Human Subjects Review
Frequently Asked Questions

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1) When is an HSR Tracking Number (HSR number) required?

An EPO HSR tracking number is usually needed for any systematic investigation or evaluation of data (e.g., surveillance data, focus groups, program evaluation) lasting more than a day regardless of whether it is research. Investigators should consult their EPO supervisors on whether to submit a request for an HSR number.

Why is an HSR number required?

An HSR number is required to prove that a project has been reviewed and determined whether it is research involving human subjects. An investigator who wishes to publish his/her study results or present the findings for nonresearch or non-human subjects research projects will need the HSR number to prove that it has been reviewed and determined not to be research or not to involve human subjects.

When is a protocol number required?

A protocol number is required when a project is determined to be research involving human subjects and a protocol is submitted to CDC IRB for review and approval. It is assigned by the CDC Human Subjects Activity in the CDC Office of the Associate Director for Science.

What is the difference between the two?

The HSR tracking number is internal to EPO, whereas the protocol number is CDC-wide. The protocol number is assigned only when a project is determined to be research involving human subjects.

2) What are the criteria for IRB exemption of a research study?

Some human subjects research may be exempt from IRB review. Research that may be exempted includes the following:

- Conducted in established or commonly accepted educational settings, involving normal educational practices.
- Involving the use of educational tests, **survey procedures**, interview procedures or observation of public behavior.
- Involving the collection or study of **existing data.**
- Designed to study, evaluate, or otherwise examine public benefit or service programs.
- Taste and food quality evaluation and consumer acceptance studies of wholesome foods.

Research on special populations, such as children, pregnant women, and prisoners are not exempt under the Common Rule (45CFR46).

3) Is a tracking number all that is needed to proceed with a project or paper?

Yes and No.

Yes, if a project is determined not to be research or research not involving human subjects.

No, if a project is deemed research involving human subjects. An approval from CDC IRB is needed before a project can begin. If it is exempted research, an exemption determination from IRB is needed from the CDC Deputy Associate Director for Science. In addition, assurance may be needed if the investigation involves a collaborating institution.

If a project is deemed research, a protocol should be submitted for review by the investigator's supervisor, division ADS, EPO ADS, and if necessary, CDC IRB.

4) Is there a quick reference guide for the IRB process?

Yes! A 2-page HSR Quick Reference Guide is available upon request from the EPO OADS. This quick reference guide will assist you in getting started on preparing your protocol for IRB.

5) What happens after a request is sent to the EPO supervisor?

Your EPO supervisor makes the initial research/nonresearch determination. Then he or she forwards the request with the additional information to the EPO OADS. The OADS will assign an HSR number and give specific instruction to your supervisor if further action is needed.

6) When do I need to submit a protocol for CDC IRB approval?

CDC employees cannot conduct or join any human subjects research study without first getting approval from CDC IRB, or if it is exempt research, getting an exemption from the CDC Deputy ADS. As soon as a project is determined to be research involving human subjects, the investigator should submit a protocol to IRB. Consult the *Overview of Scientific Procedures* document for guidance on preparing your protocol. It is a good idea to have a protocol for organizing the project even if it does not require IRB approval. You cannot begin the research project until CDC IRB approves your protocol.

7) What is the full review process for a research protocol requiring IRB approval?

The review process for a protocol is as follows:

Investigator – EPO Supervisor – Branch Chief – Division ADS – EPO ADS – CDC IRB

8) What is an expedited review and how much faster is it?

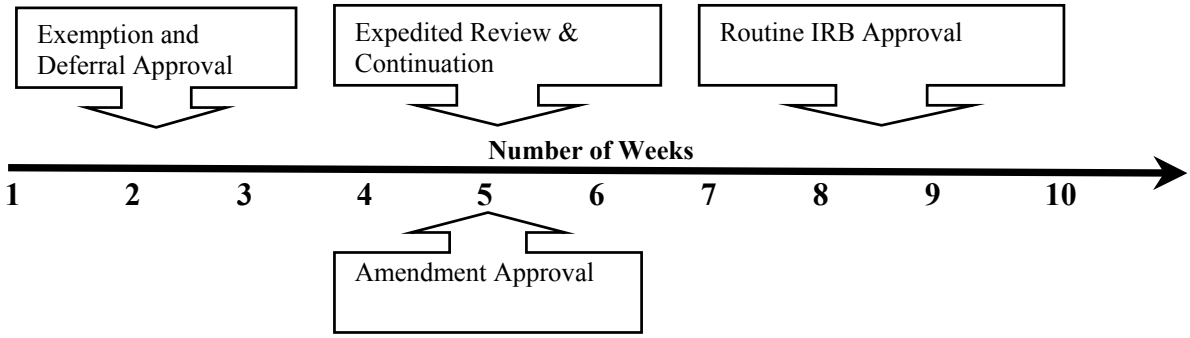
An expedited review means that the full IRB will not review the protocol. Rather, the IRB chair or his/her designee reviews and approves the protocol. An expedited review usually takes between 4 to 6 weeks from the time the protocol is received by the CDC OADS.

9) Does a full protocol need to be written to request an exemption?

No. A full protocol is preferred but is not a requirement for a request for exemption. Submit the request using the CDC form .1255 "Documentation of Exemption Determination for Protocol."

10) How long should I expect clearance to take at different stages?

- The turnaround time for an HSR number request is approximately 1 to 2 days after the request is received in the EPO OADS.
- The timeline for a protocol submitted to IRB is below:



11) What is CDC policy on deferral to another institution's IRB?

CDC is willing to consider relying on another IRB covered by an OHRP assurance (multiple project assurance or Federalwide Assurance) based on the following criteria:

1. The study involves no more than minimal risk and does not address a controversial topic.
2. CDC did not originate nor control development of the protocol.
3. CDC investigators do not have any direct interaction with study participants.

Four other considerations in the process are also reviewed:

1) The study does not involve vulnerable populations. However, certain studies involving children and adolescents that meet the other criteria above should be eligible for consideration for deferral and will be reviewed individually to ascertain the degree of risk and inclusion of appropriate parental permission and child assent procedures. Studies involving prisoners or targeting pregnant women or fetuses will not be eligible for deferral.
2) CDC investigators do not have access to individually identified data from the study.
3) CDC investigators do not retain/store specimens for future research.
4) The study has not begun (except as outlined in #12 below)

The CDC Deputy ADS makes the final determination.

12) Do I need CDC IRB approval and/or request an HSR tracking number if I was being asked to join an existing study that was IRB-approved before I arrived?

The answer depends on whether the project was approved by CDC IRB or another institutional IRB.

- **Project previously approved by CDC IRB**

If CDC IRB approved the project, it does not need to be submitted again. For EPO records, you should submit a request for an HSR number and for IRB records, the principal investigator should submit an amendment, CDC form .1252 "Request for Amendment," to add you as an investigator.

- **Project not previously approved by CDC IRB**

You should not participate in any research study as an investigator without first getting CDC approval. You may be consulted by the project staff, e.g., provide technical assistance on project design, data analysis, but you may not interact with human subjects or be an author of the study.

If you are asked to join an existing study, you need to submit a request for an HSR number. The study will need CDC IRB approval, but CDC may consider deferring review to an outside IRB based on the following criteria:

- The institution to which CDC defers must hold an OHRP assurance, and the IRB must be in a position to be responsible for review of the conduct of the study at all participating sites.
- Ongoing monitoring of the study from the lead IRB will be required, and documentation of approval of amendments, review of adverse events and continuation review must be submitted to the CDC HSA on a periodic basis not to exceed yearly on the date of annual review.
- All other conditions for reliance on another IRB must be met. No amendment or alteration of the protocol, which would substantially affect these conditions, may be

implemented without prior approval by the CDC HSA. Examples of alterations are inclusion of activities that alter the minimal risk determination, inclusion of prisoners, or targeting of pregnant women. Violation of these conditions may result in termination of CDC participation in the project.

- The investigator must provide clear and reasonable justification as to why the protocol was not submitted for CDC review before the initiation of contact with human subjects.

When the project is not submitted in the correct time frame, e.g., when the CDC investigator was involved in the project prior to submission of the request to IRB, the protocol will be reviewed by the full CDC IRB.

13) Do we need to request an HSR number if we are asked to analyze BRFSS or YRBS data that were collected before we started?

Yes. Usually, this is all that is needed.

14) If a project does not involve human subjects, but a publication or presentation will result, what is needed?

An HSR number is needed to prove that it has been reviewed and determined not to involve human subjects.

15) How does IRB approval apply to focus group research? What delineates focus group as research versus a programmatic activity such as evaluation?

A focus group study is considered research if the primary intent of the study is to generate "generalizeable knowledge." Focus group research is normally submitted for IRB review under an expedited review. An evaluation assessing a particular program is normally not considered research if the intent is to improve the program.

16) Is a pilot study of 9 or fewer persons exempt from IRB review?

No, focus group studies of 9 persons or fewer are exempted from OMB clearance, but not from IRB review.

17) If I file for IRB within our state, do I wait to get approval and then forward it to CDC or do I send CDC a simultaneous application?

If you are the PI, CDC prefers that CDC IRB first review the protocol; therefore, the protocol should at least be submitted for simultaneous review.

18) How much in advance can we send a protocol to CDC (or what is LATEST we can send it)?

Approval for a new research protocol takes between 6 to 8 weeks after the CDC Human Subject Activity receives it. However, the protocol needs to be approved within EPO by the investigator's supervisor, branch chief, division ADS, and the EPO ADS. The investigator should submit the protocol to the supervisor at least 3 months before the project implementation deadline to allow enough time for approval and revision if necessary. A research project on human participants may not be implemented without approval from IRB or exempted by the CDC DADS.

19) In which cases, if ever, will CDC IRB consider reviewing a project/study that has already started?

CDC IRB will consider reviewing an existing study if a CDC investigator is being asked to join the study and has not previously participated in the project.

20) What is needed when investigators are asked to participate in local investigations?

The same procedure as a new protocol request applies, or exemption request if applicable. Indicate that you are being asked to join an existing study.

21) Who can we contact (in ADS) when we have questions or concerns about our project and/or study with regard to preparing a protocol?

Aun Lor (404-639-1488 or alor@cdc.gov) or Denise Koo (404-639-3683 or dkoo@cdc.gov)

22) Is there an "appeal" process?

Usually, IRB will work with the investigator to clarify any outstanding issue that prevents a protocol from being approved. If a project is not approved by IRB it usually means that there are some serious violations and the investigator is unwilling to make the changes requested by IRB.

If issues cannot be resolved and IRB disapproved the protocol, please contact Mark Long, Human Subjects Manager, at the CDC ADS office at (404) 639-4035 or Mlong@cdc.gov. You may resubmit the protocol, but take note of why the IRB did not approve your protocol in the first place.

23) Where can these policies be located? How are CDC employees notified of changes in the IRB/HSR policies?

These policies can be found at the CDC ADS Website at www.cdc.gov/od/ads/hsr2.htm under the Human Subjects Documents section "Procedures for Protecting Human Research Participants."

The EPO OADS will notify EPO staff of any policy change via the EPO ADS Newsletter, EPO ADS Website, or email.

24) What online resources are accessible from outside CDC?

CDC Associate Director for Science Website	www.cdc.gov/od/ads/hsr2.htm
Office for Human Research Protection (OHRP)	http://ohrp.osophs.dhhs.gov/index.htm