



## Expedited Review Process

The purpose of this document is to provide guidance on the use of the Expedited Review procedure by the **Reach Institute** Institutional Review Board (IRB).

**An expedited review procedure consists of a review of research involving human subjects by one or more experienced reviewers of the Reach IRB in accordance with the requirements set forth in U.S. Department of Health & Human Services [45 CFR 46.110](#).**

The **Reach Institute** IRB may review student and faculty research using Expedited Review procedures if they meet specified criteria within the federal regulations, as noted below. In reviewing the research, the reviewer may exercise all of the authorities of the full IRB Committee except to issue disapproval. The reviewer may at any time refer the application to the full IRB Committee if necessary. All Expedited Protocols are reviewed at least once annually.

## Categories Of Research That May Be Reviewed By Expedited Review

Research projects qualify for an Expedited Review process if they meet the following criteria: *the research must not be greater than minimal risk and fall into at least one of the expedited categories defined by the federal regulations.*

### ***Applicability***

- A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- B. The categories in this list apply regardless of the age of subjects, except as noted.
- C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- D. The expedited review procedure may not be used for classified research involving human subjects.

**Note:** The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

## **Full Committee Research**

Proposed human subject research, which does not fall into either the exempt or expedited review categories, must be submitted for full Reach Institute IRB Committee review.