01.05: Legal provisions that require REC members to declare any conflicts of interest and prohibit members from participating in the review of any study in which they have a conflicting interest.**
Description:	REC members should be required to declare any conflicts of interest and should be prohibited from participating in the review of any study in which they have a conflicting interest. For the purposes of this Indicator, a conflict of interest exists when an REC member has a secondary interest, including but not limited to a financial stake in the research under consideration, that interferes, or may appear to interfere, with his or her primary interest in safeguarding the rights and welfare of research participants.
Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions that require REC members to declare any conflict of interest and ensure that REC members do not participate in reviewing studies in which they have conflicting interests; and ▪ any relevant guidance documents that provide interpretation of those provisions.
Rating scale:	➜ **Fully implemented:** Legal provisions require REC members to declare any conflicts of interest and prohibit REC members from participating in the review of any study in which they have a conflicting interest. ➜ **Partially implemented:** Legal provisions require REC members to declare any conflicts of interest but do not prohibit REC members from participating in the review of any study in which they have a conflicting interest. ➜ **Not implemented:** There are no legal provisions that require REC members to declare any conflict of interest.
Indicator:	**01.06 Legal provisions that ensure that an REC's decision not to approve a study cannot be overruled, except in cases of abuse of authority as determined by a regulatory agency or court.**
Description:	To maintain the public's trust in the integrity of health-related research, RECs must have the ability to act independently. In order to ensure the independence of RECs, legal provisions should ensure that a decision by an REC not to approve a study cannot be overruled, except in cases of abuse of authority as determined by a regulatory agency or court.

Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions that ensure that an REC's decision not to approve a study cannot be overruled, except in cases of abuse of authority as determined by a regulatory agency or court; and ▪ any relevant guidance documents that provide interpretation of those provisions.
Rating scale:	➜ **Fully implemented:** Legal provisions ensure that an REC's decision not to approve a study cannot be overruled, except in cases of abuse of authority as determined by a regulatory agency or court. ➜ **Partially implemented:** Legal provisions could be interpreted to prevent the overruling of an REC's decision not to approve a study in some situations, but the circumstances in which it would be possible to overrule an REC's decision are not clearly stated. ➜ **Not implemented:** There are no legal provisions to ensure that an REC's decision not to approve a study cannot be overruled except in cases of abuse of authority as determined by a regulatory agency or court.
Indicator:	**01.07: Legal provisions establish minimum standards for RECs' archiving of documents, including the length of time that records must be retained and requirements for maintaining the security and confidentiality of data.**
Description:	Documents related to the ethics review of research proposals may have to be reviewed during a study, after it is completed or as a reference in reviewing other proposals. To ensure that documents will be available when needed, legal provisions should set minimum standards for RECs' archiving of documents, including the length of time that records must be retained and requirements for maintaining the security and confidentiality of data.
Evidence to Review:	Relevant evidence may include: ▪ legal provisions that require RECs to archive all documents related to the submission, review and approval or lack of approval of research protocols; and ▪ any relevant guidance documents that provide interpretation of those provisions.
Rating scale:	➜ **Fully implemented:** Legal provisions require RECs to archive all documents related to the submission, review and approval or lack of approval of research protocols for a specified number of years and to ensure the security and confidentiality of all data. ➜ **Partially implemented:** Legal provisions require RECs to have an archiving policy, but they do not explicitly require RECs to archive all documents related to the submission, review and approval or lack of approval of research protocols for a specified number of years and/or to ensure the security and confidentiality of data. ➜ **Not implemented:** There are no legal provisions that require RECs to have an archiving policy.
Indicator:	**01.08: Legal provisions that make institutions with their own RECs responsible for ensuring that those RECs have the resources described in category 3 of this document.**
Description:	In order to operate effectively, RECs must have adequate staff, facilities, technological support and finances. Institutions with their own RECs should be responsible for ensuring that such resources are provided, by either the institution itself or external funders.
Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions that make institutions with their own RECs responsible for ensuring that those RECs have the resources described in category 3 of this document; and ▪ any relevant guidance documents that provide interpretation of those provisions.
Rating scale:	➜ **Fully implemented:** Legal provisions make institutions with their own RECs responsible for ensuring that those RECs have the resources described in category 3 of this document. ➜ **Partially implemented:** Legal provisions could be interpreted to make institutions that have their own RECs responsible for ensuring that those RECs have adequate resources, but they do not make this explicit and/or they do not cover all of the resources described in category 3 of this document.

	➔ **Not implemented:** There are no legal provisions that make institutions with their own RECs responsible for ensuring that those RECs have the resources described in category 3 of this document.
Indicator:	**01.09: Legal provisions ensure that research participants have access to medical treatment for any injuries that result directly from their participation and that participants and their dependants are protected from any financial consequences that could directly result if the participants suffer injury or death as a result of their participation.**
Description:	Consistent with internationally accepted ethical guidelines, legal provisions should require the provision of appropriate medical treatment and compensation for humans who are harmed as a result of participating in research. Compensation should be sufficient to cover the costs of medical care and any wages or other income lost as a direct result of the participant's injury or death. One way to satisfy this requirement is to require research sponsors to provide insurance, a guarantee or a similar arrangement, as appropriate to the nature and the extent of the risk.[4] In some countries, this requirement might be satisfied by national compensation systems not specific to research, such as no-fault compensation systems for medical injuries.
Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions that ensure that participants have access to medical treatment for any injuries that result directly from their participation and that participants and their dependants are protected from any financial consequences that direct result from a participant's research-related death or injury; ▪ any relevant guidance documents that provide interpretation of those provisions; ▪ evidence of implementation of these provisions in particular studies, such as insurance policies or other relevant documents; and ▪ if applicable, evidence of the application of national no-fault compensation systems in the context of research.
Rating scale:	➔ **Fully implemented:** The following legal provisions exist: (1) provisions to ensure that participants have access to medical treatment for any injuries that result directly from their participation; (2) provisions to ensure that participants are protected from any direct financial consequences if they suffer injury as a result of their participation; and (3) provisions to ensure that participants' dependants are protected from any direct financial consequences if the participants die as a result of their participation. ➔ **Partially implemented:** Some but not all of the legal provisions described under "fully implemented" exist. ➔ **Not implemented:** None of the legal provisions described under "fully implemented" exists.
Indicator:	**01.10: Legal provisions that require clinical trials to be registered in a registry that complies with the WHO registry criteria[5] before recruitment of participants begins.**
Description:	Registration of clinical trials is an internationally recognized ethical requirement. Registration provides many benefits, including minimizing the risk of publication bias and selective reporting, avoiding duplicative studies, identifying gaps in research and helping potential participants learn about trials in which they might be interested in participating. Many scientific journals will not publish the results of clinical trials that are not properly registered.
Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions that require clinical trials to be registered in a registry that complies with the WHO registry criteria; and ▪ any relevant guidance documents that provide interpretation of those provisions.

4 See, for example, REGULATION (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Article 76. (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536)

5 https://www.who.int/clinical-trials-registry-platform/network/registry-criteria.

Rating scale:	➔ **Fully implemented:** Legal provisions require clinical trials to be registered in a registry that complies with the WHO registry criteria before recruitment of participants begins. ➔ **Partially implemented:** Legal provisions requiring clinical trial registration exist, but they do not apply to all types of clinical trials and/or they do not explicitly require registry in a registry that complies with the WHO registry criteria and/or they do not explicitly require registration before recruitment of participants begins. ➔ **Not implemented:** There are no legal provisions that require clinical trials to be registered in a registry.
Indicator:	**01.11: National, subnational, multinational and/or local oversight authorities support RECs and ensure that they adhere to applicable ethical and legal requirements.**
Description:	Government entities can play an important role in ensuring the effectiveness of RECs by providing ongoing technical assistance, coordination and monitoring. For example, oversight bodies can help disseminate best practices in research ethics review, conduct training programmes, promote coordination among RECs involved in multi-site studies, and facilitate communication and collaboration among RECs, national regulatory authorities and other stakeholders involved in research. They can also identify RECs that do not adhere to applicable ethical and legal standards and work with them to develop and implement corrective plans. Entities charged with overseeing RECs should conduct regular needs assessments to determine the types of activities that would be most beneficial. Responsibility for overseeing RECs can be vested in independent agencies created for this purpose or in existing government agencies such as ministries of health. Entities with oversight responsibility should be given the legal powers and resources necessary to carry out their mission, including the authority to conduct audits of RECs on a routine or for-cause basis.
Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions that establish REC oversight bodies or grant the authority to oversee RECs to existing government agencies; ▪ information about the legal powers and resources granted to those entities; ▪ information about the mission and organizational structure of those entities; ▪ information about the process used to assess needs and the outcome of the most recent needs assessment conducted; and ▪ evidence of activities undertaken by oversight authorities in the previous year.
Rating scale:	➔ **Fully implemented:** A national, subnational, multinational and/or local oversight authority supports RECs by providing ongoing technical assistance, coordination and monitoring. ➔ **Partially implemented:** A national, subnational, multinational and/or local oversight authority to support RECs exists, but it does not provide ongoing technical assistance, coordination or monitoring. ➔ **Not implemented:** There is no national, subnational, multinational and/or local oversight authority charged with supporting RECs and ensuring that they adhere to applicable ethical and legal requirements.
Indicator:	**01.12: Legal provisions that require all RECs in the country to be registered, with the name and contact information of the REC chair or other responsible person, and require a list of registered RECs to be made publicly available.**
Description:	To promote effective oversight of RECs, legal provisions should require all RECs in the country to be registered in a government database, with the name and contact information of the REC chair or other responsible person. A list of all registered RECs should be made available to the public. Responsibility for overseeing registration may be given to existing government agencies, such as ministries of health, or to independent agencies created specifically to oversee RECs.
Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions related to REC registration; ▪ an updated list of all registered RECs operating in the country; ▪ information about the process used to ensure that all RECs in the country are registered; and

	▪ evidence that a list of registered RECs is publicly available, such as on a website, in official government documents or in other publicly available sources.
Rating scale:	➔ **Fully implemented:** Legal provisions require all RECs in the country to be registered, with the name and contact information of the REC chair or other responsible person, and a list of registered RECs is made available to the public. ➔ **Partially implemented:** Legal provisions require all RECs in the country to be registered, but they do not require inclusion of the name and contact information of the REC chair or other responsible person, and/or a list of registered RECs is not publicly available. ➔ **Not implemented:** There is no legal provision that requires RECs to be registered.
Indicator:	**01.13: Legal provisions to suspend or revoke the registration of RECs that do not adhere to applicable laws, regulations and guidelines.**
Description:	Legal provisions should provide a mechanism for independent authorities to suspend or revoke the registration of an REC to review and approve research if it is in substantial noncompliance with the laws, regulations and guidelines that govern its operations. Allowing noncompliant RECs to continue functioning creates significant risks for research participants and threatens to undermine the public's trust in the integrity of health-related research. The authority to suspend or revoke the registration of an REC may be vested in existing government agencies, such as ministries of health, or in independent agencies created specifically to oversee RECs.
Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions that provide mechanisms to suspend or revoke the registration of RECs that do not adhere to applicable laws, regulations and guidelines; ▪ any relevant guidance documents that provide interpretation of those provisions; and, ▪ if applicable, evidence of activities undertaken by government agencies or independent oversight agencies related to the suspension or revocation, or potential suspension or revocation, of the registration of an REC to review and approve research.
Rating scale:	➔ **Fully implemented:** Legal provisions provide mechanisms to suspend or revoke the registration of RECs that do not adhere to applicable laws, regulations and guidelines. ➔ **Partially implemented:** Legal provisions could be interpreted to authorize the suspension or revocation of the registration of RECs that do not adhere to applicable laws, regulations and guidelines, but the authorization is not explicitly granted and/or it is not clear how it would be exercised. ➔ **Not implemented:** There are no legal provisions to create a mechanism to suspend or revoke the registration of RECs that do not adhere to applicable laws, regulations and guidelines.
Indicator:	**01.14: Updated, publicly available information on laws, regulations and official guidelines for the ethics oversight of health-related research involving humans.**
Description:	The public should have access to updated information on laws, regulations and official guidelines related to the ethics oversight of health-related research involving humans.
Evidence to be reviewed:	Relevant evidence may include: ▪ websites or other publicly available sources of information about laws, regulations and official guidelines related to the ethics oversight of health-related research involving humans.
Rating scale:	➔ **Fully implemented:** Updated, publicly available information on laws, regulations and official guidelines for the ethics oversight of health-related research involving humans is available. ➔ **Partially implemented:** Some information on laws, regulations and official guidelines for the ethics oversight of health-related research involving humans exists, but the information is not comprehensive, publicly available and/or up to date. ➔ **Not implemented:** There is no updated, publicly available information on laws, regulations and official guidelines for the ethics oversight of health-related research involving humans.

Indicators for assessment of RECs (categories 2–6)

Category:	**02: REC STRUCTURE AND COMPOSITION**
Objective:	To determine whether RECs have appropriate mechanisms for appointing and retaining diverse, qualified members and for supplementing members' contributions with outside expertise when necessary.
Indicator:	**02.01: The REC membership satisfies the requirements of ethical principles in WHO guidance and of any national laws or policies consistent with those principles.**
Description:	According to ethical principles in WHO guidance, RECs must have a multidisciplinary, multisectoral membership that is gender balanced, reflects the social and cultural diversity of the communities from which research participants are most likely to be drawn, and includes individuals with backgrounds relevant to the areas of research that the committee is most likely to review. The following factors should be considered when appointing members: 1. RECs should consist of a reasonable number of members who collectively have the education, training, skills and experience to review and evaluate the type of research proposals the committee is most likely to receive. 2. Members should include individuals with relevant scientific expertise (depending on the type of research the REC reviews, this may include experts in behavioural and social sciences, health-care providers and pharmacologists); members who have expertise in legal matters, public health and ethics; and lay people whose primary role is to share their knowledge about the communities from which participants are likely to be drawn. 3. Lay people and other members whose primary background is not in health research involving human participants should be appointed in sufficient numbers to ensure that they feel comfortable in voicing their views. 4. To support independence, committee membership should include individuals who are not affiliated with organizations that sponsor, fund or conduct research reviewed by the REC. 5. All REC members should declare any conflicts of interest, and the REC should ensure that members do not participate in reviewing studies in which they have a conflict of interest. 6. Committees should be large enough to ensure many perspectives in the discussion. Quorum requirements should provide that at least half of the members, including at least one lay member and one non-affiliated member, are present to make decisions about proposed research.
Evidence to be reviewed:	Relevant evidence may include: ▪ legal provisions and guidance documents related to the qualifications of REC members; ▪ provisions in the REC's standard operating procedures on the recruitment and selection of members; ▪ current list of REC members; ▪ curricula vitae and/or other relevant documents that establish the background and expertise of REC members; ▪ information about the types of research the REC usually reviews; ▪ information about the social and cultural diversity of the communities from which research participants are likely to be drawn; and ▪ information about the REC's usual workload.

Rating scale:	➜ **Fully implemented:** The REC's membership: (1) is gender balanced; (2) reflects the social and cultural diversity of communities from which research participants are likely to be drawn; (3) includes individuals with relevant scientific expertise; (4) includes experts in legal matters, public health and ethics; (5) has a sufficient number of lay members whose primary background is not in health research involving human participants; (6) includes at least some members who are not affiliated with organizations that sponsor, fund or conduct research reviewed by the REC; and (7) has a reasonable number of members to effectively conduct the REC's activities. ➜ **Partially implemented:** The REC's membership satisfies some but not all of the criteria listed under "fully implemented". ➜ **Not implemented:** The REC's membership does not satisfy any of the criteria listed under "fully implemented".
Indicator:	**02.02: The roles and responsibilities of REC members are clearly defined.**
Description:	The roles and responsibilities of REC members should be clearly defined in written terms of reference. The terms of reference should make clear what decision-making mechanism will be used (e.g. consensus, majority vote), who is authorized to conduct expedited reviews, and how any conflicts of interest will be declared and managed.
Evidence to be reviewed:	Relevant evidence may include: ▪ provisions in the REC's standard operating procedures or other governing documents related to the roles and responsibilities of REC members, including provisions for decision-making, expedited review and the declaration and management of conflicts of interests; ▪ the terms of reference of REC members; and ▪ the REC's organizational chart, if there is one.
Rating scale:	➜ **Fully implemented:** The standard operating procedures or other governing documents: (1) clearly define members' roles and responsibilities; (2) state the decision-making mechanism to be used; (3) indicate who is authorized to conduct expedited reviews; and (4) indicate how any conflicts of interest will be declared and managed. ➜ **Partially implemented:** The REC's standard operating procedures or other governing documents contain some, but not all, of the provisions listed under "fully implemented". ➜ **Not implemented:** The REC's standard operating procedures or other governing documents do not contain any of the provisions listed under "fully implemented".
Indicator:	**02.03: REC members and chairs are appointed for fixed terms rather than indefinitely, and terms are staggered so that they do not all expire at the same time.**
Description:	In order to promote active engagement of members and ensure diverse perspectives, REC members and chairs should be appointed for fixed periods, rather than indefinitely. Appointments may be renewed if the conditions that justified the initial appointment continue to be satisfied. Terms should be staggered so that they do not all expire at the same time.
Evidence to be reviewed:	Relevant evidence may include: ▪ provisions in the REC's standard operating procedures or other governing documents related to the appointment of REC members and chairs, including the duration of and the policy for renewal of appointments; ▪ the terms of reference for REC members and chairs; and ▪ the dates of initial and renewal appointments of current REC members and chairs.
Rating scale:	➜ **Fully implemented:** REC members and chairs are appointed for fixed terms rather than indefinitely, and terms are staggered so that they do not all expire at the same time. ➜ **Partially implemented:** REC members and chairs are appointed for fixed terms, but their terms are not staggered. ➜ **Not implemented:** REC members and chairs are not appointed for fixed terms.

Indicator:	**02.04: REC members and chairs may not be removed before the expiration of their terms unless they have been found to have substantially breached their duties.**
Description:	In order to preserve the independence of REC members and chairs, members and chairs should not be removed before the expiration of their terms unless they are found to have substantially breached their duties by, for example, frequently failing to attend meetings or to conduct diligent reviews or failing to disclose conflicts of interest. The process for removing members and chairs before expiration of their terms should be clearly defined in the REC's standard operating procedures.
Evidence to be reviewed:	Relevant evidence may include: ▪ provisions in the REC's standard operating procedures or other governing documents related to disqualification or removal of REC members and chairs; ▪ information about any redress mechanisms available to REC members or chairs who consider that they have been inappropriately removed; ▪ the terms of reference for REC members and chairs; and ▪ information about any cases in which REC members or chairs have been removed before expiration of their terms.
Rating scale:	➜ **Fully implemented:** The process for removing members and chairs before expiration of their terms is clearly defined in the REC's standard operating procedures, and the process limits such removals to situations in which there has been a substantial breach of the member's or chair's duties. ➜ **Partially implemented:** The REC's standard operating procedures establish a process for removing members and chairs before expiration of their terms, but the procedures are not clearly defined and/or they do not limit such removals to situations in which there has been a substantial breach of the member's or chair's duties. ➜ **Not implemented:** The process for removing members and chairs before expiration of their terms is not clearly defined in the REC's standard operating procedures.
Indicator:	**02.05: The REC invites relevant non-members to contribute to the review of research that raises issues beyond the scope of the members' experience or expertise.**
Description:	When RECs review research that raises issues beyond the scope of the members' experience or expertise, they should invite non-members with relevant experience or expertise to contribute to the review. Non-members who are invited to REC meetings may fully participate in discussions, but they should not participate in decision-making. Before accepting an invitation to participate in a meeting, they should declare any relevant conflicts of interest; the REC should withdraw the invitation if it determines that the conflict of interest would make participation in the meeting inappropriate. The REC should provide non-members invited to meetings with relevant background information on the ethics review process. If non-members are given access to confidential material, they should be required to sign confidentiality agreements.
Evidence to be reviewed:	Relevant evidence may include: ▪ provisions in the REC's standard operating procedures or other governing documents related to the standards and procedures for inviting non-members to participate in meetings; ▪ correspondence with non-members to invite their participation in REC meetings; ▪ declarations of conflicts of interests submitted by non-members who have participated in REC meetings; ▪ background information on the ethics review process provided to non-members who participate in REC meetings; and ▪ confidentiality agreements signed by non-members invited to REC meetings.
Rating scale:	➜ **Fully implemented:** The REC's standard operating procedures contain provisions related to the standards and procedures for inviting non-members and meetings, and those provisions (1) require non-members invited to meetings to declare any relevant conflicts of interest; (2) state that non-members who are invited to REC meetings may fully participate in discussions but may not participate in decision-making; (3) require that

	RECs provide non-members invited to meetings with relevant background information on the ethics review process; and (4) require that non-members who are given access to confidential material sign confidentiality agreements. In addition, there is evidence that (1) the REC invites non-members to contribute to the review of research when studies raise issues beyond the scope of the members' experience or expertise; (2) non-members who have been invited to REC meetings have been asked to declare any relevant conflicts of interest; and (3) non-members who have been invited to REC meetings have been given relevant background information on the ethics review process. ➜ **Partially implemented:** Some, but not all, of the criteria listed under "fully implemented" are satisfied. ➜ **Not implemented:** None of the criteria listed under "fully implemented" is satisfied.
Category:	**03: REC RESOURCES**
Objective:	To determine whether there are adequate resources, including staffing, facilities, technological support and financial resources, to ensure that the REC can effectively meet its responsibilities.
Indicator:	**03.01: The REC has sufficient, competent staff,[6] with appropriate education, skills and experience, to support its activities.**
Description:	The REC has an adequate number of staff members who collectively have the qualifications and experience necessary to support the members' work.
Evidence to be reviewed:	Relevant evidence may include: ▪ a list of staff members; ▪ curricula vitae and/or other relevant documents that establish the background and expertise of staff members; ▪ advertisements and/or job descriptions for staff members; ▪ recruitment plans for staff positions and evidence of their implementation; ▪ the specific responsibilities assigned to each staff member, including the number of active studies for which each staff member is responsible at the time of the assessment; ▪ staff members' working hours; ▪ evaluations of staff members' performance; ▪ staff members' responses to questions about their workload; and ▪ information on whether the REC meets the timelines established in its standard operating procedures.
Rating scale:	➜ **Fully implemented:** The number of staff members is sufficient for the REC's workload, and staff members have the appropriate educational background, skills and experience to carry out their assigned responsibilities. ➜ **Partially implemented:** (1) Staff members have the appropriate educational backgrounds, skills and experience to carry out their assigned responsibilities, but the number of staff members is insufficient for the REC's workload; or, (2) the number of staff members is sufficient for the REC's workload, but staff members do not have the appropriate educational background, skills or experience to carry out their assigned responsibilities. ➜ **Not implemented:** The number of staff members is insufficient for the REC's workload, and staff members do not have the appropriate educational backgrounds, skills or experience to carry out their assigned responsibilities.
Indicator:	**03.02: The REC's members and staff receive training in ethical issues in health-related research involving humans.**
Description:	REC members and staff should receive initial training according to their background and experience and the nature of their duties and also periodic training at a frequency adequate

6 The term "staff" (sometimes referred to as the "secretariat") refers to professionals who are responsible for supporting the work of the REC but who are not REC members.

	to ensure that their knowledge is current. RECs can either provide this training themselves or send members and staff to courses offered by other entities. Training for REC members and staff should comprise: ▪ the role and responsibilities of the REC vis-à-vis researchers, research institutions and other relevant entities; ▪ the full range of ethical considerations relevant to research involving human participants; ▪ application of such ethical considerations to various types of research, including research involving novel technologies and new trial designs; ▪ basic aspects of research methodology and design; ▪ the impact of different scientific designs and objectives on the ethics of a research study; ▪ various approaches to recognizing and resolving the tensions that may arise among different ethical considerations and modes of ethical reasoning; and ▪ regulatory and procedural requirements applicable to the REC's work. The REC should have a training plan that specifies the goals and frequency of training. The REC should ensure that all training undertaken by members and staff includes mechanisms to assess participants' command of the material presented. Records of all training activities undertaken by members and staff should be maintained.
Evidence to be reviewed:	Relevant evidence may include: ▪ the REC's training plan; ▪ information about how the REC identifies training needs; ▪ documentation of the system used to design and approve specific training activities; ▪ list of training received by members and staff; ▪ examples of training materials, such as handouts or slides; ▪ examples of assessments of participants after training; and ▪ examples of evaluations of training activities.
Rating scale:	➔ **Fully implemented:** REC members and staff receive initial training on ethical issues in health-related research involving humans as necessary according to their background and experience and ongoing training at a frequency adequate to ensure that their knowledge is updated. Training programmes address (1) the role and responsibilities of the REC and its role vis-à-vis researchers, research institutions and other relevant entities; (2) the full range of ethical considerations relevant to research involving human participants; (3) application of ethical considerations to different types of research, including research involving novel technologies and new trial designs; (4) basic aspects of research methodology and design; (5) the impact of various scientific designs and objectives on the ethics of a research study; (6) various approaches to recognizing and resolving the tensions that may arise among different ethical considerations and modes of ethical reasoning; and (7) regulatory and procedural requirements applicable to the REC's work. The REC has a training plan that specifies the goals and frequency of training; it ensures that all courses followed by members and staff include mechanisms to assess participants' command of the material presented in the training; and it retains records of all training activities undertaken by members and staff. ➔ **Partially implemented:** REC members and staff receive training on ethical issues in health-related research involving humans, but the frequency, content and/or management of the training do not satisfy all the criteria listed under "fully implemented". ➔ **Not implemented:** REC members and staff do not receive training on ethical issues in health-related research involving humans.
Indicator:	**03.03: The REC has adequate facilities and equipment.**
Description:	The REC should be supported with adequate infrastructure and facilities, including office space, equipment and supplies (e.g. stationery, telephones, photocopying machine, shredding machine) to conduct administrative business, to store committee files and to keep documents secure and confidential.

Evidence to be reviewed:	Relevant evidence may include: ▪ the working facilities used by the REC; and ▪ the equipment and supplies available to the REC.
Rating scale:	➜ **Fully implemented:** The REC has adequate office space, equipment and supplies and mechanisms to keep documents secure and confidential. ➜ **Partially implemented:** The REC's office space, equipment and supplies are adequate in some respects, but there are significant gaps and/or the REC cannot keep documents secure and confidential. ➜ **Not implemented:** The REC does not have adequate office space, equipment or supplies and cannot keep documents secure and confidential.
Indicator:	**03.04: The REC has adequate technological support for its needs.**
Description:	The REC should have sufficient technological support for its work, including for conducting secure online meetings when necessary.
Evidence to be reviewed:	Relevant evidence may include: ▪ computer hardware and software systems used by the REC; ▪ technological support services available to the REC; ▪ information about the adequacy of the REC's Internet access; ▪ information about the security of the REC's computer systems; and ▪ the REC's website.
Rating scale:	➜ **Fully implemented:** The REC has sufficient technology to manage its work, including adequate access to the Internet, technological support services and secure computer hardware and software, and can conduct online meetings when necessary. ➜ **Partially implemented:** The REC satisfies some, but not all, of the criteria described under "fully implemented". ➜ **Not implemented:** The REC does not satisfy any of the criteria described under "fully implemented".
Indicator:	**03.05: The REC has adequate, stable financial resources.**
Description:	RECs must have adequate, reliable funding for their operations. Funding mechanisms should be designed to ensure that committees and their members have no financial incentive to approve or reject particular studies.
Evidence to be reviewed:	Relevant evidence may include: ▪ information about the REC's source of funding; ▪ the REC's budget for the current and the preceding year, with information on how those budgets were determined; ▪ information about any budget proposals by the REC that were denied, the basis for the denials and the impact of the denials on REC operations; ▪ the number of applications reviewed annually by the REC; ▪ member and staff surveys on the adequacy of the REC's budget, if available; ▪ the REC's annual financial report; and ▪ information about any activities that were not performed because of budgetary constraint.
Rating scale:	➜ **Fully implemented:** The REC has adequate financial resources and reliable source(s) of funding. Its funding mechanism does not create financial incentives to approve or reject particular studies. ➜ **Partially implemented:** The REC currently has adequate financial resources, but its source(s) of funding are not reliable and/or its funding mechanism creates financial incentives to approve or reject particular studies. ➜ **Not implemented:** The REC does not have adequate financial resources.

Category:	04: REC PROCEDURES
Objective:	To determine whether the REC has documented procedures to conduct its ethics oversight. The procedures should cover the submission and screening of applications, protocol review, monitoring of ongoing research and the document management system.
Indicator:	**04.01: The REC provides adequate guidelines for submission and screening of applications for ethical review of health-related research involving humans.**
Description:	The REC should provide clear guidelines for the submission and screening of applications for ethical review of health-related research involving humans. The guidelines for submission should specify the necessary content of applications, any required supporting materials, relevant deadlines, any applicable application fees, the expected timeline of the review, and any other information that researchers require in order to submit a complete, timely application. The guidelines should be supported with document templates, such as model application forms, consent forms and information sheets. The guidelines for screening should establish a clear process for determining whether applications are complete and for communicating with applicants who have submitted incomplete applications. In addition, the screening guidelines should establish procedures for rapid identification of applications that are exempt from REC review or are eligible for expedited review.
Evidence to be reviewed:	Relevant evidence may include: ▪ guidelines for submitting an application for ethical review of health-related research involving humans; ▪ application forms for ethics review; ▪ checklists for applicants; ▪ procedures for checking the completeness of applications and communicating with researchers who have submitted incomplete applications; ▪ procedures for rapid identification of applications that are exempt from REC review or are eligible for expedited review; ▪ examples of ethics review applications; ▪ examples of communications with investigators who have submitted incomplete applications; and ▪ examples of determinations that applications are exempt from REC review or eligible for expedited review.
Rating scale:	➔ **Fully implemented:** The REC has guidelines for submission that (1) specify the necessary content of applications, any required supporting materials, relevant deadlines, any applicable application fees, the expected timeline of the review, and any other information that researchers require in order to submit a complete, timely application; (2) are supported with document templates, such as model application forms, consent forms and information sheets; (3) establish a clear process for determining whether applications are complete and for communicating with applicants who have submitted incomplete applications; and (4) establish procedures for rapid identification of applications that are exempt from REC review or eligible for expedited review. ➔ **Partially implemented:** The REC's guidelines satisfy some, but not all, of the criteria described under "fully implemented". ➔ **Not implemented:** The REC's guidelines do not satisfy any of the criteria described under "fully implemented".
Indicator:	**04.02: The REC has written procedures to ensure that its deliberations adhere to the ethical criteria for review in WHO guidance.**
Description:	The REC should have written procedures to ensure that its decisions are based on coherent, consistent application of the ethical principles in WHO guidance and to any national laws or policies consistent with those principles. At a minimum, the principles addressed should include (1) the scientific design and conduct of proposed research (unless the REC's policy is to defer to the independent review of an appropriately constituted scientific review committee); (2) the risks and potential benefits; (3) selection of study populations

	and recruitment of research participants; (4) use of payments or other inducements; (5) protection of the confidentiality of research participants; (6) the informed consent process; and (7) the impact of the research on the communities in which studies are conducted and/or to whom the findings can be linked. The REC need not develop its own procedures if the procedures for review are clearly set forth in legal provisions or official guidance.
Evidence to be reviewed:	Relevant evidence may include: ▪ written procedures articulating the ethical criteria to be used in reviewing health-related research involving humans; ▪ minutes of meetings, correspondence or other documents in which the ethical criteria are applied to specific protocols; ▪ any tools, such as checklists, flowcharts or other mechanisms, used to ensure that the REC applies relevant ethical criteria in its reviews; and, ▪ for RECs that follow procedures established in legal provisions or official guidance, the applicable legal provisions and guidance.
Rating scale:	➜ **Fully implemented:** The REC has written procedures that require it to evaluate (1) the scientific design and conduct of proposed research (or, it has an explicit policy of deferring to the independent review of an appropriately constituted scientific review committee); (2) the risks and potential benefits; (3) selection of study populations and recruitment of research participants; (4) use of payments or other inducements; (5) protection of the confidentiality of research participants; (6) the informed consent process; and (7) the impact of research on the communities in which studies are conducted and/or to whom the findings can be linked. ➜ **Partially implemented:** The REC has written procedures that satisfy some, but not all, of the criteria described under "fully implemented". ➜ **Not implemented:** The REC does not have written procedures that satisfy any of the criteria described under "fully implemented".
Indicator:	**04.03: The REC members have adequate time before and during meetings for meaningful review of research proposals.**
Description:	REC members should receive all relevant documents long enough in advance of REC meetings to review them adequately. The length of meetings should be sufficient to allow full discussion of research protocols.
Evidence to be reviewed:	Relevant evidence may include: ▪ procedures for distributing meeting materials to REC members; ▪ correspondence indicating the dates on which REC members were sent meeting materials for all meetings; and ▪ agendas and minutes of all meetings held in the current and previous years, indicating the starting and ending times and the numbers of applications discussed.
Rating scale:	➜ **Fully implemented:** REC members receive relevant documents long enough in advance of meetings to review them adequately, and the length of meetings is sufficient to allow full discussion of research protocols. ➜ **Partially implemented:** (1) REC members receive relevant documents long enough in advance of meetings to review them adequately, but the length of meetings is insufficient to allow a full discussion of research protocols; or, (2) REC members do not receive relevant documents long enough in advance of meetings to review them adequately, but the length of meetings is sufficient to allow full discussion of research protocols. ➜ **Not implemented:** REC members do not receive relevant documents long enough in advance of meetings to review them adequately, and the length of meetings is insufficient to allow full discussion of research protocols.
Indicator:	**04.04: The REC has procedures to ensure that decisions are made in a timely manner and are promptly communicated to principal investigators.**
Description:	RECs should meet as a committee, either in person or on a secure online platform, on dates that are announced in advance. The REC's procedures should specify the frequency

	of meetings, which should be based on the committee's workload and should be regular enough to avoid undue delay; establish the expected timeframe for review after receipt of complete applications (distinguishing between full and expedited reviews and confirmation of exempt status); and require the REC to provide written justification in situations in which the timeframe is exceeded. REC decisions should be promptly communicated to principal investigators. Any negative decisions or requests for modifications should be accompanied by a written explanation.
Evidence to be reviewed:	Relevant evidence may include: ▪ procedures for scheduling REC meetings; ▪ procedures for establishing expected timeframes for review after receipt of complete applications (distinguishing between full and expedited reviews and confirmation of exempt status) and for requiring written justifications in situations in which the timeframe is exceeded; ▪ dates of meetings held by the REC in the current and previous years; and ▪ for each meeting held in the current and previous years, a list of applications considered; the dates on which those applications were submitted; and correspondence with the principal investigators of those applications informing them of decisions taken at the meetings.
Rating scale:	➜ **Fully implemented:** REC procedures specify the frequency of meetings, and the frequency of meetings is sufficient to avoid undue delay. The dates of REC meetings are announced in advance. REC procedures establish the expected timeframe for review after receipt of complete applications (distinguishing between full and expedited reviews and confirmation of exempt status) and require the REC to provide written justification if the established timeframe is exceeded. There is evidence that the timelines are generally respected and that, when they are exceeded, a written justification is provided. REC decisions are promptly communicated to principal investigators, and any negative decisions or requests for modifications are accompanied by written explanations. ➜ **Partially implemented:** Some, but not all, of the criteria described under "fully implemented" are satisfied. ➜ **Not implemented:** None of the criteria described under "fully implemented" is satisfied.
Indicator	**04.05: The REC has procedures for ensuring fast-track review of research proposals in public health emergencies.**
Description:	As specified in WHO guidance,[7] the REC should have procedures to ensure fast-track review of time-sensitive proposals relevant to responding to public health emergencies. The mechanisms should not compromise thorough assessment of the ethical issues raised by the proposed research. One way of facilitating fast-track review is for RECs to conduct "pre-reviews" of generic protocols or parts of protocols in advance of emergencies, which can then be incorporated into more detailed protocols when an emergency arises. Escalation of a proposal for fast-track review and the timeliness of the review should be proportionate to its potential importance for an emergency response.
Evidence to be reviewed:	Relevant evidence may include: ▪ procedures to ensure fast-track review of research proposals in public health emergencies; ▪ any examples of applications for research related to a public health emergency, including the dates of the applications and the dates of final decisions; and ▪ any examples of generic protocols or parts of protocols that the REC has reviewed.
Rating scale:	➜ **Fully implemented:** The REC has procedures to ensure fast-track review of time-sensitive proposals relevant to responding to public health emergencies, and those procedures do not compromise thorough assessment of the ethical issues raised by the proposed research.

7 Guidance for research ethics committees for rapid review of research. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240006218).

	➔ **Partially implemented:** The REC has procedures to ensure fast-track review of time-sensitive proposals relevant to responding to public health emergencies, but the procedures could potentially compromise a thorough assessment of the ethical issues raised by the proposed research. ➔ **Not implemented:** The REC does not have procedures to ensure fast-track review of time-sensitive proposals relevant to responding to public health emergencies.
Indicator:	**04.06: The REC engages in and/or contributes to monitoring ongoing research at intervals appropriate to the degree of risk to humans.**
Description:	RECs should have procedures for conducting ethics monitoring of approved studies at intervals appropriate to the degree of risk to humans. At a minimum, the REC's procedures should include requesting regular reports on studies.
Evidence to be reviewed:	Relevant evidence may include: ▪ evidence that the REC regularly requests researchers to provide regular reports on their studies; ▪ for RECs that review clinical trials, procedures for meeting the continuing review requirements of Good Clinical Practice guidelines; and ▪ information about all ethics monitoring of ongoing research conducted in the previous year, including any action taken in response to researchers who fail to submit the required reports.
Rating scale:	➔ **Fully implemented:** The REC has procedures for conducting ethics monitoring of approved studies. At a minimum, the procedures require researchers to provide regular reports on their studies; for RECs that review clinical trials, the procedures ensure compliance with Good Clinical Practice guidelines. There is evidence that the REC consistently follows its monitoring procedures and takes action when researchers fail to submit the required reports. ➔ **Partially implemented:** Some, but not all, of the criteria described under "fully implemented" are satisfied. ➔ **Not implemented:** None of the criteria described under "fully implemented" is satisfied
Indicator:	**04.07: The REC maintains a good document management system.**
Description:	All documents related to the REC's review of protocols and communication with researchers should be dated, filed and archived according to the committee's policies and written procedures. Such policies should be consistent with any relevant local laws or institutional policies. REC records may be kept in hard copy, electronically or both. Sufficient safeguards should be established to maintain confidentiality (e.g. locked cabinets for hard copy files, password protection and encryption for electronic files). An adequate system should be in place for the storage, security, retrieval and eventual disposal of documents, and policies should be set for the duration of storage. The system should enable the REC to identify and trace documentation of previous decisions. REC staff should be sufficiently trained to understand their responsibilities in relation to record-keeping, retrieval and confidentiality. The REC's procedures should outline who is authorized to access committee files and documents.
Evidence to be reviewed:	Relevant evidence may include: ▪ the REC's database or archiving system; ▪ procedures for document storage and access; ▪ procedures for maintaining archives and related documents; ▪ information about staff training related to record-keeping, retrieval and confidentiality; and ▪ evidence that documents associated with all meetings held in the current and previous years have been properly archived.
Rating scale:	➔ **Fully implemented:** The REC has policies and procedures for archiving documents related to its review of protocols and communications with researchers. All documents related to the REC's review of protocols and communications with

	researchers are dated, filed and archived according to the REC's policies and written procedures. Sufficient safeguards exist to maintain the confidentiality of documents, including limitations on who is authorized to access archived documents. An adequate system is in place for the storage, security, retrieval and eventual disposal of documents, and the system enables the REC to identify and trace documents of relevant previous decisions. Policies exist for the duration of document storage. REC staff are sufficiently trained to understand their responsibilities with respect to record-keeping, retrieval and confidentiality. ➜ **Partially implemented:** Some, but not all, of the criteria described under "fully implemented" are satisfied. ➜ **Not implemented:** None of the criteria described under "fully implemented" is satisfied.
Category:	**05: MECHANISMS TO PROMOTE REC TRANSPARENCY AND ACCOUNTABILITY**
Objective:	To determine whether mechanisms are in place to promote REC transparency and accountability. The mechanisms should provide the public with information about the ethics review process, the sources of REC funding, the composition of RECs and the research proposals that the REC approves. In addition, they should enable current and prospective research participants and researchers to pose questions to RECs and to obtain a response.
Indicator:	**05.01: Updated information on the REC's guidelines and procedures is publicly available.**
Description:	The REC should ensure that updated information on its guidelines and procedures (e.g. how to submit a protocol, review timelines, standard operating procedures) is publicly available.
Evidence to be reviewed:	Relevant evidence may include: ▪ websites and other publicly available sources of information about the REC's guidelines and procedures; and ▪ information about the process used to ensure that information remains up to date.
Rating scale:	➜ **Fully implemented:** Complete information on the REC's guidelines and procedures is publicly available, and the information is up to date. ➜ **Partially implemented:** Information on the REC's guidelines and procedures is publicly available, but the information is not complete and/or not up to date. ➜ **Not implemented:** No information on the REC's guidelines and procedures is publicly available.
Indicator:	**05.02: Updated information about the REC's sources of funding is publicly available.**
Description:	RECs may be funded from a variety of sources, including national and local governments, research institutions and research sponsors. In all cases, the source of funding for the REC's activities should be made publicly available.
Evidence to be reviewed:	Relevant evidence may include: ▪ information about the sources of the REC's funding; ▪ evidence that the sources of the REC's funding are publicly available, such as on a website or in an annual report or other publicly available documents; and ▪ information about the process used to ensure that public information about the sources of the REC's funding remains up to date.
Rating scale:	➜ **Fully implemented:** Complete information about the sources of the REC's funding is publicly available and is up to date. ➜ **Partially implemented:** Information about the sources of the REC's funding is publicly available, but the information is not complete and/or not up to date. ➜ **Not implemented:** No information about the sources of the REC's funding is publicly available.

Indicator:	**05.03: An updated list of all the REC's members is publicly available or available on request.**
Description:	In order to promote transparency and accountability, a list of the REC's members should be publicly available or available on request. If the list is available only on request, a mechanism should exist to ensure a timely response to requests.
Evidence to be reviewed:	Relevant evidence may include: ▪ an updated list of the REC's members; ▪ information about the process used to ensure that the list remains up to date; ▪ evidence that the list is publicly available (such as on a website or in an annual report or other publicly available document) or available on request; and, ▪ if the list is available only on request, information about the process for responding to requests and examples of any requests for information and the REC's response to those requests.
Rating scale:	➔ **Fully implemented:** A list of the REC's members is publicly available or available on request, and the list is up to date. If the list is available only on request, a mechanism exists to ensure a timely response to requests. ➔ **Partially implemented:** A list of the REC's members is publicly available or available on request, but it is not up to date; or, for lists that are available only on request, no mechanism exists to ensure a timely response to requests. ➔ **Not implemented:** No list of the REC's members is publicly available or available on request.
Indicator:	**05.04: A list of the titles, principal investigators and dates of approval of all research proposals approved by the REC is publicly available or available on request.**
Description:	Information about studies that receive REC approval, excluding confidential information, should be publicly available through mechanisms such as clinical trial registries, websites, newsletters and bulletin boards. The information should be presented as a list of the titles, principal investigators and dates of approval of all research proposals approved by the REC. RECs should have the authority not to disclose information about a study when doing so would expose investigators and/or participants to a risk of harm (e.g. in studies involving illegal or stigmatized behaviour, such as drug use or sexual activity, or studies involving national security). If the list is available only on request, a mechanism should exist to ensure a timely response to requests. RECs should be encouraged to include short summaries of approved studies, to the extent feasible; however, this is not a requirement for this indicator. To facilitate publication of short summaries by the REC, investigators should be encouraged to submit a brief description of the study in easily understandable language.
Evidence to be reviewed:	Relevant evidence may include: ▪ standard operating procedures or other documents that require that a list of the titles, principal investigators and dates of approval of all research proposals approved by the REC be made publicly available or available on request; ▪ a list of the titles, principal investigators and dates of approval of all research proposals approved by the REC; ▪ information about the process used to ensure that the list is updated at least annually; ▪ evidence that the list is publicly available (such as publication on a website or in an annual report or in other publicly available document) or available on request; ▪ if the list is available only on request, information about how responses are made to requests and examples of any requests for the list and the REC's responses to those requests; and ▪ information about studies for which information was not disclosed on the grounds that doing so would expose investigators and/or participants to a risk of harm.
Rating scale:	➔ **Fully implemented:** The titles, principal investigators and dates of approval of all research proposals approved by the REC are made publicly available or available on request, except when the REC has determined that disclosing such information about a study would expose researchers and/or participants to a risk of harm. The list is updated at least annually. If the list is available only on request, there is an adequate

process for a timely response to requests.

- ➔ **Partially implemented:** The titles, principal investigators and/or dates of approval of some research proposals approved by the REC are made publicly available or available on request, but the information is not up to date and/or, for lists that are available only on request, there is no adequate process to ensure a timely response.
- ➔ **Not implemented:** The titles, principal investigators and/or dates of approval of research proposals approved by the REC are not made publicly available or available on request.

Indicator:	**05.05: The REC enables current and prospective research participants to ask questions, raise concerns or lodge complaints about their rights as research participants and about the ethics review process, and it responds to questions and complaints in a timely manner.**
Description:	The REC should enable current and prospective research participants to ask questions, raise concerns or lodge complaints about their rights as research participants and about the ethics review process. A simple means of doing this is to require inclusion of phone number(s) and/or email address(es) on informed consent forms. The REC should ensure that individuals who ask questions or lodge complaints receive timely responses. The REC can minimize the burden of responding to individual questions by including a section on frequently asked questions ("FAQ") on its website.
Evidence to be reviewed:	Relevant evidence may include: ▪ the REC's website, with particular attention to the section on frequently asked questions, if there is one; ▪ informed consent forms approved by the REC; ▪ any other means by which the REC disseminates its contact information to research participants or prospective participants; and ▪ examples of questions, concerns or complaints submitted by research participants or prospective research participants in the current and previous years and the REC's responses.
Rating scale:	➔ **Fully implemented:** The REC provides an accessible mechanism for current and prospective research participants to ask questions, raise concerns or lodge complaints about their rights as research participants and the ethics review process, and timely responses are made to questions and complaints. ➔ **Partially implemented:** The REC provides a mechanism for current and prospective research participants to ask questions, raise concerns or lodge complaints about their rights as research participants and the ethics review process, but the mechanism is not easily accessible and/or the REC does not provide timely responses. ➔ **Not implemented:** The REC does not provide an accessible mechanism for current and prospective research participants to ask questions, raise concerns or lodge complaints about their rights as research participants and the ethics review process.
Indicator:	**05.06: The REC enables investigators to questions, raise concerns or lodge complaints about the ethics review process, and it responds to questions and complaints in a timely manner.**
Description:	The REC should enables investigators to questions, raise concerns or lodge complaints about the ethics review process about the ethics review process. A simple means is to provide a phone number and/or email address on its website. The REC should ensure that investigators who ask questions, raise concerns or lodge complaints receive timely responses. The REC can minimize the burden of responding to individual questions by including a section of frequently asked questions on its website.
Evidence to be reviewed:	Relevant evidence may include: ▪ the REC's website; ▪ any other mechanisms by which the REC disseminates its contact information to investigators, such as correspondence; and ▪ examples of questions, concerns or complaints posed by investigators in the current and previous years and the REC's responses.

Rating scale:	➜ **Fully implemented:** The REC provides an accessible mechanism for investigators to ask questions, raise concerns or lodge complaints about the ethics review process, and timely responses are made to questions and complaints. ➜ **Partially implemented:** The REC provides a mechanism for investigators to ask questions, raise concerns or lodge complaints about the ethics review process, but the mechanism is not easily accessible and/or the REC does not provide timely responses. ➜ **Not implemented:** The REC does not provide an accessible mechanism for investigators to ask questions, raise concerns or lodge complaints about the ethics review process.
Category:	**06: MECHANISMS FOR RECS TO MONITOR THEIR PERFORMANCE**
Objective:	To determine whether the REC has mechanisms in place to ensure its adherence to ethical standards and to assess and improve its performance.
Indicator:	**06.01: The REC has a mechanism for obtaining feedback from investigators and research participants about their experience of the research study.**
Description:	To promote effective ethics oversight, the REC should have a mechanism for obtaining feedback from investigators and research participants about their experience of research studies. If the feedback reveals problems with an ongoing study, the REC should take appropriate remedial action, which in some cases may include suspending or terminating the study. If the feedback reveals problems with the ethics review process, the REC should institute changes in the process to address the identified problems. The REC should make it possible for investigators and research participants to provide feedback anonymously.
Evidence to be reviewed:	Relevant evidence may include: ▪ standard operating procedures or other documents that specify policies and procedures for obtaining feedback from investigators and research participants about their experience of a research study, such as questionnaires; ▪ evidence that the policies and procedures have been implemented; ▪ feedback from investigators and research participants as a result of these policies and procedures in the current and previous years; and ▪ information about any follow-up actions the REC has taken in response to feedback received, including changes to the process of ethics review.
Rating scale:	➜ **Fully implemented:** The REC's standard operating procedures or other documents specify policies and procedures for obtaining feedback from investigators and research participants about their experience of a research study, and there is evidence that these policies and procedures are regularly followed and that the REC has taken action in response to the feedback received. ➜ **Partially implemented:** The REC's standard operating procedures or other documents specify policies and procedures for obtaining feedback from investigators and research participants about their experience of a research study, but the policies and procedures do not appear to be regularly followed and/or the REC does not appear to have taken action in response to the feedback received. ➜ **Not implemented:** The REC's standard operating procedures or other documents do not specify policies or procedures for obtaining feedback from investigators and research participants about their experience of a research study.
Indicator:	**06.02: The REC monitors its adherence to its standard operating procedures.**
Description:	The REC should evaluate whether its staff and members routinely follow its policies, rules and written procedures, with particular attention to whether the ethical considerations in international guidelines and national standards are considered and applied consistently and coherently. Procedures for conducting such assessments could include interviews with members and staff, regular review of meeting minutes, and self-assessments of selected protocol reviews.

Evidence to be reviewed:	Relevant evidence may include: ▪ procedures for monitoring REC staff and members' compliance with the REC's policies, rules and procedures; ▪ examples of monitoring conducted by the REC in the previous year; and ▪ the REC's annual report, if there is one.
Rating scale:	➜ **Fully implemented:** The REC has policies and procedures for monitoring staff and members' compliance with its policies and procedures, and there is evidence of regular compliance with the policies and procedures. ➜ **Partially implemented:** The REC has policies and procedures for monitoring staff and members' compliance with its policies and procedures, but there is no evidence of regular compliance with the policies and procedures. ➜ **Not implemented:** The REC does not have policies or procedures for monitoring staff and members' compliance with its policies and procedures.
Indicator:	**06.03: The REC regularly conducts internal reviews of its performance.**
Description:	The REC should regularly conduct internal reviews of its performance to ensure that it is maintaining high standards of quality and productivity and that its work is having a positive impact on the protection of research participants.[8] For most RECs, the reviews should be conducted annually; however, RECs with a very low volume of work or that review only minimal-risk studies might choose to conduct them less frequently. RECs should select criteria for the review based on applicable legal standards, ethical guidance and internal policies and procedures. Examples of criteria that could be measured include: ▪ measures of productivity, such as time between submission and approval; ▪ the quality of REC deliberations, such as reviews of meeting minutes to determine whether all relevant ethical criteria are discussed and whether sufficient attention is paid to core issues such as risk-benefit assessment and informed consent; ▪ comparison of the REC's assessment of the risk of studies with information on the number and types of adverse events reported in those studies; ▪ the number and nature of complaints received by the REC; and ▪ feedback from REC members about the strengths and weaknesses of the ethics review process. The REC should use the information from these reviews to continually improve the ethics review process.
Evidence to be reviewed:	Relevant evidence may include: ▪ standard operating procedures and other documents that specify the mechanisms used by the REC to conduct regular internal reviews of its performance; ▪ a list of the criteria designed to be measured in the REC's internal reviews; ▪ the results of all internal reviews conducted in the current and previous years; and ▪ evidence of any follow-up actions taken by the REC in response to the internal reviews, including changes to the process of ethics review.
Rating scale:	➜ **Fully implemented:** The REC's standard operating procedures or other documents specify mechanisms for conducting internal reviews of the REC's performance, and the REC conducts internal reviews of its performance at least annually (or, for RECs with a very low volume of work or that review only minimal-risk studies, regularly according to the number and type of protocols they review). The REC has clear criteria for reviews that are based on applicable legal standards, ethical guidance and internal policies and procedures. There is evidence that the REC has used information from such reviews to improve the ethics review system. ➜ **Partially implemented:** Some, but not all, of the criteria described under "fully implemented" are satisfied. ➜ **Not implemented:** None of the criteria described under "fully implemented" is satisfied.

8 Quality management systems – Requirements. International Standard ISO 9001:2015. Geneva: International Organization for Standardization, 2015 (https://www.iso.org/iso-9001-quality-management.html).

Indicators for assessment of research institutions (category 7)

Category	07: RESPONSIBLE RESEARCH INSTITUTIONS
Objective:	To assess whether research institutions fulfil their responsibility to ensure that any health-related research under their purview adheres to ethical principles in WHO guidance, as well as any national laws and policies consistent with those principles. These indicators are not designed to provide a comprehensive assessment of research institutions; rather, they focus on clear markers of institutions' commitment to the protection of research participants.
Indicator:	**07.01: The institution verifies that all proposals for health-related research involving humans are submitted to a registered REC if any part of the research is to be conducted by a researcher affiliated with the institution.[9]**
Description:	Research institutions should expressly commit to complying with international and national ethical standards in health-related research involving humans. As part of this commitment, they should verify that all proposals for health-related research involving humans are submitted to a registered REC if any part of the research is to be conducted by a researcher affiliated with the institution.
Evidence to be reviewed:	Relevant evidence may include: ▪ institutional policies that require that all health-related research involving humans be submitted to an REC if any part of the research is to be conducted by a researcher affiliated with the institution; ▪ institutional policies specifying the REC(s) on which the institution relies for reviewing research conducted by researchers affiliated with it; ▪ evidence that the institution ensures that researchers affiliated with it comply with these policies; ▪ information about any actions taken against researchers who failed to comply with these policies; ▪ information about all health-related research involving humans conducted by researchers affiliated with the institution in the current and previous years, with evidence that the studies were submitted to RECs; and ▪ evidence of the institution's express commitment to comply with international and national ethical standards in health-related research involving humans.
Rating scale:	➜ **Fully implemented:** The institution has a policy that requires that all health-related research involving humans be submitted to a registered REC if any part of the research is to be conducted by a researcher affiliated with the institution, and there is evidence that researchers affiliated with the institution comply with those policies. In addition, there is evidence of the institution's express commitment to comply with international and national ethical standards in health-related research involving humans. ➜ **Partially implemented:** The institution has a policy that requires that all health-related research involving humans be submitted to a registered REC if any part of the research is to be conducted by a researcher affiliated with the institution; however, all researchers affiliated with the institution do not appear to comply with those policies and/or the institution has not made an express commitment to comply with international and national ethical standards in health-related research involving humans. ➜ **Not implemented:** The institution does not have a policy that requires that all health-related research involving humans be submitted to a registered REC if any part of the research is to be conducted by a researcher affiliated with the institution.

9 Whether a researcher is "affiliated with" an institution should be determined according to local laws and policies.

Indicator:	**07.02: The institution has policies and procedures for declaration and management of conflicts of interest of researchers affiliated with the institution and of the institution itself.**
Description:	In order to protect the integrity of research and public confidence in the research system, research institutions should develop and implement policies and procedures for declaration and management of conflicts of interest of researchers affiliated with the institution and of the institution itself.
Evidence to be reviewed:	Relevant evidence may include: ▪ institutional policies and procedures for declaration and management of conflicts of interest of researchers affiliated with the institution and of the institution itself; ▪ evidence that those policies and procedures are consistently followed; ▪ declarations of conflict of interest submitted to the institution in the current and previous years; ▪ information about actions taken by the institution when conflicts of interest have been declared; and ▪ information about actions taken against individuals who fail to disclose conflicts of interest pursuant to the institution's policy.
Rating scale:	➔ **Fully implemented:** The institution has policies and procedures for declaration and management of conflicts of interest of researchers affiliated with the institution and of the institution itself. There is evidence that these policies and procedures are consistently followed and that the institution takes appropriate action when conflicts of interest are declared. ➔ **Partially implemented:** (1) The institution has policies and procedures for declaration and management of conflicts of interest, but the policies do not apply to all researchers affiliated with the institution and/or do not cover conflicts of interest of the institution itself; or, (2) the institution has adequate policies for conflicts of interest, but it does not appear that the policies and procedures are consistently followed and/or that the institution takes appropriate action in cases in which conflicts of interest have been declared. ➔ **Not implemented:** The institution does not have policies or procedures for declaration and management of conflicts of interest related to research involving humans.
Indicator	**07.03: Institutions with their own RECs have policies and procedures for declaration and management of conflicts of interest of REC members and non-member participants in REC meetings.**
Description:	Institutions with their own RECs should have policies and procedures for declaration and management of conflicts of interest of REC members and non-member participants in REC meetings. The policies should be harmonized with the policies on conflicts of interests of the REC. Institutions with RECs should also ensure that their institutional governance structure does not create conflicts of interest for REC members. For example, individuals should not simultaneously serve on the REC and a committee charged with investigating allegations of research misconduct.
Evidence to be reviewed:	Relevant evidence may include: ▪ institutional policies and procedures for declaration and management of conflicts of interest of REC members and non-member participants; ▪ evidence that these policies and procedures are consistently followed; ▪ declarations of conflicts of interest submitted to the institution in the current and previous years; ▪ information about actions taken by the institution when conflicts of interest have been declared; ▪ information about actions taken against individuals who fail to disclose conflicts of interest pursuant to the institution's policy; and ▪ information about the institution's internal governance structure as it pertains to the conduct of health-related research involving human participants.

Rating scale:	➜ **Fully implemented:** The institution has policies and procedures for declaration and management of conflicts of interest of REC members and of non-member participants in REC meetings. The policies are harmonized with the REC's policies for conflicts of interest. There is evidence that the policies and procedures are consistently followed and that the institution takes appropriate action when conflicts of interest have been declared. The institution's internal governance structure does not create conflicts of interest for REC members. ➜ **Partially implemented:** Some, but not all, of the criteria described under "fully implemented" are satisfied. ➜ **Not implemented:** None of the criteria described under "fully implemented" is satisfied.
Indicator:	**07.04: The institution has a policy that requires that all researchers affiliated with it be trained in their responsibilities for ethical conduct of research.**
Description:	Research institutions should have policies that require all researchers affiliated with them to be trained in their responsibilities for ethical conduct of research. Institutions may either offer such training themselves or rely on courses provided by external entities. Researchers should be required to provide proof to the institution that they have complied with their training obligations.
Evidence to be reviewed:	Relevant evidence may include: ▪ institutional policies that require that all researchers affiliated with the institution be trained in their responsibilities for ethical conduct of research; ▪ institutional policies that require researchers to provide proof of compliance with their training obligations; ▪ evidence or proof of training submitted by researchers affiliated with the institution in the previous year; and ▪ information about actions taken against researchers who fail to satisfy their training obligations.
Rating scale:	➜ **Fully implemented:** The institution has a policy that requires all researchers affiliated with the institution to be trained in their responsibilities for ethical conduct of research. The institution requires researchers to provide proof of compliance with their training obligations, and there is evidence that researchers submit the required proof. ➜ **Partially implemented:** The institution has a policy that requires all researchers affiliated with the institution to be trained in their responsibilities for ethical conduct of research, but the institution does not require researchers to provide proof of compliance with their training obligations, and/or it does not appear that all researchers submit the required proof. ➜ **Not implemented:** The institution does not have a policy that requires that all researchers affiliated with the institution be trained in their responsibilities for ethical conduct of research.
Indicator:	**07.05: If the institution has its own REC, it ensures that the REC has the resources described in category 3 of this document.**
Description:	In order to operate effectively, RECs must have adequate staff, facilities, technological support and finances. Institutions that have their own RECs should be responsible for ensuring that these resources are provided, either by the institution itself or by external funders.
Evidence to be reviewed:	Relevant evidence may include: ▪ provisions in the institutional budget to support the REC; and ▪ any other information about the sources of funding and other resources provided to the REC.
Rating scale:	➜ **Fully implemented:** The institution ensures that its REC has the resources described in category 3 of this document. ➜ **Partially implemented:** The institution ensures that its REC has some resources, but not all the resources described in category 3 of this document. ➜ **Not implemented:** The institution does not ensure that the REC has any of the resources described in category 3 of this document..

Indicator:	**07.06: The institution facilitates lodging of complaints by research participants and prospective research participants about studies conducted by researchers affiliated with the institution, either through the institution itself or at national or regional level. If the complaint system is established within the institution, the institution has a process for reviewing and responding to complaints.**
Description:	Research institutions should facilitate lodging of complaints by research participants and prospective research participants about studies conducted by researchers affiliated with the institution. A simple way of doing this is to post a phone number and/or the email address of an institutional official authorized to respond to complaints on the institution's website. If there is a national or regional system for lodging complaints about research, the institution can post information about how to submit complaints through that system. When a complaint system is established in the institution, the institution should establish a process for reviewing and responding to complaints. If a complaint reveals problems with an ongoing study, the institution should take appropriate remedial action, which in some cases may include suspending or terminating the study. If the complaint reveals problems with the ethics review process, the institution should alert the relevant REC of the identified problems.
Evidence to be reviewed:	Relevant evidence may include: ▪ evidence that the institution provides research participants and prospective participants with either (a) contact information for an institutional official authorized to respond to complaints about research, or (b), if there is a national or regional system for lodging complaints about research, information about how to submit complaints through that system; ▪ for institutions with an internal complaint system, evidence of all complaints received in the current and previous years and the institution's responses to those complaints; and, ▪ for institutions with an internal complaint system, evidence of any follow-up actions the institution has taken in response to complaints received, including remedial actions in ongoing studies and changes to the process of ethics review.
Rating scale:	➔ **Fully implemented:** A national or regional system for lodging complaints about research exists, or the institution has established an internal complaints system. The institution gives research participants and prospective research participants information about how to submit complaints about studies conducted by researchers affiliated with the institution. If the institution has established a complaints system, there is evidence that it consistently responds to all complaints submitted. ➔ **Partially implemented:** (1) A national or regional system for lodging complaints about research exists, or the institution has established an internal complaints system, but the institution does not give research participants and prospective research participants information about how to submit complaints about studies conducted by researchers affiliated with the institution; or, (2) if the institution has established its own complaints system, it does not appear to respond consistently to all complaints submitted. ➔ **Not implemented:** There is no system for lodging complaints about research, either nationally, regionally or in the institution.
Indicator:	**07.07: The institution has a process for investigating allegations of unethical conduct by researchers and for imposing consequences when unethical conduct is determined to have occurred.**
Description:	Research institutions should have a process for investigating allegations of unethical conduct by researchers and for imposing consequences when unethical conduct is determined to have occurred. The consequences might include temporary or permanent prohibition from conducting further research involving humans, termination of employment or changes in job titles or responsibilities, financial penalties, and public reprimands. Any investigations conducted should provide researchers who are accused of misconduct with due process protections, including adequate notice of the allegations against them and an opportunity to be heard before penalties are imposed.

Evidence to be reviewed:	The assessor should review: ▪ institutional policies that specify a process for investigating allegations of unethical conduct by researchers and for imposing consequences when unethical conduct is determined to have occurred; ▪ information about the range of consequences that might be imposed on researchers who are determined to have engaged in misconduct; ▪ information about the due process protections provided to researchers accused of misconduct; and ▪ information about any investigations conducted of researchers accused of unethical conduct and the outcome of those investigations.
Rating scale:	➔ **Fully implemented:** The institution has policies that specify a process for investigating allegations of unethical conduct by researchers and for imposing consequences when unethical conduct is determined to have occurred. Those policies provide due process protections for researchers, including adequate notice of the allegations against them and an opportunity to be heard before penalties are imposed. ➔ **Partially implemented:** The institution has policies that specify a process for investigating allegations of unethical conduct by researchers, but those policies do not impose consequences when unethical conduct is determined to have occurred and/or they do not provide due process protections for researchers. ➔ **Not implemented:** The institution does not have policies specifying a process for investigating allegations of unethical conduct by researchers.
Indicator:	**07.08: If the institution has its own REC, it ensures that the REC has adequate legal support.**
Description:	Research institutions that have their own RECs should ensure that the REC has sufficient legal support for its activities. This includes ensuring that the REC has adequate representation if its actions are challenged in court.
Evidence to be reviewed:	Relevant evidence may include: ▪ information about the legal support available to the REC; and ▪ information on any cases in which the REC's actions were challenged in court and on the legal support the REC received from the institution in those cases.
Rating scale:	➔ **Fully implemented:** The institution provides its REC with sufficient legal support to carry out its activities. If the institution's REC has been challenged in court, the institution provided it with adequate legal support. ➔ **Partially implemented:** The institution provides its REC with legal support for its activities, but the support is not sufficient. ➔ **Not implemented:** The institution does not provide its REC with legal support for its activities.

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