What does “Expedited” review mean?

Expedited is a review category as defined by the Federal Regulations. It, unfortunately, does not mean faster. It means a few things:

1. Risks posed to study participants are no greater than minimal such as blood draws within certain limits, collection of biological specimens via noninvasive means, use of specimens collected for clinical purposes, and use of data collected for clinical purposes.

2. Fits into one of the Expedited Categories as defined by the Federal Regulations.

3. Deadlines do not apply.

Expedited studies comprise the largest amount of studies reviewed by the IRBs (IRB-01, IRB-02, and IRB-03). Because they pose no greater than minimal risks, they are reviewed by one Member of the Executive Committee (the Chair and vice-Chairs).

For IRB-01, the proposed new study is pre-reviewed by an IRB staff member to determine if acceptability standards have been met. These standards include verifying the correct review type has been chosen and that all necessary attachments are present. After the pre-review, the submission is forwarded to a vice-Chair for review.

The vice-Chair has four to six weeks to review the submission. This timeframe is true EACH time the submission has to be re-reviewed including any subsequent replies to changes requested. Please be mindful that while deadlines do not apply to Expedited submissions, the length of review should be considered when developing the timeline for study implementation.

Frequently Asked Question:

Question: My study was approved. Where do I find my stamped Consent?

Answer: Your stamped Consent is available in the study workspace under the “Stamped Documents” tab. Please pay particular attention when selecting the appropriate document if the study has had multiple Consents approved during its history. It is helpful if the Consent is named with the study number, type of submission, and date to make this process easier.

Announcements:

The IRB-02 Main Office will be closed from December 22, 2014 through January 5, 2015.

The IRB-01 Main Office will be closed from December 25, 2014 through January 1, 2015. myIRB will be available during that time period.

Note that effective March 2015, CITI Program’s website will block use of Internet Explorer version 7, which is now more than 8 years old, as it does earlier versions of IE. Site users will need to have IE 8 or later, or use a current version of Chrome, Firefox, or Safari.