Drexel UNIVERSITY

Office of Research

Types of Review: Exempt, Expedited, and Full

Depending on the **level of risk** and subject demographic, a protocol will fall into one of three categories: exempt, expedited, or full board review. The IRB committee members, and if necessary the IRB Chair, will determine the correct level of review.

Exempt level of review

"Exempt" means review by a HRP staff member, sometimes in consultation with others. A research activity may be declared exempt if it is considered low-risk and the only involvement of human subjects will be in the categories outlined in **45 CFR 46.101(b)**. Briefly described, these categories are:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices**.**
2. Research using anonymous **or** benign tests, surveys, interviews, or observations.
3. Research involving the collection or study of existing data if it is publicly available or if subjects cannot be identified.
4. Research examining public benefit or service programs.
5. Taste and food quality evaluation and consumer acceptance studies.

Although subject consent is always needed by way of a handout outlining elements of consent, signed consent forms are typically not recommended if they are the only identifying variable in an otherwise anonymous project.

Expedited level of review

Projects not eligible for an exempt review may be eligible for an expedited review. Expedited **does not** mean that the review is less rigorous or happens more quickly than convened review. It refers, instead, to certain types of research considered to involve minimal risk.

In general, research may qualify for expedited review if it is judged to involve only minimal risk, does not include intentional deception, and includes appropriate informed consent procedures. Common protocols reviewed and approved as expedited include the following:

- Studies involving the collection of identifiable information in surveys, interviews, or focus groups, and sensitive information that is also identifiable.
- Study involving the analysis of voice recordings.
- Study of blood samples from healthy volunteers, depending on volume of blood drawn.
- Study involving collection of hair or saliva samples.
- Retrospective and Prospective Chart Reviews. Please note: prospective research requires informed consent.

The full list of categories of research that may be reviewed as expedited can be found in 45 CFR 46.110.

Full board review

A full board review is required for research that is not eligible for exempt or expedited review. In summary, research that is judged to involve more than minimal risk would undergo full board review. Depending on the scope of the study, full board review would also occur for research involving protected populations such as children, prisoners, or disabled individuals.

Additional examples of full board studies include the following:

1. Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).
2. Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.

Individuals intending to conduct research that requires a full board review should submit well before the IRB submission deadlines. Please refer to IRB calendar for deadlines specific to each board).