**Full Board Review** is required when:

- The study poses **more than minimal risk** to participants
- The research involves **vulnerable populations** not covered by an exemption (e.g., minors outside of standard educational settings, prisoners, cognitively impaired individuals)
- The study includes **active deception**
- There is potential for **mandatory reporting obligations** (e.g., disclosures of abuse or harm)
- The IRB chair or staff determines that the protocol requires **broader expertise or ethical consideration beyond** what is feasible under expedited review

**Additional study considerations for Full Board Review:**

1. **Study Complexity:** The complexity of the study design or the sensitivity of the research questions can trigger a full review.
    a. A complex research design requiring the expertise of multiple board members to evaluate;
    b. Randomized treatment studies;
    c. Behavioral studies involving risky interventions, observations of illegal behavior or very sensitive data/questions;
    d. Sensitive topics, including illegal behaviors which may require an NIH Certificate of Confidentiality (CoC) to protect subject data from compelled disclosure.
2. **Specific Procedures:** Certain procedures or interventions may inherently involve greater risk and thus require full board deliberation.
    a. Clinical procedures with drugs, devices, or biologics, or innovative research into new medical or surgery procedures.
3. **FDA Oversight:** Research regulated by the Food and Drug Administration (FDA), such as studies involving investigational drugs or devices, often requires full review.
4. **Limited Expertise (Collaborative IRB):** In multi-site studies where the Pepperdine IRB is the single IRB of record, if Pepperdine determines it does not have sufficient expertise to review certain aspects, this might affect the review path or reliance agreement.

**Examples of Full Board versus Expedited:**

*Expedited Review* - An observational study examining stress behaviors in minor children in a classroom setting. PI has no interactions with students or teachers, and does not alter the curriculum, introduce novel interventions, or collect sensitive personal data. This typically falls under **Expedited Review** category 7 (Research on individual or group characteristics or behavior) or may even be **Exempt** if it is observation of public behavior and the data is recorded without identifiers.

*Full Board Review* - A study of a new, intensive 12-week stress-reduction curriculum implemented in three elementary schools. The study requires students (minors) to complete validated psychological surveys (some sensitive) and includes a component where parents and teachers report on observed changes in student behavior. The curriculum is a non-standard educational intervention and involves more than minimal risk/sensitive data collection, thus requiring **Full Board Review** due to the sensitive nature of the data, the use of minors, and the complexity of the intervention.

**Explanation of our Full Board Review Process:**

Pepperdine's two IRB committees meet at regular intervals to review proposals which require full board review. Application materials will be made available to committee members for review approximately 1-2 weeks prior to the convened IRB meeting.

IRB members may not serve as reviewers of any research with which they are directly affiliated (e.g., principal investigator, co-investigator, faculty advisor, dissertation committee member, etc) or otherwise have a conflict of interest. According to the federal regulations, members with a conflict of interest will be absent during discussion and voting.

No action may be taken by the IRB at convened meetings unless a quorum of its members are present, including at least one member whose primary concerns are in nonscientific areas. In order for research to be approved, it must receive the approval of a majority of those members present at the meeting.

In addition, the IRB may be required or may elect to invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond that available on the IRB.

Investigators may be invited to meetings to answer questions and/or offer clarification about the proposed research project, however the investigator must be absent during discussion and voting.

The full board review will result in an IRB determination that the application is:

(a) approved without stipulation;
(b) contingent approval;
(c) not approved as proposed.

Findings will be documented in the IRB meeting minutes and will be communicated to the investigator in writing via email and/or the eProtocol IRB system. A copy of all IRB minutes, which contains IRB findings and actions, will be sent to and retained by Pepperdine's Human Protections Administrator.