

Tip Sheet: Working with an Institutional Review Board

This document provides guidance for Personal Responsibility Education Program (PREP) grantees on working with an institutional review board (IRB). An IRB is an administrative group that (1) protects the rights and welfare of human subjects who are recruited to participate in research activities and (2) ensures that risks to research participants are minimal and are offset by potential gains in knowledge for the benefit of communities. IRBs are established and governed by different institutions, and each IRB sets its own standards for review and approvals.

PREP grantees are expected to determine whether local IRB approvals are necessary for collecting performance measures data. Grantees should identify which IRB has jurisdiction over a data collection effort for performance management purposes and whether the IRB requires the grantee to initiate an approval process. If IRB approval is necessary, grantees will need to follow all of the IRB's review requirements.

Find out whether IRB approval is needed

- To identify a local IRB, check with your partner organizations or search this database from the Office of Human Research Protections at the U.S. Department of Health and Human Services: <http://ohrp.cit.nih.gov/search>.
- Determine whether you need IRB review to collect and report performance measures data.
- Seek a Letter of Determination from the IRB that indicates whether the performance measures must be reviewed and, if so, what type of review will be done.

Research versus performance measurement

Some IRBs consider the performance measures data collection exempt from review because its purpose is for performance management, not to conduct research.¹ Your local IRB will decide whether your data collection is exempt. IRB approval is typically needed for research projects with the following features:

- Data are collected through an intervention or interaction with people.
- Personally identifiable information is collected, or sensitive personal questions are asked.
- Data will be analyzed for research reports that contribute to generalizable knowledge.

¹ In working with an IRB to determine whether review is necessary, grantees may find the Centers for Disease Control and Prevention's Distinguishing Public Health Research and Public Health Nonresearch report helpful: <https://www.cdc.gov/os/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>.

Actions an IRB may take

After you contact an IRB, it may take one of the following actions:

- Determine that performance measures are not research and therefore not in their purview
- Determine that performance measures are research but are exempt from review
- Require an expedited review (by a subset of the IRB committee)
- Require a full review

IRB time frame

The length of an IRB process varies depending upon the IRB and the type of review needed. Full reviews take longer than expedited reviews. Ask your IRB when materials need to be submitted and how much time to allow for the review.

Information typically needed for an IRB application	Documents often included with an IRB application
<ul style="list-style-type: none">• Purpose of the data collection• Number of participants to be recruited and their characteristics• How prospective participants will be selected and contacted• Procedures for obtaining informed consent, if applicable• How data will be collected and maintained• Risks and benefits of data collection• Safeguards to minimize risks	<ul style="list-style-type: none">• Data collection instruments• Recruitment materials• Memoranda of understanding with partner organizations• Consent and assent forms, if applicable• Survey administration script• Staff confidentiality agreement• Any IRB-specific submission forms

What to expect after IRB submission

After reviewing your application, the IRB might ask for more information or changes to your data collection forms. If no clarification or changes are required, the IRB will grant approval. Share the IRB approval letter with your federal project officer and keep a copy for your records. IRBs typically require approval to be updated annually.

Additional information about the Personal Responsibility Education Program (PREP) performance measures is available at www.prepeval.com. For further support, contact the Mathematica PREP Performance Measures technical assistance team at PREPPerformanceMeasures@mathematica-mpr.com or call toll-free 1-855-267-6270.