IRB Review Types

Exempt Review – certain types of projects are deemed "exempt" from most regulatory requirements governing human subjects research. However, these projects still require review by IRB Administrative staff to assess whether they eligible for exemption.

Exemption is allowable only when *all of the following conditions* are met:

1. Research presents little to no risk of harm to participants; AND
2. All research procedures fit into one or more of six regulatory exemptions; AND
3. Confidentiality of participants will be protected when results are disseminated (no deductive disclosure concerns); AND
4. The research does not include prisoners.

Common examples of exempt research include:

- Anonymous surveys of adults
- Interviews/focus groups with adults where the topics are not sensitive or overly personal (would not present any risk if accidentally disclosed)
- Research in established/accepted educational settings involving normal educational practice
- Research using de-identified existing data or records (e.g., de-identified student record data) or data that are publicly available (public blog posts, public meeting minutes, etc.);
- Taste tests of food products, that involve only wholesome foods without additives, or where additives/ingredients are at levels deemed safe by the FDA or USDA.

  Note: Surveys and interviews with children are not eligible for exempt review.

  Although there are fewer regulatory requirements for exempt research, **researchers are expected to honor basic ethical considerations, such as voluntary informed consent, protecting confidentiality, etc.**

Non-Exempt Review – The IRB is responsible for ensuring that all non-exempt research meets regulatory requirements governing human subjects research. Non-exempt research is reviewed in one of two ways:

1. **Review and approval by an IRB Chair** (including the Co-Chair or Vice Chair) on behalf of the IRB. This is also known as "Expedited" review, and is allowable under the following conditions:
    1. The research presents minimal risk – risk commensurate with routine physical/psychological exams or daily life; AND
    2. All research procedures fit into one or more of nine regulatory categories (including minor changes to research previously approved by the full-board); AND
    3. Confidentiality of participants will be protected when results are disseminated (no deductive disclosure concerns); AND
    4. The Chair(s) have the appropriate disciplinary expertise to evaluate the research.

    Common examples of research eligible for Chair/Expedited review include:

    - Many social/behavioral research methods (that do not involve thorny ethical issues, such as deception, coercion concerns, or inclusion of vulnerable populations, or collection of highly sensitive information);
    - Use of private and identifiable existing data
    - Use of non-invasive, FDA cleared sensors (EEG, EKG, etc.), or Noninvasive specimen collection (hair clippings, skin cells, saliva samples, etc.);
    - Mild to moderate exercise, height/weight measures;
    - Blood draws (under certain amounts and for certain populations)

2. **Review by the convened board during a meeting – also known as "full-board review". The full- board reviews:**

    1. Research projects not eligible for *exempt* or *IRB Chair ("expedited")* review;
    2. Research projects that the Chair(s), at their discretion, refer for board review;
    3. Adverse events, unanticipated problems, cases of noncompliance, and similar issues;
    4. IRB policies

    Common examples of research requiring full-board review

- Research involving vulnerable populations (prisoners, children in some cases, subjects with cognitive impairment, employees/students in some cases);
- Collection of highly sensitive or personal information (detailed health/mental health, sexual practices, illegal behavior, drug/alcohol use, etc.);
- Invasive or strenuous procedures, x-rays or DXA scans, some blood draws;
- Research on drugs, food additives/products, dietary supplements, or medical devices