DHR Health
Institute for Research and Development

TO DISCOVER • TO INNOVATE • TO EXCEL

Full Board Review

All other studies that cannot be reviewed and approved through the **Exempt** or **Expedited** review processes, must be reviewed by a convened meeting of the DHR Health Institute for Research and Development Institutional Review Board (IRB). Board members will receive a copy of all relevant protocol materials (application, consent forms, surveys, recruiting information, etc.) before each meeting. Each member of the IRB will be given an appropriate amount of time to review all relevant information needed for an effective review in accordance with federal regulations. Thus, a Full Board review requires additional time and resources for review. A Full Board review is initially conducted by the IRB Chair who presents the pre-reviewed protocol to the IRB at a convened meeting. The Principal Investigator or study personnel can provide attend the convened meeting to present the study or address any issues or concerns that might come up during a Board meeting, especially with complex, unusual or higher risk research projects.

What are the criteria for a Full Board Review?

The following are some conditions that define studies under Full Board review

1. Studies that cannot reviewed and approved through an **Exempt** or **Expedited** review process.
    a. **Exempt Studies**
        i. Some studies that are "minimal risk" may qualify for an exempt review process.
        ii. Involve only procedures defined by one of the six exempt categories outlined in the federal regulations

        Note: Although studies may be submitted view the exempt review process, all human subject research must be reviewed by the DHR Health Institute for Research and Development IRB to ensure they meet the requirements of if they will require additional review.
    b. **Expedited Studies**
        i. These research studies present no more than minimal risk to human subjects
        ii. Involve only procedures defined by one of the seven expedited categories outlined in the federal regulations

        Note: Although studies may be submitted view the exempt review process, all human subject research must be reviewed by the DHR Health Institute for Research and Development IRB to ensure they meet the requirements of if they will require additional review.
2. **Studies that have been determined to be "more than minimal risk"**
    a. Minimal risk is defined as :
    The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102(i))
    b. Risk to subject assessment is initially evaluated by the Office of Human Research Protection Program. If it is determined that a project is "more than minimal risk", it will be prepared to be distributed to all IRB members and discussed at convened IRB meeting.
3. **Studies involving elements, procedures or interventions that require additional provisions or safeguards, as stated by federal regulations and guidance.**
    a. Vulnerable or certain Special Subject Populations (e.g., children, incapacitated subjects, prisoners, etc.)
    b. Studies taking place in foreign countries, especially those with little or no provisions for protection of human subjects in which the procedures pose "more than minimal risk".

c. Studies where information may be disclosed that could require reporting (e.g., child or elder abuse, illegal activities, etc.)
d. All sponsored and non-sponsored clinical trials (investigational drug or device) that is subject to FDA regulations.