WHO TOOL FOR
BENCHMARKING ETHICS OVERSIGHT OF HEALTH-RELATED
RESEARCH WITH HUMAN PARTICIPANTS
DRAFT VERSION FOR PILOTING
ACKNOWLEDGMENTS

This tool was jointly developed by Alireza Khadem (Regulatory System Strengthening, Regulation and Safety Unit), and Andreas Reis (Co-Unit Head, Health Ethics & Governance, RFH). Prof. Carl Coleman (Seton Hall University, USA), and Dr. Juliati Dahlan (National Agency of Drugs and Food Control, Indonesia) were the lead writers for drafting and development of the tool. This work was guided by an international expert group with the following members:

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A draft version of the tool was published on the WHO Website for public comment from January to March 2022. Over 360 comments were received and integrated into the current draft version of the tool.

This preliminary version is being used for pilot-testing in various countries, with a view to produce a final document in 2023.
INTRODUCTION

OBJECTIVES
The tool is intended to assist WHO Member States in evaluating their capacity to provide appropriate ethical oversight of health-related research with 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 the assessment of countries’ progress in implementing those recommendations. In addition to assisting in capacity-building efforts, 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.

SCOPE
This tool is designed for all entities involved in the ethical 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 health-related research involving humans, including research involving biospecimens or data derived from humans. The tool is intended to be adaptable to systems in which a small number of RECs exist at the national or regional level (either as public or private entities) as well as systems in which multiple RECs throughout the country (often, but not exclusively, within research institutions).

USING THESE INDICATORS
The first indicator in this document is intended to be assessed at the national level. All of the other indicators are designed to be measured at the level of individual RECs or research institutions. In countries with multiple RECs and/or research institutions, national assessors should seek to obtain assessments of a representative sample of RECs and institutions. They can then aggregate this information to generate country-level results. Further information on this process is provided in the accompanying manual.

\(^1\) WHO defines “research with human participants” as “any social science, biomedical, behavioral, 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.
Indicator for Assessment of the Legal and Regulatory Context

**Indicator:** 01: Legal provisions and regulatory framework

**Objective:** The objective of this indicator is to determine whether an adequate legal and regulatory framework exists to support ethical oversight of health-related research involving humans.

**Subindicator:** 01.01: Legal provisions requiring health-related research with humans to be reviewed and approved by RECs.

**Description:** Consistent with WHO guidance and internationally accepted ethical standards, countries should have legal provisions that explicitly require the ethical review and approval of health-related research with humans before recruitment of participants begins (or, in studies using previously collected biological specimens or data, before the research commences). Countries may choose to exempt specified categories of low-risk studies from this requirement.

**Objective:** The objective of this subindicator is to determine whether there are legal provisions requiring health-related research with humans to be reviewed and approved by RECs.

**Evidence to review:** The assessor should ask for and review:

1. Legal provisions requiring RECs to review and approve health-related research with humans in accordance with internationally accepted ethical standards.
2. Any relevant guidance documents interpreting these provisions.

**Rating Scale:**

- NOT IMPLEMENTED (NI): There are no legal provisions requiring health-related research with humans to be reviewed and approved by RECs.
- IMPLEMENTED (I): Comprehensive legal provisions requiring health-related research with humans to be reviewed and approved by RECs have been fully adopted.
- PARTIALLY IMPLEMENTED (PI): Legal provisions requiring health-related research with humans to be reviewed and approved by RECs have been developed, but they have not been fully adopted and/or are not comprehensive.

**Subindicator:** 01.02: Legal provisions requiring RECs to review proposed research to determine whether it is consistent with the ethical standards articulated in WHO guidance.

**Description:** WHO guidance sets forth specific ethical issues that RECs should consider in their review of proposed research, including but not limited to the scientific design and conduct of the study; the risks and potential benefits of research; the selection of the study population and recruitment of research participants; the use of inducements; protection of research participants’ privacy and confidentiality; the informed consent process; and community considerations. Countries should have legal provisions that require RECs to consider all of these issues. For issues related

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

to the scientific design of a study, RECs may either conduct their own review or defer to the independent review of an appropriately constituted scientific review committee.

<table>
<thead>
<tr>
<th>Objective:</th>
<th>The objective of this subindicator is to determine whether there are legal provisions requiring RECs to review proposed health-related research with humans to determine that it satisfies the ethical standards articulated in WHO guidance.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review:</td>
</tr>
<tr>
<td></td>
<td>1. Legal provisions setting forth the considerations RECs must take into account in reviewing proposed health-related research with humans.</td>
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<td></td>
<td>2. Any relevant guidance documents interpreting these provisions.</td>
</tr>
<tr>
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<td>➢ NOT IMPLEMENTED (NI): There are no legal provisions requiring RECs to review proposed research to determine that it satisfies the ethical standards articulated in WHO guidance.</td>
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<tr>
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</tr>
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<td></td>
<td>➢ PARTIALLY IMPLEMENTED (PI): Legal provisions requiring RECs to review proposed research to determine that it satisfies the ethical standards articulated in WHO guidance have been developed, but they have not been fully adopted and/or are not comprehensive.</td>
</tr>
<tr>
<td>Subindicator:</td>
<td>01.03: Legal provisions requiring RECs to conduct continuing review of ongoing research at intervals appropriate to the risk to humans.(^4)</td>
</tr>
<tr>
<td>Description:</td>
<td>In addition to reviewing proposed research before it begins, legal provisions should require RECs to provide continuing review 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 occur at intervals appropriate to the degree of risk to human participants (generally, at least once per year) and should take place as long as the research remains active for long-term follow-up of participants. To enable RECs to carry out continuing review, legal provisions should require researchers to provide RECs with reports on their projects on a regular basis and to report any serious unexpected adverse events or other serious unanticipated risks as they occur.</td>
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<tr>
<td>Evidence to review:</td>
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<td></td>
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<td>2. Any relevant guidance documents interpreting these provisions.</td>
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</tbody>
</table>

\(^4\) See also Subindicator 04.07
humans have been developed, but they have not been fully adopted and/or not comprehensive.

<table>
<thead>
<tr>
<th>Subindicator:</th>
<th>01.04: Legal provisions allowing RECs to terminate health-related research with humans if they determine that a study no longer meets the criteria that justified its initial approval.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>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. In situations where national regulatory authorities (NRA) are responsible for suspension/termination decisions, the NRA should be required to carry out an REC’s recommendation to suspend or terminate a study.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this subindicator is to determine whether there are legal provisions authorizing RECs to suspend or terminate health-related research with humans if they determine that a study no longer meets the criteria that justified its initial approval.</td>
</tr>
</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Legal provisions authorizing RECs to suspend or terminate health-related research with humans if they determine that a study no longer meets the criteria that justified its initial approval.  
2. In situations where NRAs are responsible for suspension/termination decisions, legal provisions requiring NRAs to carry out an REC’s recommendation to suspend or terminate a study.  
3. Any relevant guidance documents interpreting these provisions.  
4. If applicable, evidence of situations in which an REC has suspended or terminated, or considered suspending or terminating, health-related research with humans. |
| Rating Scale: | ➢ NOT IMPLEMENTED (NI): There are no legal provisions authorizing RECs to suspend or terminate health-related research with humans if they determine that a study no longer meets the criteria that justified its initial approval.  
➢ IMPLEMENTED (I): Comprehensive legal provisions authorizing RECs to suspend or terminate health-related research with humans if they determine that a study no longer meets the criteria that justified its initial approval have been fully adopted.  
➢ PARTIALLY IMPLEMENTED (PI): Legal provisions authorizing RECs to suspend or terminate health-related research with humans if they determine that a study no longer meets the criteria that justified its initial approval have been developed, but they have not been fully adopted and/or not comprehensive. |

<table>
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<tr>
<th>Subindicator:</th>
<th>01.05: Legal provisions requiring REC members to declare any conflicts of interest and prohibiting members from participating in the review of any study in which they have a conflicting interest.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>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 purposes of this subindicator, 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 intereferes, or may appear to interfere, with his or her primary interest in safeguarding the rights and welfare of research participants.</td>
</tr>
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<td>Objective:</td>
<td>The objective of this subindicator is to determine whether there are legal provisions requiring REC members to declare any conflicts of interest and prohibiting members from participating in the review of any study in which they have a conflicting interest.</td>
</tr>
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</table>
Evidence to review:
The assessor should ask for and review:
1. Legal provisions requiring REC members to declare any conflicts of interest and ensuring that REC members do not participate in the review of studies in which they have conflicting interests.
2. Any relevant guidance documents interpreting these provisions.

Rating Scale:
- NOT IMPLEMENTED (NI): There are no legal provisions requiring REC members to declare any conflicts of interest and ensuring that REC members do not participate in the review of studies in which they have conflicting interests.
- IMPLEMENTED (I): Comprehensive legal provisions requiring REC members to declare any conflicts of interest and ensuring that REC members do not participate in the review of studies in which they have conflicting interests have been fully adopted.
- PARTIALLY IMPLEMENTED (PI): Legal provisions requiring REC members to declare any conflicts of interest and ensuring that REC members do not participate in the review of studies in which they have conflicting interests have been developed, but they have not been fully adopted and/or they are not comprehensive.

Subindicator: 01.06 Legal provisions ensuring that REC s’ decisions cannot be overruled except in cases of abuse of authority as determined through a formal judicial process.

Description:
In order for RECs to function effectively, they need to have the authority to act independently. This independence is essential maintaining public trust in the integrity of health-related research. In order to ensure RECs’ independence, legal provisions should ensure that RECs’ decisions cannot be overruled except in cases of abuse of authority as determined through a formal judicial process.

Objective:
The purpose of this subindicator is to determine whether legal provisions exist that ensure that RECs’ decisions cannot be overruled except in cases of abuse of authority as determined through a formal judicial process.

Evidence to review:
The assessor should ask for and review:
1. Legal provisions ensuring that RECs’ decisions cannot be overruled except in cases of abuse of authority as determined through a formal judicial process.
2. Any relevant guidance documents interpreting these provisions.

Rating Scale:
- NOT IMPLEMENTED (NI): There are no legal provisions ensuring that RECs’ decisions cannot be overruled except in cases of abuse of authority as determined through a formal judicial process.
- IMPLEMENTED (I): Comprehensive legal provisions ensuring that RECs’ decisions cannot be overruled except in cases of abuse of authority as determined through a formal judicial process have been fully adopted.
- PARTIALLY IMPLEMENTED (PI): Legal provisions ensuring that RECs’ decisions cannot be overruled except in cases of abuse of authority as determined through a formal judicial process have been developed, but they have not been fully adopted and/or they are not comprehensive.

Subindicator: 01.07: Legal provisions ensuring that research participants have access to medical treatment for any injuries that directly result from their participation, and that participants and their dependants are protected from any financial consequences that could directly result if they 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 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. Alternatively, 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.

**Objective:**
The objective of this subindicator is to determine whether there are legal provisions ensuring that participants have access to treatment for any injuries that directly result from their participation, and that participants and their dependents are protected from any financial consequences that could directly result if they suffer injury or death as a result of their participation.

**Evidence to review:**
The assessor should ask for and review:
1. Legal provisions ensuring that participants have access to treatment for any injuries that directly result from their participation, and that participants and their dependents are protected from any financial consequences as a direct result of their participation is available.
2. Any relevant guidance documents interpreting these provisions.
3. Evidence of mechanisms undertaken to in particular studies to implement these provisions, such as insurance policies or other relevant documents.
4. If applicable, evidence of the application of national no-fault compensation systems in the context of research.

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** There are no legal provisions ensuring that participants have access to treatment for any injuries that directly result from their participation, and that participants and their dependents are protected from any financial consequences that could directly result if they suffer injury or death as a result of their participation.
- **IMPLEMENTED (I):** Comprehensive legal provisions ensuring that participants have access to treatment for any injuries that directly result from their participation, and that participants and their dependents are protected from any financial consequences that could directly result if they suffer injury or death as a result of their participation have been fully adopted.
- **PARTIALLY IMPLEMENTED (PI):** Legal provisions ensuring that participants have access to treatment for any injuries that directly result from their participation, and that participants and their dependents are protected from any financial consequences that could directly result if they suffer injury or death as a result of their participation have been developed, but they have not been fully adopted and/or not comprehensive.

**Subindicator:**
01.08: Legal provisions requiring clinical trials to be registered on a registry that complies with the WHO Registry Criteria before recruitment of participants begins.

**Description:**
Registration of clinical trials is an internationally recognized ethical requirement. Registration provides multiple benefits, including minimizing the risk of publication bias and selective reporting, avoiding duplicative studies, identifying gaps in research, and making potential participants aware of trials in which they may be interested in participating. Many scientific journals will not publish the results of clinical trials that are not properly registered.

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6 [https://www.who.int/clinical-trials-registry-platform/network/registry-criteria](https://www.who.int/clinical-trials-registry-platform/network/registry-criteria)
### Objective:
The objective of this subindicator is to determine whether countries have legal provisions requiring clinical trials to be registered on a registry that complies with the WHO Registry Criteria before recruitment of participants begins.

### Evidence to review:
The assessor should ask for and review:
1. Legal provisions requiring clinical trials to be registered on a registry that complies with the WHO Registry Criteria before recruitment of participants begins.
2. Any relevant guidance documents interpreting these provisions.

### Rating Scale:
- **NOT IMPLEMENTED (NI):** There are no legal provisions requiring clinical trials to be registered on a registry that complies with the WHO Registry Criteria.
- **IMPLEMENTED (I):** Comprehensive legal provisions requiring clinical trials to be registered on a registry that complies with the WHO Registry Criteria before recruitment of participants begins have been fully adopted.
- **PARTIALLY IMPLEMENTED (PI):** Legal provisions requiring clinical trials to be registered on a registry that complies with the WHO Registry Criteria have been developed, but they have not been fully adopted and/or not comprehensive.

### Subindicator:
01.09: National, regional, and/or local oversight authorities supporting RECs and ensuring that they adhere to applicable ethical and legal requirements.

### Description:
Governmental entities can play an important role in ensuring the effectiveness of RECs by providing technical assistance, coordination, and ongoing monitoring. For example, oversight bodies can help disseminate best practices in research ethics review, promote coordination among RECs involved in multi-site studies, and facilitate communication between RECs and other stakeholders involved in research. They also can identify RECs that are not adhering to applicable ethical and legal standards and work with them to develop and implement corrective plans.

Responsibility for overseeing RECs can be vested in independent agencies created for this specific purpose, or in existing governmental 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.

### Objective:
The objective of this subindicator is to determine whether there are national, regional, and/or local oversight authorities supporting RECs and ensuring that they adhere to applicable ethical and legal requirements.

### Evidence to review:
The assessor should ask for and review:
1. Legal provisions establishing REC oversight bodies or granting the authority to oversee RECs to existing governmental agencies.
2. Information about the legal powers and resources granted to these entities.
3. Information about the mission and organizational structure of these entities.
4. Evidence of activities undertaken by oversight authorities in the previous year.

### Rating Scale:
- **NOT IMPLEMENTED (NI):** There are no governmental entities with authority to provide support to RECs and ensure that they adhere to applicable ethical and legal requirements.
- **IMPLEMENTED (I):** Governmental entities with authority to provide support to RECs and ensure that they adhere to applicable ethical and legal requirements exist, and these entities have adequate legal powers and resources to carry out their work.
- **PARTIALLY IMPLEMENTED (PI):** Governmental entities with authority to provide support to RECs and ensure that they adhere to applicable ethical and legal requirements exist, but they have not been fully adopted and/or not comprehensive.
requirements exist, but these entities lack sufficient legal powers and/or resources.

**Subindicator:** 01.10: Legal provisions creating mechanisms for independent authorities to suspend or revoke the authority 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 an REC’s authority to review and approve research if it is in serious 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 RECs’ authority may be given to existing governmental agencies, such as ministries of health, or to independent agencies created specifically to oversee RECs.

**Objective:** The objective of this subindicator is to determine whether there are legal provisions creating mechanisms to suspend or revoke the authority of RECs that do not adhere to applicable laws, regulations, and guidelines.

**Evidence to review:** The assessor should ask for and review:
1. Legal provisions creating mechanisms to suspend or revoke the authority of RECs that do not adhere to applicable laws, regulations, and guidelines.
2. Any relevant guidance documents interpreting these provisions.
3. 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 an REC’s authority to review and approve research.

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** There are no legal provisions creating a mechanism to suspend or revoke the authority of RECs that do not adhere to applicable laws, regulations, and guidelines.
- **IMPLEMENTED (I):** Comprehensive legal provisions creating a mechanism to suspend or revoke the authority of RECs that do not adhere to applicable laws, regulations, and guidelines have been fully adopted.
- **PARTIALLY IMPLEMENTED (PI):** Legal provisions creating a mechanism to suspend or revoke the authority of RECs that do not adhere to applicable laws, regulations, and guidelines have been developed, but they have not been fully adopted and/or not comprehensive.

**Subindicator:** 01.11: Updated, publicly available information on laws, regulations, and official guidelines related to the ethics oversight of health-related research with humans.

**Description:** The public should have access to updated information regarding, laws, regulations and official guidelines related to the ethics oversight of health-related research with humans.

**Objective:** The objective of this subindicator is to determine whether updated information on laws, regulations, and official guidelines related to the ethics oversight of health-related research with humans is publicly available.

**Evidence to review:** The assessor should ask for and review:
1. Websites or other publicly available sources of information about laws, regulations, and official guidelines related to the ethics oversight of health-related research with humans.

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** Updated information on laws, regulations, and official guidelines related to the ethics oversight of health-related research with humans is not publicly available.
- **IMPLEMENTED (I):** Comprehensive updated information on laws, regulations, and official guidelines related to the ethics oversight of health-related research with humans is publicly available.
- **PARTIALLY IMPLEMENTED (PI):** Some information on laws, regulations, and official guidelines related to the ethics oversight of health-related research with humans is publicly available, but it is not comprehensive and/or not up to date.

**Subindicator:** 01.12: An updated, publicly available list of all RECs in the country.

**Description:** A list of all RECs operating in the country should be publicly available. This requirement could be satisfied by one of the following methods:
- Publication of a list of RECs by a government ministry or other official entity
- Publication of a list of RECs by a university or nonprofit institution
- In countries that require RECs to be registered, publication of a list of registered RECs by the entity in charge of the registry
- In countries where all RECs are created by specific legal provisions, publication of a list of those legal provisions

**Objective:** The objective of this subindicator is to determine whether a list of registered RECs is publicly available.

**Evidence to review:** The assessor should ask for and review:
1. An updated list of all RECs operating in the country.
2. Information about the process used to include RECs in the list.
3. Information about the process used to ensure that the list remains up to date.
4. Evidence that the list is publicly available, such as publication on a website, in official government documents, or in other publicly available sources.

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** An updated list of all RECs in the country does not exist.
- **IMPLEMENTED (I):** An updated list of all RECs in the country is publicly available.
- **PARTIALLY IMPLEMENTED (PI):** A list of all RECs in the country exists, but it is not publicly available and/or it is not regularly updated.
### Indicators for Assessment of Individual RECs and Research Institutions

**Indicator:** 02: REC structure and composition

**Objective:** The objective of this indicator is to determine whether RECs have an effective structure and composition.

**Subindicator:** 02.01: The REC’s membership satisfies the requirements of relevant ethical guidelines.

**Description:**
According to internationally accepted ethical guidelines, RECs must have a multidisciplinary and multisectoral membership that is gender balanced, that reflects the social and cultural diversity of the communities from which research participants are most likely to be drawn, and that includes individuals with backgrounds relevant to the areas of research the committee is most likely to review.

The following factors should be taken into consideration 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 scientific expertise, including expertise in behavioural and social sciences; health care providers; pharmacologists; members who have expertise in legal matters, public health, and ethics; and lay people whose primary role is to share their insights 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 with human participants, should be appointed in sufficient numbers to ensure that they feel comfortable voicing their views.
4. In order to enhance independence, committee membership should include members who are not affiliated with organizations that sponsor, fund, or conduct research reviewed by the REC. In addition, all REC members should declare any conflicts of interest, and the REC should ensure that members do not participate in the review of studies in which they have a conflict of interest.
5. Committees should be large enough to ensure that multiple perspectives are brought into 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.

**Objective:** The objective of this subindicator is to determine whether the REC’s membership satisfies the requirements of relevant ethical guidelines.

**Evidence to review:**

1. Legal provisions and guidance documents related to the composition of REC members.
2. Provisions in the REC’s standard operating procedures related to the recruitment and selection of members.
3. Current list of REC members.
4. CVs and/or other relevant documents establishing the background and expertise of REC members.

**Rating Scale:**

- **NOT IMPLEMENTED (NI):** The REC’s membership does not meet the requirements of relevant ethical guidelines.
- **IMPLEMENTED (I):** The REC’s membership meets all of the requirements of relevant ethical guidelines.
- **PARTIALLY IMPLEMENTED (PI):** The REC’s membership meets some of the requirements of relevant ethical guidelines.
<table>
<thead>
<tr>
<th>Subindicator:</th>
<th>02.02: The roles and responsibilities of REC members are clearly defined.</th>
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</thead>
<tbody>
<tr>
<td>Description:</td>
<td>The roles and responsibilities of REC members should be clearly defined in written terms of reference. Among other things, the terms of reference should make clear what decision-making mechanism (e.g., consensus, majority vote, etc.) will be used, who is authorized to conduct expedited reviews, and how any conflicts of interest should be declared and managed.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this subindicator is to determine whether the roles and responsibilities of REC members are clearly defined.</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review:</td>
</tr>
<tr>
<td></td>
<td>1. Provisions in the REC’s standard operating procedures or other governing documents related to the roles and responsibilities of REC members, including provisions related to decision-making mechanisms, the process of expedited review, and the declaration and management of conflicts of interests.</td>
</tr>
<tr>
<td></td>
<td>2. The terms of reference for REC members.</td>
</tr>
<tr>
<td></td>
<td>3. The REC’s organizational chart, if one exists.</td>
</tr>
<tr>
<td>Rating Scale:</td>
<td>➢ NOT IMPLEMENTED (NI): The roles and responsibilities of REC members are not clearly defined.</td>
</tr>
<tr>
<td></td>
<td>➢ IMPLEMENTED (I): The roles and responsibilities of REC members are clearly defined.</td>
</tr>
<tr>
<td></td>
<td>➢ PARTIALLY IMPLEMENTED (PI): The roles and responsibilities of REC members are partially defined, but important elements are missing.</td>
</tr>
<tr>
<td>Subindicator:</td>
<td>02.03: REC members and chairs are appointed for specific terms, rather than on an indefinite basis.</td>
</tr>
<tr>
<td>Description:</td>
<td>In order to promote the active engagement of members and ensure a diversity of perspectives, REC members and chairs should be appointed for fixed periods of time, rather than an indefinite basis. Appointments may be renewable if the conditions justifying the initial appointment continue to be satisfied.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this subindicator is to determine whether REC members and chairs are appointed for specific terms, rather than on an indefinite basis.</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask and review:</td>
</tr>
<tr>
<td></td>
<td>1. 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 appointments and the policy for renewal of appointments.</td>
</tr>
<tr>
<td></td>
<td>2. The terms of reference for REC members and chairs.</td>
</tr>
<tr>
<td></td>
<td>3. The dates of initial appointment (and renewals, if applicable) of existing REC members and chairs.</td>
</tr>
<tr>
<td>Rating Scale:</td>
<td>➢ NOT IMPLEMENTED (NI): REC members and chairs are not appointed for specific terms.</td>
</tr>
<tr>
<td></td>
<td>➢ IMPLEMENTED (I): REC members and chairs are appointed for specific terms.</td>
</tr>
<tr>
<td></td>
<td>➢ PARTIALLY IMPLEMENTED (PI): Some REC members and chairs have been appointed for specific terms, but there is no clear policy requiring that this be done in all cases.</td>
</tr>
<tr>
<td>Subindicator:</td>
<td>02.04: REC members and chairs are protected from being removed prior to the expiration of their terms, except for legitimate reasons.</td>
</tr>
<tr>
<td>Description:</td>
<td>In order to preserve the independence of REC members and chairs, members and chairs should be protected from being removed prior to 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 prior to their terms should be clearly defined in the REC’s standard operating procedures.</td>
</tr>
</tbody>
</table>
Objective: The objective of this subindicator is to determine whether REC members and chairs are protected from being removed prior to the expiration of their terms, except for legitimate reasons.

Evidence to review:
The assessor should ask and review:
1. Provisions in the REC’s standard operating procedures or other governing documents related to the disqualification or removal of REC members and chairs.
2. The terms of reference for REC members and chairs.
3. Documents related to any case in which REC members or chairs have been removed prior to the expiration of their terms.

Rating Scale:

➢ NOT IMPLEMENTED (NI): REC members and chairs are not protected from being removed prior to the expiration of their terms in the absence of legitimate reasons.

➢ IMPLEMENTED (I): REC members and chairs are explicitly protected from being removed prior to the expiration of their terms unless legitimate reasons for their removal exist.

➢ PARTIALLY IMPLEMENTED (PI): There are some limits on the circumstances in which REC members and chairs may be removed prior to the expiration of their terms, but these limits do not fully protect members and chairs from being removed without legitimate reasons.

Subindicator: 02.05: The REC invites relevant non-members to contribute to the review of research that raises issues beyond the scope of the members’ own expertise.

Description:
When RECs review research that raises issues beyond the scope of the members’ own expertise, they should invite non-members with relevant expertise to contribute to the review. Non-members who are invited to REC meetings may fully participate in discussions, but they should not have the right to 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 they determine that the conflict of interest would make their 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 will have access to confidential material, they should be required to sign confidentiality agreements.

Objective: The objective of this subindicator is to determine whether RECs invite non-members to contribute to the review of research that raises issues beyond the scope of members’ own expertise.

Evidence to review:
The assessor should ask and review:
1. 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.
2. Correspondence to non-members seeking their participation in REC meetings.
3. Conflict of interest declarations submitted by non-members who have participated in REC meetings.
4. Background information on the ethics review process provided to non-members who participate in REC meetings.
5. Confidentiality agreements signed by non-members invited to REC meetings.

Rating Scale:

➢ NOT IMPLEMENTED (NI): The REC does not invite non-members to contribute to the review of research that raises issues beyond the scope of the members’ own expertise.
### Indicator: 03: REC resources

**Objective:**
The objective of this indicator is to determine whether there are adequate resources, including staffing, facilities, technological support, and financial resources, to allow the REC to effectively carry out its responsibilities.

**Subindicator:**

<table>
<thead>
<tr>
<th>03.01: The REC has sufficient competent staff, with appropriate education, training, skills and experience, to support its activities.</th>
</tr>
</thead>
</table>

**Description:**
The REC has staff members who collectively have the qualifications and experience to support the members’ work, in numbers adequate to support the REC’s workload.

**Objective:**
The objective of this subindicator is to determine whether the existing human resources for the RECs are sufficient, in terms of numbers, experience, and specific competencies, to support the REC’s activities.

**Evidence to review:**
The assessor should ask for and review:
1. List of staff members
2. CVs and/or other relevant documents establishing the background and expertise of staff members.
3. Advertisements and/or job descriptions for staff members
4. Recruitment plans for staff positions and evidence of their implementation.
5. Information about 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
6. Information about staff members’ work hours
7. Performance evaluations of staff members
8. Staff members’ responses to questions about their workloads
9. Evidence as to whether the REC is meeting the timelines established in its standard operating procedures

**Rating Scale:**

- **NOT IMPLEMENTED (NI):** The REC does not have sufficient competent staff, with appropriate education, training, skills and experience, to support its activities.
- **IMPLEMENTED (I):** The REC has sufficient competent staff, with appropriate education, training, skills and experience, to support its activities.
- **PARTIALLY IMPLEMENTED (PI):** The REC has some competent staff, but does not have a full complement of staff with adequate education, skills and experience to support its activities.

**Subindicator:**

<table>
<thead>
<tr>
<th>03.02: The REC’s members and staff receive training on ethical issues in health-related research with humans.</th>
</tr>
</thead>
</table>

**Description:**
REC members and staff should receive initial training as needed in light of their background and experience and the nature of their duties, as well as periodic training at a frequency adequate to ensure that they have updated knowledge. RECs can either provide this training themselves or send members and staff to trainings offered by other entities.

Training for REC members and staff should focus on:

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7 The term “staff” (sometimes referred to as the “secretariat”) refers to professionals who responsible for supporting the work of the REC but who are not REC members.
## 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 machines, shredding machine) to conduct administrative business, to store committee files, and to keep documents secure and confidential.

**Objective:**
The objective of this subindicator is to determine whether there are adequate facilities and equipment to support ethics oversight activities.

<table>
<thead>
<tr>
<th>Evidence to review:</th>
<th>NOT IMPLEMENTED (NI): The REC lacks essential facilities and/or equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IMPLEMENTED (I): The REC has adequate facilities and equipment.</td>
</tr>
<tr>
<td></td>
<td>PARTIALLY IMPLEMENTED (PI): The REC has facilities and equipment that satisfy some of its needs, but that are not sufficient.</td>
</tr>
</tbody>
</table>

**Subindicator:** 03.04: The REC has adequate technological support in light of its needs.
<table>
<thead>
<tr>
<th>Description:</th>
<th>The REC should have sufficient technological support to manage the ethics oversight process, including support for conducting secure online meetings when necessary. The adequacy of the system depends on the REC’s workload.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective:</td>
<td>The objective of this subindicator is to determine whether the REC has adequate technological support in light of its needs.</td>
</tr>
</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Computer hardware and software systems used by the REC.  
2. Technological support services available to the REC.  
3. Information about the adequacy of the REC’s internet access.  
4. Information about the security of the REC’s computer systems.  
5. The REC’s web site. |
| Rating Scale: | ➢ NOT IMPLEMENTED (NI): The REC lacks essential technological support.  
➢ IMPLEMENTED (I): The REC has technological support adequate to its needs.  
➢ PARTIALLY IMPLEMENTED (PI): The REC has some technological support, but it is not adequate to support the REC’s needs. |
| Subindicator: | 03.05: The REC has adequate and stable financial resources. |
| Description: | RECs need funding to support their operations. Funding mechanisms should be designed to ensure that committees and their members have no financial incentive to approve or reject particular studies. If RECs charge research sponsors a fee for review by the committee, there should be an objective, transparent method for determining the amount of the fee (e.g., a percentage of the study budget or the time required for the REC to conduct the review). It is not inappropriate for RECs to have different fee schedules for different categories of research sponsors (e.g., commercial vs. nonprofit entities). |
| Objective:  | The objective of this subindicator is to determine whether the REC has adequate and stable financial resources. |
| Evidence to review: | The assessor should ask for and review:  
1. Information about the REC’s source of funding.  
2. The REC’s budget for the current year and at least one previous year, along with information about how those budgets were determined.  
3. 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.  
4. The number of applications reviewed annually by the REC.  
5. Member/staff surveys on the adequacy of budget (if any).  
6. The REC’s annual financial report.  
7. Information about any activities not performed due to budget constraints. |
| Rating Scale: | ➢ NOT IMPLEMENTED (NI): The REC’s financial resources are inadequate or unstable.  
➢ IMPLEMENTED (I): The REC has adequate and stable financial resources.  
➢ PARTIALLY IMPLEMENTED (PI): The REC has some financial resources, but they are unstable and/or insufficient to fully implement the REC’s mandate. |
| Indicator: | 04: REC procedures |
| Objective:  | The objective of this indicator is to determine whether the REC has documented procedures to carry out its ethics oversight activities. The procedures should cover the submission and screening of applications, the protocol review process, the monitoring of ongoing research, and the document management system. |
| Subindicator: | 04.01: The REC provides adequate guidelines for the submission and screening of applications for the ethical review of health-related research with humans. |
| Description: | The REC should provide clear guidelines for the submission and screening of applications for ethical review of health-related research with 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 process, and any other information investigators need to know in order to submit a complete and timely application. The guidelines should be supported with document templates, such as model application forms, consent forms, information sheets, etc.

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 rapidly identifying applications that are exempt from REC review or eligible for expedited review.

**Objective:** The objective of this subindicator is to determine whether the REC has well-defined guidelines for the submission and screening of applications for ethical review of health-related research with humans.

**Evidence to review:**

| 1. Guidelines for submitting an application for ethical review of health-related research with humans. |
| 2. Application forms. |
| 3. Checklists for applicants. |
| 4. Procedures for checking the completeness of applications and communicating with investigators who have submitted incomplete applications. |
| 5. Procedures for rapidly identifying applications that are exempt from REC review or eligible for expedited review. |
| 6. Examples of ethics review applications. |
| 7. Examples of communications with investigations who have submitted incomplete applications. |
| 8. Examples of determinations that applications are exempt from REC review or eligible for expedited review. |

**Rating Scale:**

- **NOT IMPLEMENTED (NI):** There are no guidelines for the submission and screening of applications for the ethical review of health-related research with humans.
- **IMPLEMENTED (I):** The REC has adequate guidelines for the submission and screening of applications for the ethical review of health-related research with humans.
- **PARTIALLY IMPLEMENTED (PI):** Guidelines for the submission and screening of applications for the ethical review of health-related research with humans exist, but they do not contain all necessary information.

**Subindicator:** 04.02: The REC has written procedures to ensure that it explicitly considers the ethical criteria for review identified in WHO guidance.

**Description:** The REC should have written procedures to ensure that its decisions are based on a coherent and consistent application of the ethical principles articulated in WHO guidance, as well as any national laws or policies consistent with those principles. At a minimum, the principles addressed should include (1) scientific design and conduct of the study (unless the REC’s policy is to defer to the independent review of an appropriately constituted scientific review committee); (2) risks and potential benefits; (3) selection of study populations and recruitment of research participants; (4) inducements, financial benefits, and financial costs; (5) protection of research participant confidentiality; (6) informed consent process, and (7) community considerations.
<table>
<thead>
<tr>
<th>Subindicator: 04.03</th>
<th>The REC members have adequate time before and during meetings for meaningful review of research proposals.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>REC members should receive all relevant documents in advance of the meetings with enough time to adequately review them. The length of meetings should be sufficient to allow for a full discussion of research protocols.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to determine whether the REC members have adequate time before and during meetings for meaningful review of research proposals.</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review:</td>
</tr>
<tr>
<td></td>
<td>1. Procedures for distributing meeting materials to REC members.</td>
</tr>
<tr>
<td></td>
<td>2. Correspondence indicating the dates REC members were sent meeting materials for all meetings held in the previous year.</td>
</tr>
<tr>
<td></td>
<td>3. Agendas and minutes for all meetings held in the previous year, indicating the starting and ending times and the number of applications discussed.</td>
</tr>
<tr>
<td>Rating Scale:</td>
<td>➢ NOT IMPLEMENTED (NI): REC members do not have adequate time before and during meetings for meaningful review of research proposals.</td>
</tr>
<tr>
<td></td>
<td>➢ IMPLEMENTED (I): REC members have adequate time before and during meetings for meaningful review of research proposals.</td>
</tr>
<tr>
<td></td>
<td>➢ PARTIALLY IMPLEMENTED (PI): REC members sometimes have adequate time before and during meetings for meaningful review of research proposals, but not on a consistent basis.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Subindicator: 04.04</th>
<th>The REC has procedures to ensure that decisions are made in a timely manner and that decisions are promptly communicated to principal investigators.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>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</td>
</tr>
<tr>
<td>Objective:</td>
<td></td>
</tr>
<tr>
<td>Evidence to review:</td>
<td></td>
</tr>
<tr>
<td>Rating Scale:</td>
<td>➢ NOT IMPLEMENTED (NI): REC does not have written procedures to ensure that it explicitly considers the ethical criteria for review identified in WHO guidance and no such provisions exist in legal provisions or official guidance.</td>
</tr>
<tr>
<td></td>
<td>➢ IMPLEMENTED (I): The REC has written procedures that ensure that it explicitly considers the ethical criteria for review identified in WHO guidance, or such procedures are contained in legal provisions or official guidance, and there is adequate evidence to indicate that those procedures are regularly followed.</td>
</tr>
<tr>
<td></td>
<td>➢ PARTIALLY IMPLEMENTED (PI): The REC has written procedures that ensure that it explicitly considers some of the ethical criteria for review identified in WHO guidance, or such procedures are contained in legal provisions or official guidance, but the procedures are not complete and/or not regularly followed.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this subindicator is to determine whether the REC has procedures to ensure that decisions are made in a timely manner and that they are promptly communicated to principal investigators.</td>
</tr>
<tr>
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</tr>
</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Procedures for scheduling REC meetings.  
2. Procedures establishing maximum timeframes for review after receipt of complete applications, and for requiring written justifications in situations where that timeframe is exceeded.  
3. Dates of meetings held by the REC in the previous year.  
4. For each meeting held in the previous year, a list of applications considered; the dates on which those applications were submitted; and correspondence with principal investigators of those applications informing them of decisions taken at the meetings. |
| Rating Scale: |  
➢ **NOT IMPLEMENTED (NI):** The REC does not have procedures to ensure that its decisions are made in a timely manner and that they are promptly communicated to principal investigators.  
➢ **IMPLEMENTED (I):** The REC has procedures to ensure that its decisions are made in a timely manner and that they are promptly communicated to principal investigators, and there is adequate evidence to indicate that those procedures are regularly followed.  
➢ **PARTIALLY IMPLEMENTED (PI):** The REC has some procedures to ensure that its decisions are made in a timely manner and that they are promptly communicated to principal investigators, but those procedures are not adequate and/or are not regularly followed. |
| Subindicator | **04.05:** The REC has procedures for ensuring the rapid review of research proposals in public health emergencies. |
| Description: | As specified in WHO guidance, the REC should have procedures to ensure the rapid review of time-sensitive proposals relevant to responding to public health emergencies. Those mechanisms should not compromise the REC’s ability to conduct a thorough assessment of the ethical issues raised by proposed research. The escalation of a proposal for rapid review, and the timeliness of the review, should be proportionate to its potential importance for an emergency response. |
| Objective: | The objective of this subindicator is to determine whether the REC has procedures to ensure the rapid review of research proposals in public health emergencies. |
| Evidence to review: | The assessor should review:  
1. Procedures to ensure the rapid review of research proposals in public health emergencies.  
2. Any examples of applications for research related to a public health emergency, including the dates of the applications and the dates of final decisions. |

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<table>
<thead>
<tr>
<th>Rating Scale:</th>
<th>➢ NOT IMPLEMENTED (NI): The REC has no procedures to ensure the rapid review of research proposals in public health emergencies. ➢ IMPLEMENTED (I): The REC has comprehensive procedures to ensure the rapid review of research proposals in public health emergencies. ➢ PARTIALLY IMPLEMENTED (PI): The REC has developed procedures to ensure the rapid review of research proposals in public health emergencies, but these procedures have not been fully adopted and/or are not comprehensive.</th>
</tr>
</thead>
</table>

### Subindicator: 04.06: The REC has procedures for considering relevant previous decisions in its review of protocols.

**Description:** The REC should have procedures for considering relevant previous decisions in its review of protocols, such as a searchable computerized database, in order to ensure that it can draw on relevant prior decisions and minimize the likelihood of unintentional inconsistencies (i.e., inconsistencies that are not based on a conscious decision to revise an approach taken in the past).

**Objective:** The objective of this subindicator is to determine whether the REC has procedures for considering relevant previous decisions in its review of protocols.

**Evidence to review:** The assessor should review:
1. Procedures to ensure that RECs have access to relevant previous decision in its review of protocols.
2. The database or archiving system for REC decisions.
3. Minutes of REC meetings indicating consideration of relevant previous decisions.

### Subindicator: 04.07: The REC engages in and/or contributes to monitoring of ongoing research at intervals appropriate to the degree of risk to humans.

**Description:** RECs should have procedures for monitoring studies for which a positive decision has been reached, at intervals appropriate to the degree of risk to humans. At a minimum, the REC’s procedures should include asking researchers to provide reports on their studies on a regular basis. For clinical trials, the procedures should address continuing review, review of amendment requests, review of protocol deviations, and adverse event review.

**Objective:** The objective of this subindicator is to determine whether the REC engages in and/or contributes to monitoring of ongoing research at intervals appropriate to the degree of risk to humans.

**Evidence to review:** The assessor should ask for and review:
1. Evidence that the REC regularly requests researchers to provide reports of their studies on a regular basis.
2. For RECs that review clinical trials, procedures related to continuing review, review of amendment requests, review of protocol deviations, and adverse event review.
3. Information about all monitoring activities conducted in the previous year.

### Rating Scale:

<table>
<thead>
<tr>
<th>Rating Scale:</th>
<th>➢ NOT IMPLEMENTED (NI): The REC does not engage in and/or contribute to monitoring of ongoing research.</th>
</tr>
</thead>
</table>
### Subindicator: 04.08: 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 exist regarding the duration of storage. This system should enable the REC to identify and trace documents of relevant previous decisions. REC staff should be sufficiently trained to understand their responsibilities related to record keeping, retrieval, and confidentiality. The REC’s procedures should outline who is authorized to access committee files and documents.

**Objective:**
The objective of this subindicator is to determine whether the REC maintains a good document management system.

**Evidence to review:**
The assessor should ask for and review:
1. The REC’s database or archiving system.
2. Procedures for document storage and access.
3. Procedures for the maintenance of archives and related documents.
4. Information about staff training activities related to record keeping, retrieval, and confidentiality.
5. Evidence that documents associated with all meetings held within the past year have been properly archived.

**Rating Scale:**
- NOT IMPLEMENTED (NI): The REC has no document management system.
- IMPLEMENTED (I): The REC has a comprehensive document management system and there is adequate evidence to show that the system is regularly used.
- PARTIALLY IMPLEMENTED (PI): The REC has a document management system, but it is not comprehensive and/or not consistently used.

### Subindicator: 04.09: 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 special attention to whether the ethical considerations articulated in international guidelines and national standards are being considered and applied consistently and coherently. Procedures for conducting these assessments might include interviews with members and staff, regular review of meeting minutes, and self-audits of selected protocol reviews.

**Objective:**
The objective of this subindicator is to determine whether the REC monitors its adherence to its standard operating procedures.

**Evidence to review:**
The assessor should ask for and review:
1. Procedures for monitoring REC staff and members’ compliance with the REC’s policies, rules and procedures.
2. Examples of monitoring activities undertaken by the REC in the previous year.

**Rating Scale:**
- NOT IMPLEMENTED (NI): The REC has no internal mechanisms to monitor its adherence to its standard operating procedures.
<table>
<thead>
<tr>
<th>Subindicator</th>
<th>Description</th>
<th>Objective</th>
<th>Evidence to review</th>
<th>Rating Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.02:</td>
<td>The REC should ensure that updated information regarding its own guidelines and procedures (e.g., how to submit a protocol, review timelines, SOPs) is publicly available.</td>
<td>The objective of this subindicator is to determine whether REC’s sources of funding are publicly available.</td>
<td>The assessor should ask for and review: 1. Websites or other publicly available sources of information about the REC’s guidelines and procedures. 2. Procedures for ensuring that these materials are up to date.</td>
<td>NOT IMPLEMENTED (NI): REC does not make updated information on its own procedures publicly available. IMPLEMENTED (I): REC makes updated information on its own guidelines and procedures publicly available. PARTIALLY IMPLEMENTED (PI): REC makes some information on its own guidelines and procedures publicly available, but the information is not complete and/or not easily accessible.</td>
</tr>
<tr>
<td>05.03:</td>
<td>An updated list of all the REC’s members is publicly available.</td>
<td>The objective of this indicator is to determine whether mechanisms are in place to promote REC transparency and accountability. These mechanisms should provide the public with information about the ethics review process, the sources of REC’s funding, the composition of RECs, and all research proposals that REC approves. In addition, they should enable research participants, prospective research participants, and investigators to pose questions to RECs and to obtain a response.</td>
<td>The assessor should ask for and review: 1. Websites or other publicly available sources of information about the REC’s guidelines and procedures. 2. Procedures for ensuring that these materials are up to date.</td>
<td>NOT IMPLEMENTED (NI): REC does not make updated information on its own guidelines and procedures publicly available. IMPLEMENTED (I): REC makes updated information on its own guidelines and procedures publicly available. PARTIALLY IMPLEMENTED (PI): REC makes some information on its own guidelines and procedures publicly available, but the information is not complete and/or not easily accessible.</td>
</tr>
<tr>
<td>Subindicator</td>
<td>Description</td>
<td>Objective</td>
<td>Evidence to review</td>
<td>Rating Scale</td>
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</tr>
<tr>
<td>05.04: A list of the titles, principal investigators, and dates of approval of all research proposals approved by the REC is publicly available.</td>
<td>In order to promote transparency and accountability, a list of the REC’s members should be publicly available or available on request.</td>
<td>The objective of this subindicator is to determine whether an updated list of the REC’s members is publicly available or available on request.</td>
<td>The assessor should ask and review: 1. An updated list of the REC’s members. 2. Information about the process used to ensure that the list remains up to date. 3. Evidence that the list is publicly available (such as publication on a website, in an annual report, or in other publicly available documents) or available on request.</td>
<td>➢ NOT IMPLEMENTED (NI): The REC does not make a list of its members publicly available or available on request. ➢ IMPLEMENTED (I): An updated list of the REC’s members is publicly available or available on request. ➢ PARTIALLY IMPLEMENTED (PI): Information about the REC’s members is made available in limited circumstances only.</td>
</tr>
<tr>
<td>05.05: The REC facilitates the ability of research participants or prospective research participants to ask questions, raise concerns, or lodge complaints about their rights</td>
<td>REC decisions, excluding confidential information, should be made publicly available, through mechanisms such as clinical trial registries, web sites, 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 the 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 highly stigmatized behavior, such as drug use or same-sex sexual activity). RECs should be encouraged to include short summaries of approved studies to the extent this is feasible, but doing so is not a requirement for satisfying this sub-indicator. To make it possible for RECs to publish short summaries, investigators should be encouraged to submit a brief description of the study in language understandable to a reasonable person.</td>
<td>The objective of this subindicator is to determine whether a list of the titles, principal investigators, and dates of approval of all research proposals approved by the REC is publicly available.</td>
<td>The assessor should ask for and review: 1. Standard operating procedures or other documents requiring that a list of the titles, principal investigators, and dates of approval of all research proposals approved by the REC are made publicly available. 2. A list of the titles, principal investigators, and dates of approval of all research proposals approved by the REC. 3. Information about the process used to ensure that the list remains up to date. 4. Evidence that the list is publicly available, such as publication on a website, in an annual report, or in other publicly available documents.</td>
<td>➢ NOT IMPLEMENTED (NI): There is no list of the titles, principal investigators, and dates of approval of all research proposals approved by the REC. ➢ IMPLEMENTED (I): A list of the titles, principal investigators, and dates of approval of all research proposals approved by the REC is publicly available. ➢ PARTIALLY IMPLEMENTED (PI): A list of the titles, principal investigators, and dates of approval of all research proposals approved by the REC exists, but it is not publicly available and/or not regularly updated.</td>
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</table>
as research participants and about the ethics review process, and it provides timely responses to those questions, concerns, and complaints.

**Description:** The REC should make it easy for research participants or prospective participants to ask questions, raise concerns, or lodge complaints about their rights as research participants and the ethics review process. A simple way to do this is to provide a phone number and/or email address on its website and to require the inclusion of this information on all informed consent forms. The REC should ensure that individuals 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 Frequently Asked Questions (FAQ) section on its website.

**Objective:** The objective of this subindicator is to determine whether the REC facilitates the ability of research participants or prospective research participants to ask questions, raise concerns, or lodge complaints about their rights as research participants and about the ethics review process, and whether it provides responses to those questions, concerns, and complaints.

**Evidence to review:** The assessor should ask for and review:
1. The REC’s website.
2. Informed consent forms approved the REC.
3. Any other mechanisms by which the REC disseminates its contact information to research participants or prospective participants.
4. Examples of questions, concerns, or complaints submitted by research participants or prospective research participants in the previous year and the REC’s responses.

**Rating Scale:**
- NOT IMPLEMENTED (NI): The REC does not provide its contact information to research participants or prospective research participants.
- IMPLEMENTED (I): The REC facilitates the ability of participants or prospective research participants to ask questions or raise concerns about their rights as research participants and about the ethics review process, and it consistently responds to all questions, concerns, and complaints.
- PARTIALLY IMPLEMENTED (PI): Contact information for the REC is available to research participants and prospective research participants, but it is not easy to find, and/or the REC does not consistently respond to questions, concerns, and complaints.

**Subindicator:** 05.06: The REC facilitates the ability of investigators to ask questions, raise concerns, or lodge complaints about the ethics review process, and it provides responses to those questions, concerns, and complaints.

**Description:** The REC should make it easy for investigators to ask questions, raise concerns, or lodge complaints about the ethics review process. A simple way to do this 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 Frequently Asked Questions (FAQ) section on its website.

**Objective:** The objective of this subindicator is to determine whether the REC facilitates the ability of investigators to ask questions, raise concerns, or lodge complaints about the ethics review process, and whether it provides responses to those questions, concerns, and complaints.

**Evidence to review:** The assessor should ask for and review:
1. The REC’s website.
2. Any other mechanisms by which the REC disseminates its contact information to investigators, such as correspondence.
3. Examples of questions, concerns, or complaints posed by investigators in the previous year and the REC’s responses.

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** The REC does not provide its contact information to investigators.
- **IMPLEMENTED (I):** The REC facilitates the ability of investigators to ask questions, raise concerns, or lodge complaints about the ethics review process, and it consistently responds to all questions, concerns, and complaints.
- **PARTIALLY IMPLEMENTED (PI):** Contact information for the REC is available to investigators, but it is not easy to find and/or the REC does not consistently provide responses to questions.

**Indicator:** 06: Mechanisms for RECs to monitor their performance

**Objective:** The objective of this indicator is to determine whether the REC has mechanisms in place to ensure their adherence to ethical standards and to assess and improve the quality of their performance.

**Subindicator:** 06.01: The REC proactively solicits feedback from investigators and research participants about their experience of research and the system of research participant protection.

**Description:** To assist in the REC’s ability to provide effective ethics oversight, the REC should proactively solicit feedback from investigators and research participants about their experience of research and the system of research participant protection. 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.

**Objective:** The objective of this subindicator is determine whether that the REC proactively solicits feedback from investigators and research participants about their experience of research and the system of research participant protection.

**Evidence to review:**
1. Standard operating procedures or other documents that specify policies and procedures for soliciting feedback from investigators and research participants about their experience of research and the system of research participant protection.
2. Evidence that these policies and procedures have been implemented.
3. Feedback received from investigators and research participants as a result of these policies and procedures in the past year.
4. Evidence of any follow-up actions the REC has taken based on feedback received, including changes to the process of ethics review.

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** The REC does not proactively solicit feedback from investigators and research participants about their experience of research and the system of research participant protection.
- **IMPLEMENTED (I):** The REC regularly solicits feedback from investigators and research participants about their experience of research and the system of research participant protection.
- **PARTIALLY IMPLEMENTED (PI):** The REC occasionally solicits feedback from investigators and research participants about their experience of research and the system of research participant protection.

**Subindicator:** 06.02: The REC conducts internal audits of its performance on a regular basis.
**Description:**
The REC should conduct internal audits of its performance on a regular basis, in order 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. These audits should normally occur on an annual basis, but RECs with a very low volume of work might choose to conduct them on a less frequent basis.

RECs should select criteria to audit based on applicable legal standards, ethical guidance, and internal policies and procedures. Examples of criteria that RECs could measure include the following:

- Productivity metrics, such as time from submission to approval
- 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 like risk/benefit assessment and informed consent
- Metrics comparing the REC’s assessment of studies’ risks with information about the number and type of adverse events reported in those studies
- Number and nature of complaints received by the REC
- Outcomes of surveys assessing participants’ comprehension of the informed consent process
- Outcomes of surveys assessing participants’ experience of participating in research
- Outcomes of surveys of REC members about the strengths and weaknesses of the ethics review process.

The REC should use the information generated through these audits to make ongoing improvements in the ethics review system.

**Objective:**
The objective of this subindicator is to determine whether the REC conducts internal audits of its performance on a regular basis.

**Evidence to review:**
The assessor should ask for and review:
1. Standard operating procedures or other documents that specify mechanisms the REC uses to conduct internal audits of its performance on a regular basis.
2. A list of the criteria the REC’s internal audits are designed to measure.
3. The results of all internal audits conducted in the past year.
4. Evidence of any follow-up actions the REC has taken based on these internal audits, including changes to the process of ethics review.

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** The REC has no mechanisms to conduct internal audits of its performance on a regular basis.
- **IMPLEMENTED (I):** The REC has mechanisms to conduct internal audits of its performance on a regular basis, and there is adequate evidence to indicate that these mechanisms are consistently used.
- **PARTIALLY IMPLEMENTED (PI):** The REC has some mechanisms to conduct internal audits of its performance, but they are not consistently used.

**Indicator:** **07: Responsible Research Institutions**

**Objective:**
The objective of this indicator is to assess whether research institutions fulfil their responsibility to ensure that any health-related research with humans affiliated with the institution adheres to internationally recognized ethical standards. This indicator is not designed to provide a comprehensive assessment of research

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WHO Tool, Ethics Oversight: Indicators and Factsheets. 21 September 2022

<table>
<thead>
<tr>
<th>Subindicator</th>
<th>Description</th>
<th>Objective</th>
<th>Evidence to review</th>
<th>Rating Scale</th>
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</thead>
</table>
| 07.01: The institution verifies that all proposals for health-related research with humans are submitted to an REC if any part of the research will be conducted by a researcher affiliated with the institution. | Research institutions should verify that all proposals for health-related research with humans are submitted to an REC if any part of the research will be conducted by a researcher affiliated with the institution. In some systems, the institution may automatically fall under the jurisdiction of a particular REC. In others, institutions need to create their own RECs or establish affiliations with external RECs in order to satisfy this subindicator. | The objective of this subindicator is to determine whether the institution verifies proposals for health-related research with humans are submitted to an REC. | The assessor should ask for and review:  
- Institutional policies requiring all health-related research with humans to be submitted to an REC if any part of the research will be conducted by a researcher affiliated with the institution.  
- Institutional policies specifying the REC(s) the institution relies on for reviewing research conducted by researchers affiliated with it.  
- Evidence that the institution ensures that researchers affiliated with the institution comply with these policies.  
- Information about any actions taken against researchers who fail to comply with these policies.  
- Information about all health-related research with humans conducted by researchers affiliated with the institution in the past year, along with evidence that these studies were submitted to RECs.  
- Evidence of the institution’s express commitment to complying with international and national ethical standards in health-related research with humans. | ✓ NOT IMPLEMENTED (NI): the institution does not make any effort to ensure that proposals for health-related research with humans are submitted to an REC.  
✓ IMPLEMENTED (I): the institution verifies that all proposals for health-related research with humans are submitted to an REC.  
✓ PARTIALLY IMPLEMENTED (PI): the institution requires proposals for health-related research with humans to be submitted to an REC, but it does not verify that all researchers affiliated with the institution adhere to this requirement. |

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<tr>
<th>Subindicator</th>
<th>Description</th>
<th>Objective</th>
<th>Evidence to review</th>
<th>Rating Scale</th>
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<tbody>
<tr>
<td>07.02: The institution has policies and procedures related to the declaration and management of conflicts of interest of researchers affiliated with the institution and of the institution itself.</td>
<td>In order to protect the integrity of research and public confidence in the research system, research institutions should develop and implement policies and procedures related to the declaration and management of conflicts of interest of researchers affiliated with the institution and of the institution itself, REC members and the institution itself.</td>
<td>The objective of this subindicator is to determine whether the institution has policies and procedures related to the declaration and management of conflicts of interest of researchers affiliated with the institution and of the institution itself.</td>
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10 Whether a research is “affiliated with” an institution should be determined according to local laws and policies.
### Evidence to review:

The assessor should ask for and review:

1. Institutional policies and procedures related to the declaration and management of conflicts of interest of researchers affiliated with the institution and of the institution itself.
2. Evidence that these policies and procedures are consistently followed.
3. Conflict of interest declarations submitted to the institution in the past year.
4. Information about actions taken by the institution in cases in which conflicts of interest have been declared.
5. Information about actions taken against individuals who fail to disclose conflicts of interest pursuant to the institution’s policy.

### Rating Scale:

- **NOT IMPLEMENTED (NI):** The institution does not have policies and procedures related to the declaration and management of conflicts of interest of researchers affiliated with the institution and the institution itself.
- **IMPLEMENTED (I):** The institution has policies and procedures related to the declaration and management of conflicts of interest of researchers affiliated with the institution and the institution itself, and there is adequate evidence to indicate that these policies and procedures are consistently followed.
- **PARTIALLY IMPLEMENTED (PI):** The institution has policies and procedures related to the declaration and management of conflicts of interest of researchers affiliated with the institution and the institution itself, but these policies and procedures are not consistently followed.

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### Subindicator 07.03: If the institution has its own REC, it has policies and procedures related to the declaration and management of conflicts of interest of REC members and non-member participants in REC meetings,

### Description:

Institutions that have their own RECs should also have policies and procedures related to the declaration and management of conflicts of interest of REC members and non-member participants in REC meetings. These policies should be harmonized with the REC’s own conflict of interests policies. Institutions with RECs should also ensure that their own 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.

### Objective:

The objective of this subindicator is to determine whether the institution has policies and procedures related to the declaration and management of conflicts of interest of REC members and non-member participants in REC meetings.

### Evidence to review:

The assessor should ask for and review:

1. Institutional policies and procedures related to the declaration and management of conflicts of interest of REC members and non-member participants.
2. Evidence that these policies and procedures are consistently followed.
3. Conflict of interest declarations submitted to the institution in the past year.
4. Information about actions taken by the institution in cases in which conflicts of interest have been declared.
5. Information about actions taken against individuals who fail to disclose conflicts of interest pursuant to the institution’s policy.

### Rating Scale:

- **NOT IMPLEMENTED (NI):** The institution does not have policies and procedures related to the declaration and management of conflicts of interest of REC members and non-member participants in REC meetings.
- **IMPLEMENTED (I):** The institution has policies and procedures related to the declaration and management of conflicts of interest of REC members and non-member participants in REC meetings.
member participants in REC meetings, and there is adequate evidence to indicate that these policies and procedures are consistently followed.

- PARTIALLY IMPLEMENTED (PI): The institution has policies and procedures related to the declaration and management of conflicts of interest of REC members and non-member participants in REC meetings, but these policies and procedures are not consistently followed.

<table>
<thead>
<tr>
<th>Subindicator:</th>
<th>07.04: The institution has a policy requiring all researchers affiliated with it to be trained on their responsibilities related to the ethical conduct of research.</th>
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<tbody>
<tr>
<td>Description:</td>
<td>Research institutions should have policies requiring all researchers affiliated with them to be trained on their responsibilities related to the ethical conduct of research. Institutions may either offer this training themselves or rely on training conducted by external entities. Researchers should be required to provide proof to the institution that they have complied with their training obligations.</td>
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<tr>
<td>Objective:</td>
<td>The objective of this subindicator is to determine whether the institution has a policy requiring all researchers affiliated with it to be trained on their responsibilities related to the ethical conduct of research.</td>
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</table>
| Evidence to review: | The assessor should ask for and review:  
  1. Institutional policies requiring all researchers affiliated with the institution to be trained on their responsibilities related to the ethical conduct of research.  
  2. Institutional policies requiring researchers to provide proof of compliance with their training obligations.  
  3. Evidence of proof of training submitted by researchers affiliated with the institution in the previous year.  
  4. Information about actions taken against researchers who fail to satisfy their training obligations. |
| Rating Scale: | ➢ NOT IMPLEMENTED (NI): The institution does not have a policy requiring all researchers affiliated with it to be trained on their responsibilities related to the ethical conduct of research.  
  ➢ IMPLEMENTED (I): The institution has a policy requiring all researchers affiliated with it to be trained on their responsibilities related to the ethical conduct of research, and there is adequate evidence to indicate that the policy is consistently followed.  
  ➢ PARTIALLY IMPLEMENTED (PI): The institution has a policy requiring all researchers affiliated with it to be trained on their responsibilities related to the ethical conduct of research, but the policy is not consistently followed. |

<table>
<thead>
<tr>
<th>Subindicator:</th>
<th>07.05: The institution facilitates the ability of research participants and prospective research participants to lodge complaints about studies conducted by researchers affiliated with the system, either through the institution itself or at the national or regional level. If the complaint system is established within the institution, the institution has a process for reviewing and responding to complaints.</th>
</tr>
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</table>
| Description:  | Research institutions should make it easy for research participants and prospective research participants to lodge complaints about studies conducted by researchers affiliated with the institution. A simple way to do this is to post a phone number and/or email address of an institutional official authorized to respond to complaints on the institution’s website. Alternatively, if system for lodging complaints about research exists at the national or regional level, the institution can post information about how to submit complaints through that system.  
  When a complaint system is established within 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.

**Objective:** The objective of this subindicator is to determine whether the institution facilitates the ability of research participants and prospective research participants to lodge complaints about studies conducted by researchers affiliated with the institution, either through the institution itself or at the national or regional level.

**Evidence to review:** The assessor should ask for and review:
1. 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 a system for lodging complaints about research exists at the national or regional level, information about how to submit complaints through that system.
2. For institutions with an internal complaint system, evidence of all complaints received in the previous year and the institution’s responses to those complaints.
3. For institutions with an internal complaint system, evidence of any follow-up actions the institution has taken based on complaints received, including remedial actions in ongoing studies and changes to the process of ethics review.

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** The institution does not give research participants and prospective research participants information about how they can submit complaints about studies conducted by researchers affiliated with the institution.
- **IMPLEMENTED (I):** The institution gives research participants and prospective research participants information about how they can submit complaints about studies conducted by researchers affiliated with the institution; however, there is no system for lodging complaints about research at the national or regional level, and the institution does not consistently provide responses to complaints lodged internally.
- **PARTIALLY IMPLEMENTED (PI):** The institution gives research participants and prospective research participants information about how they can submit complaints about studies conducted by researchers affiliated with the institution and, if the institution has its own complaint system, there is adequate evidence to indicate that it consistently responds to all complaints submitted.

**Subindicator:** 07.07: The institution has a process for investigating allegations of unethical conduct by researchers and imposing consequences in cases where unethical conduct is determined to have occurred.

**Description:** Research institutions should have a process for investigating allegations of unethical conduct by researchers and imposing consequences in cases where unethical conduct is determined to have occurred. Such consequences might include a temporary or permanent prohibition on conducting further research with humans, changes in job titles or responsibilities, financial penalties, public reprimands, and/or other remedies. Any investigations conducted should provide researchers accused of misconduct with basic due process protections, including adequate notice of the allegations against them and an opportunity to be heard before penalties are imposed.

**Objective:** The objective of this subindicator is to determine whether the institution has a process for investigating allegations of unethical conduct by researchers and imposing consequences in cases where unethical conduct is determined to have occurred.
**Evidence to review:**

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<tr>
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<th>The assessor should review:</th>
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<tbody>
<tr>
<td>1.</td>
<td>Institutional policies specifying a process for investigating allegations of unethical conduct by researchers and imposing consequences in cases where unethical conduct is determined to have occurred.</td>
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<tr>
<td>2.</td>
<td>Information about the range of consequences that may be imposed on researchers determined to have engaged in misconduct.</td>
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<tr>
<td>3.</td>
<td>Information about the due process protections provided to researchers accused of misconduct.</td>
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<tr>
<td>4.</td>
<td>Information about investigations conducted related to researchers accused of unethical conduct and the outcome of those investigations.</td>
</tr>
</tbody>
</table>

**Rating Scale:**

- NOT IMPLEMENTED (NI): The institution has no process for investigating allegations of unethical conduct by researchers and imposing consequences where unethical conduct is determined to have occurred.
- IMPLEMENTED (I): The institution has a process for investigating allegations of unethical conduct by researchers and for imposing consequences where unethical conduct is determined to have occurred, and this mechanism contains adequate due process protections.
- PARTIALLY IMPLEMENTED (PI): The institution has a process for investigating allegations of unethical conduct by researchers, but it does not impose consequences where unethical conduct is determined to have occurred, and/or the process does not contain adequate due process protections.
REFERENCES

1. Standards and operational guidance for ethics review of health-related research with human participants. WHO; 2011 (https://apps.who.int/iris/bitstream/handle/10665/44783/9789241502948_eng.pdf;jsessionid=90EC6DA1E51844C8AC88C60235511D7E?sequence=1)

2. Research ethics committees: basic concepts for capacity-building. WHO; 2009 (https://www.who.int/ethics/Ethics_basic_concepts_ENG.pdf)


4. ICH E6(R2) Addendum Step 4 version (https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf)
