

Tool for the accreditation of research ethics committees



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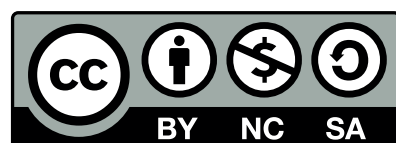
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Acknowledgments

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Introduction

The ethical governance of research requires the existence of a national body (or subnational, if applicable, by the country's constitution) tasked with the oversight of research ethics committees (RECs) that review and monitor research with human participants ([Indicators for Strengthening National Research Ethics Systems](#)). This oversight includes the accreditation of RECs that authorizes them to function in their corresponding jurisdiction.

The Regional Program on Bioethics, which is part of the Unit on Science and Knowledge for Impact of the Department of Evidence and Intelligence for Action in Health of PAHO, developed this tool to facilitate the accreditation of RECs and ensure that it is carried out in adherence with international ethical standards, such as the [International Ethical Guidelines for Health-related Research Involving Humans](#) of the Council of International Organizations of Medical Sciences (CIOMS). These standards evolve as our understanding of ethics and research ethics systems advances. For example, the COVID-19 pandemic has led to greater clarity on how ethics oversight of research should be conducted in public health emergencies and has provided essential lessons on how to improve the functioning of RECs in ordinary situations, which are not limited to emergency scenarios ([Catalyzing Ethical Research in Emergencies. Ethics Guidance, Lessons Learned from the COVID-19 Pandemic, and Pending Agenda](#)). However, some challenges remain regarding the optimal functioning of RECs within different research ethics systems. For example, topics such as a possible appeal of a REC's decision require further conceptualization to be usefully incorporated into a REC accreditation tool. They are, therefore, part of our pending agenda.

Overview

The accreditation document used by the body in charge of the oversight of RECs must specify: (i) the legal instrument that governs research ethics in the jurisdiction and under which the accreditation of RECs is carried out; (ii) the entity conducting the accreditation; (iii) the RECs period of accreditation; and (iv) the type of accreditation that is carried out.

Accreditation can be of two types: basic and complementary. **Basic accreditation** is sufficient for RECs that review research involving human participants but do not review clinical trials on drugs, medical devices, or other products or technologies seeking authorization from the National Regulatory Authority (NRA). **Complementary accreditation** to the basic accreditation is required for RECs reviewing these clinical trials. It must, therefore, comply with the guidelines of Good Clinical Practice (GCP) of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). This tool is used for both types of accreditation (Figure 1). **Highlighted in purple are the criteria that are only relevant for complementary accreditation.**

This tool allows RECs to review their standard operating procedures (SOPs)¹ and ensure they adhere to the most up-to-date international ethical standards.

¹ SOPs govern the functioning of RECs. Two documents describe this functioning in some countries or institutions: the REC policy and the manual of procedures. For accreditation purposes, whether the rules for the functioning of RECs are centralized in a single document or divided into two documents is irrelevant. This tool will refer to SOPs as the document that includes both the REC policy and the manual of procedures.

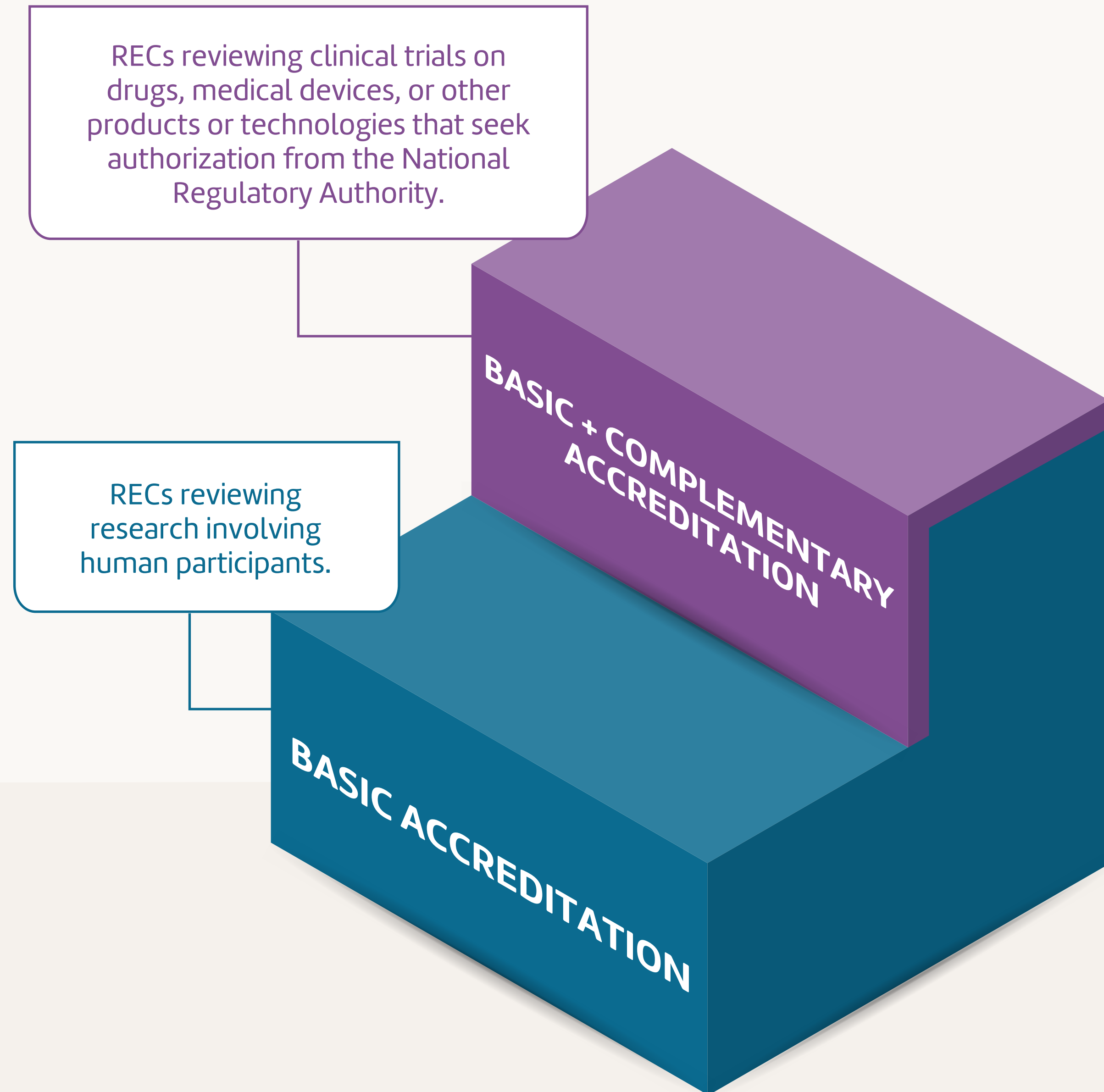


Figure 1. Types of accreditation

Criteria for the accreditation of research ethics committees

1. Constitution

- Independence
- Adequate and sustainable resources
 - » Financial
 - » Human
 - » Logistics
- Standard operating procedures (SOPs)

Is there a document issued by the institution that creates the REC and enables it to function?

Is it specified in the creation and enablement document or other REC documents (e.g., SOPs) that the REC operates independently and has the autonomy to conduct ethics reviews and make decisions?

Does the institution have mechanisms to protect REC members from eventual retaliation related to REC decisions?

Does the institution ensure the necessary financial resources for the committee's continuous functioning?

Does the institution ensure the necessary human resources for a technical secretariat (and administrative support, if necessary) to enable the committee to function?

Does the institution ensure the infrastructure, IT resources (e.g., computers, cloud server or storage service, virtual meeting platforms, etc.), and office supplies necessary for the proper functioning of the committee?

Has the committee formally approved written SOPs for the governance of its functioning?

The ethics review includes the analysis of the scientific validity of the study, regardless of whether a scientific committee has previously reviewed the study.

It is not inappropriate for RECs to charge for ethics review or different amounts depending on the characteristics of the study. These charges do not create a conflict of interest as long as they are not associated with the review's outcome.

2.

Functions

- Scope
- Activities

Does the REC define its function in overseeing research involving human participants, including the ethics review of studies before they are initiated and monitoring ongoing studies?

Do SOPs specify that the REC can approve, disapprove, request modifications, suspend, and terminate a study?

RECs review research involving human subjects, defined in a way that meets the following two conditions:

- 1. Research: any biomedical, behavioral, epidemiological, or social science activity that entails systematic collection or analysis of data to develop or contribute to generalizable knowledge.*
- 2. With humans: involves human beings who (i) become individually identified through the researcher's collection, preparation, or use of biological material or medical or other records; or (ii) are exposed to manipulation, intervention, observation, or other interaction with researchers, either directly or through alteration of their environment.*

Therefore, it is not the responsibility of the RECs to review research involving laboratory animals, research with environmental impact that does not constitute research involving human subjects, or public health activities involving human subjects but not constituting research.

3. Membership

- **Number of members**
- **Member characteristics**
- **Responsibilities**
- **Structure**
- **Training**
 - » **Good clinical practice**
- **Mechanisms for selecting members**
 - » **Election**
 - » **Renovation**
 - » **Removal**

Do SOPs specify that the REC should include at least five members?

Do SOPs specify that the composition of the members:

- Are multidisciplinary to ensure a balance between different disciplines and perspectives (e.g., medicine, social sciences, ethics, research methodology, etc.)?
- Include gender and age diversity?
- Include at least one person not affiliated with the REC institution?
- Include at least one person whose occupation is not associated with research or health and who may have the perspective of the community or society or represent the interests of potential research participants?

Do SOPs mention how members will be compensated for their work in the REC (e.g., through a salary or considering the hours assigned to the REC as working hours)?

Do SOPs specify that the authorities, directors, and main personnel in charge of the institution of the REC may not be members of or chair the REC?

Do SOPs indicate that members are responsible for reviewing research protocols, participating in meetings and deliberation, and monitoring ongoing research?

Do SOPs establish the structure of the REC (e.g., chair and technical secretariat)?

Establishing a structure of full members and alternate members is not mandatory. Membership organization will depend on the characteristics and needs of the REC.

Although members may come from different institutions, their participation in the REC is not on behalf of their institution. Members participate in their personal capacity as part of a collegiate group.

The persons in charge of making the institution's main decisions due to the hierarchical position they hold should not belong to the REC or sign its decisions (e.g., the head of an institution, a university's rector or dean, a hospital's head, a minister, or another high-ranking official).

All members have equal responsibility for the protocol review, even if 'lead reviewers' are designated for each protocol. Participation of community representatives (or members who do not have health expertise) should not be limited to reading the informed consent documents.

4.

Documentation and archiving

- Member CVs
- Meeting minutes
- Confidentiality statements and conflicts of interest
- Protocols, information, and documents related to the studies

Do SOPs require members to have training in research ethics and for the REC to have an ongoing training plan?

Do SOPs require Good Clinical Practice (GCP) training from all members?

Do SOPs indicate mechanisms for:

- Electing new members?
- Renewing members?
- Removing members who do not fulfill their responsibilities?

Do the mechanisms for electing and renewing members consider the need to balance the REC's continued experience and expertise with the contribution of new approaches and perspectives?

Do SOPs indicate the process for maintaining the file (electronic or paper) of:

- Members' documentation (e.g., CVs and statements of confidentiality and conflicts of interest)?
- Protocols, including all supporting documentation, communications with researchers, REC observations and decisions, and documents associated with study monitoring?
- The minutes of the REC meetings?

Do SOPs establish protocol archiving after the study for at least five years or the period specified by local regulations?

While adding new membership is valuable, it should not be mandatory to require members to leave the REC after a certain period. Having members with the relevant knowledge and experience is a priority for a REC.

5. Submission of protocols

- Mechanism for submitting protocols
- Documentation required for review
- Procedure for determining whether ethics review is necessary
- Procedure for determining the type of review

Do SOPs explain how protocols should be submitted for ethics review?

Do SOPs indicate the documents required to review a study (e.g., protocol, documentation of the informed consent process, plans and materials for participant recruitment, study instruments, prior reviews by other ethics or scientific committees, etc.)?

Do SOPs specify that the documents required for the review of clinical trials also include:

- The investigator's brochure?
- The insurance policy?
- GCP training of the principal investigator and the research team according to the responsibilities delegated for the conduct of the study?
- The commitment to adhere to the GCP?
- The authorization and licensing of the institution or research center where the clinical trial will be conducted?

Do SOPs specify how they determine whether a protocol constitutes research with human participants and, therefore, requires ethics review?

Do SOPs indicate when an expedited review that does not require the REC to deliberate at a regular meeting is appropriate?

Review process

- **Types of reviews**
- **Ethical basis for protocol analyses**
- **Review strategies**
- **Mechanisms for convening external experts**
- **Handling confidentiality**
- **Managing conflicts of interest**
- **Meetings**
- **Decision-making**
 - » **Quorum**
 - » **Decision-making mechanism**
- **Types of decisions**
- **Communication of the decision**
- **Process deadlines**

Do SOPs establish the process for performing:

- Exemption from a review?
- An expedited review?
- An ordinary review?

Do SOPs indicate that ethics review and monitoring are guided by the ethical standards established by [CIOMS](#)?

Do SOPs define whether all members will have an equal role in reviewing each protocol or whether lead reviewers will be appointed?

Do SOPs explain how the REC will proceed to invite external experts to contribute to reviewing a specific protocol?

Do SOPs mention how the confidentiality of the information associated with the protocols and the REC deliberation will be protected?

Do SOPs explain how to handle conflicts of interest that could affect the review of a protocol?

Do SOPs define how to convene meetings and how often to hold them?

Do SOPs establish the quorum needed to make decisions?

Guiding questions for ethics review of research involving human subjects can be found in [this tool](#).

The REC's deliberation is confidential to ensure that members have complete freedom to discuss the protocol. However, the basic information about the protocol and the REC's decisions are not confidential and may be made public.

Inviting researchers to participate in the discussion of their protocol (e.g., to explain details and answer questions) may be considered. However, researchers should not be involved in the deliberation of the protocol. The REC may also meet with researchers to explain their observations.

6.

Do SOPs indicate how decisions will be made (e.g., by unanimity, majority, or consensus)?

Do SOPs determine the decisions the REC may issue (e.g., approval, request for comments, disapproval, etc.)?

Do SOPs define how REC will communicate its decisions?

Do SOPs set deadlines for:

- Determining that a protocol requires ethical review?
- Conducting a protocol review?
- Communicating REC decisions to researchers?
- Answering REC observations?

The people chairing the REC do not have the right to veto protocols, and their vote does not carry more weight than the other members.

Decisions made by consensus do not imply that all members agree with the decision but that they consider it acceptable and no one deems it inadmissible.

- *Establishing deadlines is recommended to ensure the timely functioning of the REC. However, it may be necessary to address deadlines flexibly to prioritize a rigorous review given several factors, such as the protocol's complexity and level of development, the number of observations, etc.*

7.

Monitoring ongoing research

- Extension of approvals
- Adverse events
- Amendments
- Progress reports
- Final report

Do SOPs explain how to:

- Extend the period of approval of the protocol?
- Report any adverse events or other problems associated with the study?
- Submit an amendment to the approved protocol?
- Report on the progress of the study?
- Report on the end of the study?

Do SOPs specify how to proceed if RECs identify any breaches of the rules?

For the monitoring of clinical trials, do SOPs mention:

- The procedures and timelines for receiving and evaluating safety reports, including any corrective action that may be necessary?
- The procedure and deadlines for notifying the REC of any amendments that may be necessary to protect participant safety.

RECs do not impose sanctions on researchers for breaches of the rules. RECs should notify the institution, sponsor, and relevant authorities so they can act as appropriate.

8.

Procedures in health emergencies

- Expedited procedures if the REC is required to review research in emergencies

If the REC is required to review research in response to a health emergency as established by the relevant authority, do SOPs explain the expedited procedures to use for the ethics review and monitoring of these protocols?

Annex 1 of [Catalyzing Ethical Research in Emergencies. Ethical Guidance, Lessons Learned from the COVID-19 Pandemic, and Pending Agenda](#) contains an SOP emergency template.

9. Transparency and accountability

- **REC website**
 - » Procedures
 - » Members
- **Annual reports**

Does the REC have a website that:

- Inform about the reviews and monitoring processes of the REC?
- Indicate how to submit protocols for ethics review?
- Publish SOPs?
- Provide the list of REC members?
- Provide the contact information of the REC?

Do SOPs indicate that the REC has to prepare an annual report on its activities that allows it to self-assess its management?

10. Coordination and communication mechanisms

Does the REC have a mechanism to communicate with the public (e.g., through the website or social media), if necessary?

Does the REC have a mechanism to be contacted by participants in the studies it approves, if necessary?

Do SOPs mention the communication mechanisms to coordinate with other RECs, researchers, and relevant authorities?

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