



Tip Sheet: Counting the Number of Studies

Related Accreditation Topic: Section A and the Annual Report

Organizations applying for initial accreditation and organizations maintaining accreditation must provide an accurate count of open research studies. Because AAHRPP accredits an organization's entire HRPP, the total number of open studies means all open research studies in which the organization is engaged, regardless of which institutional review board or ethics committee ("IRB") reviews the research.

AAHRPP uses this information to assess the size and complexity of the organization based on its research portfolio. The information is used:

- when conducting the review of written materials
- when planning site visits
- when calculating an organization's initial and annual fee

Overview

Total number of open studies reviewed by the organization's own internal <u>convened</u> IRB	
Total number of open studies reviewed using the <u>expedited</u> procedure by the organization's own internal IRB	
Total number of studies reviewed by an <u>external</u> IRB	
Total number of exempt determinations in the last 12 months	
Total	

1. Count the total number of open studies in which the organization is engaged, not just those under review by the organization's own IRB.
2. The total number of open studies in which the organization is engaged includes the following (additional information about each is discussed in separate sections below):
 - For organizations that have their own IRBs, count the number of open studies reviewed by the organization's convened IRB (regardless of when the study was first approved). These are generally greater than minimal risk studies.
 - For organizations that have their own IRBs, count the total number of open studies reviewed using the expedited procedure by the organization's IRB (regardless of when

the study was first approved). These studies are not greater than minimal risk.

- For organizations that rely on one or more external IRBs, count the total number of open studies reviewed by an external IRB (regardless of when the study was first approved).
 - The number of exemption determinations in the last 12 months only, including exemption determinations made using a limited IRB review procedure, if applicable.
3. Do not count other activities, such as determining whether an activity is quality improvement or research, or whether an activity involves human participants.
 4. For organizations outside the US, AAHRPP expects organizations to apply IRB review to all research involving human subjects in which the organization is engaged. AAHRPP's requirements may cover more studies than are required to undergo IRB review under country law. For example, a country's law may only require IRB review of research involving unapproved investigational drugs, devices, or biologics. If the organization conducts other types of research – such as social science research, research involving patient or medical records, or research involving data – then the organization needs to count these research studies also.

See Element I.1.A.

Counting Studies Reviewed by the Organization's Convened IRB

This section applies to studies requiring convened IRB review. For studies originally approved by the convened IRB that have become eligible for expedited review, see the following section on "Counting Studies Reviewed Using the Expedited Procedure."

1. Identify the total number of studies reviewed by the organization's convened IRB. Alternately, it is acceptable to count the total number of greater than minimal risk studies. Count all open studies reviewed by the convened IRB regardless of the date they were originally approved.
 - a. IRBs may review minor modifications of greater than minimal risk studies reviewed by a convened IRB using the expedited procedure. If the most recent IRB action on a greater than minimal risk study was an expedited review of a minor modification, the study is still

- considered under review by a convened IRB, unless and until it becomes eligible for expedited review.
- b. If a minimal risk study originally approved using the expedited procedure is brought to the convened IRB for whatever reason, continue to count this as an expedited study, unless and until the convened IRB requires the study to be reviewed by the convened IRB (for example, due to a change in risk level). Expedited studies may be brought to the convened IRB for various reasons, including review of noncompliance, or unanticipated problems. Unless the convened IRB decides something has changed the risk level and the study must be reviewed by the convened IRB, the study should continue to be counted as an expedited study.
2. Count studies reviewed by external IRBs separately from those reviewed by the organization's own IRB (see the following section on "Counting Studies Reviewed by External IRBs").
 3. During an emergency, such as COVID-19, organizations may require researchers to pause research, but IRBs may have no ability to track this. AAHRPP does not expect organizations to develop special reports or track the status of particular studies reviewed by a convened IRB and whether they were stopped by the researcher or organization during the emergency. Count studies as open unless and until the researcher closes the study with the IRB or the IRB closes the study.
 4. If the organization's own internal IRB reviews all research, including minimal risk research, at a convened IRB meeting, contact AAHRPP about how to count studies. Organizations that review all studies by a convened IRB should maintain a record of the risk level, and records for each study should indicate whether the study is greater than minimal risk or not greater than minimal risk.
 5. Studies originally reviewed by the convened IRB, but that are now eligible for expedited review under categories 8 or 9, or because the study has progressed to the point that the only remaining research activities are data analysis or follow-up clinical data, should be listed under expedited review, unless the IRB has required the study to continue to be reviewed by the convened IRB.

See Element II.2.D., Element II.2.E., and Element II.2.H.

Counting Studies Reviewed by the Expedited Procedure by the organization's own internal IRB

When minimal risk research is reviewed outside a convened IRB meeting by an experienced board member, this is generally called "expedited review."

Studies that undergo expedited review are minimal risk studies, so alternately it is acceptable to count the total number of minimal risk studies under "expedited review."

For organizations that follow the Common Rule, research that qualifies for initial review by the expedited procedure is not required to have ongoing continuing review by the IRB. However, AAHRPP expects organizations to continue to count expedited studies as long as they are open, even if the IRB is no longer maintaining direct oversight through continuing review.

1. Identify the total number of studies reviewed using the expedited procedure by the organization's IRB (regardless of the date they were originally approved).
2. If the organization is no longer requiring continuing review of minimal risk expedited research, continue to count those studies as under expedited review as long as they are open.
3. As noted above, during an emergency, such as COVID-19, organizations may require researchers to pause research, but IRBs may have no ability to track this. AAHRPP does not expect organizations to develop special reports or track the status of particular expedited studies and whether they were stopped by the researcher or organization during the emergency. Count studies as open unless and until the researcher closes the study with the IRB.
4. If the organization adopts another minimal risk review procedure and does not differentiate between expedited review and exempt review, then count studies reviewed outside a convened meeting as expedited review. Count all such studies, regardless of when they were approved, until such time as they are closed with the IRB.
5. For organizations that use an external IRB, count those under external IRB review (see below).

Counting Studies Reviewed by External IRBs

Some organizations rely on external IRBs for review of some or all research. External IRBs include, but are not limited to:

- Independent IRBs, whether for profit or nonprofit
- IRBs at other universities or hospitals
- Central IRBs, such as the NCI Central IRB or the Department of Veterans Affairs Central IRB

Organizations that rely upon external IRBs may not know the review type (whether the study is reviewed by a convened IRB or expedited procedure). Instead, count all open studies reviewed by external IRBs as “external review.”

Counting Studies Determined to be Exempt

Research involving human participants that meets certain criteria in US regulations, or equivalent criteria in organization policy or regulations in other countries, may be exempt from IRB review (or under US regulations, be eligible for “limited” IRB review).

1. Identify the total number of studies determined to be exempt from IRB review.
2. Count studies that are exempt from IRB review for the last 12 months only. Unlike research reviewed by the convened IRB or expedited procedure, AAHRPP only needs a count of exempt determinations in the last 12 months.
3. Do not count other activities, such as determining whether an activity is quality improvement or research, or whether an activity involves human participants. When counting research, only include research involving human participants that meets exempt review criteria. Some examples of activities that may not be research involving human subjects, depending on the laws the organization follows, include, but are not limited to:
 - a. Oral history.
 - b. Quality improvement.
 - c. Public health surveillance or investigations.
4. Count both studies determined to be exempt by the researcher's own organization or by an external HRPP at another organization, including:
 - a. Private independent IRBs, whether for profit or not-for-profit.
 - b. IRBs at other universities or hospitals.
 - c. Central IRBs such as the NCI Central IRB or the Department of Veterans Affairs Central IRB.
5. If the organization adopts another minimal risk review procedure and does not differentiate between expedited review and exempt review, then count studies reviewed outside a convened meeting as expedited review.
6. Organizations that conduct limited IRB review may categorize this research in different ways, or not record the fact that a study was reviewed using limited IRB review. AAHRPP does not expect organizations to manually identify

those reviewed under “limited IRB review” if this is not known. If the organization's records do not identify which exemption determinations were made by limited IRB review, AAHRPP does not expect organizations to manually identify these studies. Instead, in this case, count limited IRB reviews under exempt determinations.

See Element II.2.A., Element II.2.B., and Element II.2.C.

Counting Studies Determined to be Exempt under Limited IRB Review

The US Common Rule provides for an additional review procedure for certain types of exempt research. Called “limited IRB review,” it is used for certain exemption determinations and has various requirements in addition to those for other exemption determinations, including that limited IRB review must be conducted by an IRB member, whereas other exemption determinations may be made by staff who are not IRB members. Limited IRB review generally does not apply to organizations outside the US, unless they are required to follow the Common Rule.

1. Identify the total number of studies determined to be exempt using the limited IRB review procedure.
2. Count exemption determinations under the limited IRB review procedure made in the last 12 months only. Unlike research reviewed by the convened IRB or expedited procedure, AAHRPP only needs a count of exempt determinations in the last 12 months.
3. If the organization conducts limited IRB review, but does not differentiate between different types of exemptions, count limited IRB reviews under exempt determinations.
4. Organizations that conduct limited IRB review may categorize this research differently, or not record the fact that a study was reviewed using limited IRB review. AAHRPP does not expect organizations to manually identify those reviewed under “limited IRB review” if this is not known. If the organization's records do not identify which exemption determinations were made by limited IRB review, AAHRPP does not expect organizations to manually identify these studies. Instead, in this case, count limited IRB reviews under exempt determinations.

See Element II.2.C.

Points to consider

Please be aware:

- AAHRPP staff stand ready to answer questions about how to count studies and are happy to discuss questions.
- Organizations should consider having multiple people check the count of studies.
- There are marginal cases – for example, minimal risks studies that were originally reviewed using the expedited procedure, and something changed where the study was subsequently reviewed by the convened IRB. AAHRPP expects organizations to make a reasonable attempt to categorize research, but if there are relatively few marginal cases that will not impact the description of the organization's overall portfolio, then organizations can categorize in the way that is easiest to report.
- This and other Tip Sheets and guidance documents are "living documents" that undergo periodic revisions based on questions from organizations, so your questions and suggestions are helpful.

Additional Resources

AAHRPP's Guidance on Completing the Application/Annual Report Forms