Review Process and Type of Reviews

New Submissions

When a complete submission package is submitted to the Research Ethics Program (REP) Manager, she conducts an initial review to ensure that the package is complete and, if so, shares it with the REB Chair. Both the REP Manager and the REB Chair conduct an administrative review of every submission by reading the Submission Form and Study Design in detail. The goal of the administrative review is to determine the type of review (exempt, expedited or full board). In some cases, there is not enough information in the submission package to make this decision and the REP Manager sends back a list of questions (also called contingencies) to the PI before a determination can be made about how the study will be reviewed.

Definitions of and conditions for exempt, expedited and full board reviews are as follows:

**Exempt Research:** Exempt is a determination allowed by the US Regulations and it means that the activity has been determined to be research but, after the contingencies raised by the REB review are addressed by the PI, the study will have no further oversight by the REB. This means modification requests and continuing review are not required to be submitted to the REB unless researchers need to change the study design in such a way that the changes alter its exemption status.

Broadly speaking, a research protocol may be determined exempt if it falls into one of the six categories described below. The regulatory language and more detailed descriptions of the six categories can be found here (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101). The most common categories used by PSI are in italics.

- Research conducted in established or commonly accepted educational settings to evaluate educational strategies, instructional techniques or classroom management methods
- Research involving survey procedures, interview procedures or observation that does not directly or indirectly identify the subjects and where any disclosure of human subject responses outside the research context would not put the subject at risk
- The use of existing data sources that are publicly available or if the data does not contain direct or indirect identifiers
- Demonstration Projects conducted by the U.S. Federal Government
- Research on public benefit programs
- Taste and food quality evaluation and consumer acceptance studies

**Expedited Research:** Expedited research means that a protocol does not require discussion by the full convened board. These protocols are reviewed by the REP Manager, the REB Chair and experienced board member/expert reviewers as necessary.

It is important to note that expedited reviews, although typically processed faster than studies reviewed by the full board, are held to the same regulatory standards and receive the same rigorous review as those reviewed by the full board.
According to federal regulations, a study may be expedited if the research involves **minimal risk**\(^1\) and meets the criteria for one of nine categories. The nine categories are described in general terms below and the regulatory language can be found here ([http://www.hhs.gov/ohrp/policy/expedited98.html](http://www.hhs.gov/ohrp/policy/expedited98.html)). The most common categories used by PSI are in italics.

- Clinical studies of drugs and medical devices when research on drugs does not require an investigational new drug application/investigational device exemption application or the medical device is cleared for marketing and it is being used within its cleared/approved labeling
- Blood samples collected by finger stick, heel stick, ear stick or venipuncture (with specific restrictions, see regulations)
- Prospective collection of biological specimens for research purposes by noninvasive means.
- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).**
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- **Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**
- **Continuing review of research previously approved by the convened IRB when the protocol is nearing closure and subjects have finished all activities or only data analysis remains or only active subjects are those for long-term follow-up.**
- **Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.**

**Full board review:** Research that is reviewed by the full board presents more than minimal risk, as determined by the PSI/REB Chair. This determination may be made because of the presence of vulnerable groups, sensitive information, identifying information, or any other issue that causes the REB to believe the study warrants discussion by the full board. Submission packages can undergo several rounds of clarifications and modifications before they are ready for review by the full board. The full board meets once per month and deadlines for submissions are listed on the REB page of the PSI website.

The full board can either approve (with or without contingencies), disapprove, or table a study. Disapproving a study means that the study is so flawed that it must be totally redesigned before resubmission. Tabling a study means that the study lacks sufficient information for the board to make a determination on the risk benefit ratio posed to subjects. Researchers can then address the contingencies raised by the board and re-submit. In the case of approving with contingencies, the researchers must revise the study documents to address the contingencies and submit them to the REB. The REP Manager and REB chair will typically review these changes and decide whether the study can commence.

Note that no PSI platform can begin any research related activities without a letter of approval (regardless of type of review) from the Research Ethics Program (REP) Manager.

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\(^1\) **Minimal risk** is defined as risks no greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests.
Modifications
If researchers find a need to make changes to the REB approved study design, researchers must submit a request to review a modification prior to implementing these changes.

Protocols reviewed through the expedited review process for the initial review will more than likely have modifications also reviewed through an expedited process unless modifications include increases to the risks posed to subjects.

If the protocol was reviewed by the full board, modification requests that do not impact the risk/benefit ratio would be reviewed through the expedited review process and modification requests that increase risks to subjects or decreases the direct benefit to subjects must be reviewed by the full board.

Continuing Reviews
Regulations permit the PSI/REB to approve protocols up to and no more than one year. If a study is a multi-year study then it must receive a continuing review or annual review prior to the REB approval expiration date. Although there are exceptions, protocols approved through expedited review will receive an expedited continuing review and those protocols reviewed by a full board for the initial review will receive a continuing review by the full board. The regulations state that the timely submission for the continuing review is the responsibility of the PI and researchers should plan accordingly.

Timelines: Submission to Approval
Efficiency is important to the REB so it is a key metric of the program. Studies may be submitted to the REB at any time. If they are determined to be either exempt or expedited as described above, they will undergo the complete review process starting with the administrative review and ending with a final determination.

Administrative reviews typically take no longer than five business days from the date of receipt of the complete submission packet by the REP Manager. These reviews may take longer if the REB requests review by other experts, including other Research and Metrics staff, expert consultants, etc. The REB will keep the Principal Investigators updated as to the status and timing of the review of their submission.

When revised documents are sent in by researchers, the REB again commits to providing a response within five business days – with the same caveat as presented above.

Studies that likely involve more than minimal risk must be submitted to the REB on or before the submission deadline listed on the PSI website. REB experience is that several rounds of modifications/clarifications are necessary before the study materials are ready for board review. These changes to the study documents are necessary to improve the quality of the submission and give the submission the best chance of approval by the board. Time must also be allowed for translation if necessary. The study documents are sent to board members exactly one week prior to the board meeting. As a result of this rather tight timeline for board reviewed studies, the REB decides whether each study is ready for full board review. If it is not ready, it will be deferred until the next month’s board meeting.