Types of IRB Reviews: Exempt, Expedited and Full Reviews

Depending on the type of project that you are submitting, you may need an exempt, an expedited, or a full board review. The type of review is determined by the subject's risk level and categories as defined by federal regulations. As an example of a risk category:

> Minimal Risk: 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 routine physical or psychological examinations or tests**.** (45. CFR. 46.102(j))(Common Rule).

- **Exempt IRB Review**

  The Federal Code at 45 CFR 46 identifies several different categories of minimal risk research as being exempt from the regulations. This does not mean that they are exempt from IRB review, just that some of the federal requirements that apply to non-exempt studies are not applicable to studies deemed exempt. For example, exempt studies are not required to obtain written informed consent, do not need to be reviewed annually, and are not required to submit modifications prior to implementation (unless they may affect the exempt status of the study). Research using de-identified archival data may fall into this category.

  Exempt reviews are performed administratively by the IRB.

  At NDNU, some precedent as to what may be viewed as exempt may help address possible questions:

  The following are *not considered to be research* and do not need IRB approval**:**

  Research practical or training activities: individuals who are being trained to perform a certain technique or therapy, such as art therapy, psychotherapy, interview technique.

  Classroom exercises: the objective of the activity is to teach proficiency in performing certain tasks, such as design of research, implementation, or analysis.

  Additionally:

  1. Some studies in the field of education or other disciplines, such as in psychology, business, or communication, where a model or pilot of a certain type of program or intervention is being carried out with a specific group as a

means of determining its efficacy, use, or implementation may be exempt from IRB review.

2. A survey design study wherein participants' anonymity and confidentiality are assured, the personal nature of information is non-invasive and personally identifiable information is not obtained would also be exempt. In both of the above cases, some form of informed consent should be obtained, either passive or active, in writing from the participant. Participants should be advised that their participation is voluntary, non-coercive, and non-discriminatory, and in no way will impact their affiliation, employment, etc. with the organization; in addition, they are free to withdraw at any time without adverse repercussions. (These all came out of the Nuremberg Trials and are part of federally mandated ethical conduct). Surveys that maintain anonymity, confidentiality, have no other manipulations, involve minimal risk and/or deception, and which cannot in any way be linked to the individual, and does not include any vulnerable populations, can be reviewed at the departmental level, under the professional purview of the instructor or the larger department, and are thus exempt from IRB review.
3. Archival research, whereby all personal and identifiable information about an individual is anonymous and therefore confidential, on data already obtained and maintained via database, public records, or other public domain information also qualifies under exempt research. Note that no individual party should be in any way jeopardized by any linkable information to their identity via such data.

- **Expedited IRB Review**

  Unlike exempt review, expedited review falls under the full protection of regulations and is reviewed administratively by the IRB Exempt/Expedited Team. Expedited studies must fall into one of the Expedited Review Categories and must meet all of the following conditions, at a minimum:

  - Presents no more than minimal risk to subjects
  - Falls into one of the expedited categories authorized by 46 CFR 46 and 21 CFR 56 (FDA regulations). Inclusion of an activity on the list does not automatically deem it to be minimal risk
  - Identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that

risks related to invasion of privacy and breach of confidentiality are no greater than minimal
- Research is not classified

All expedited studies must adhere to the requirements for informed consent or its waiver or alteration. Expedited studies may or may not be required to undergo annual review. All modifications must be approved by the IRB prior to their implementation, unless they are necessary for the immediate safety of subjects.

At NDNU, some precedent as to what may be viewed as appropriately defined as expedited research may help address possible questions:

Any study entailing any form of manipulation whereby participants are exposed to a form of experimental or non-experimental manipulation (such as viewing a film, playing a video game, observing a behavior, or reading a text) that in some way alters their perception or behavior from how they were prior to participation in the study falls under non-exempt status. Expedited review entails consultation with and approval of the supervisor of the research, who will then arrange a meeting with one member of the IRB to review and potentially approve the proposal. In the event the IRB committee member is unsure or uncomfortable about approval, they may consult with one or more committee members prior to approval.

- **Full IRB Review**

Studies that are not eligible for expedited review (do not meet the definition of minimal risk and/or do not fit into an expedited category) must be reviewed by the convened IRB.

All full board studies must adhere to the requirements for informed consent or its waiver or alteration. Full board studies must undergo annual renewal. All aspects of the research must be approved by the IRB prior to their implementation, unless they are necessary for the immediate safety of subjects.

At NDNU, some precedent as to what may be viewed as appropriately defined as research requiring full IRB review may help address possible questions:

Thesis or dissertation projects, when applicable, conducted to meet the requirements of a degree *are* considered generalizable and meet the regulatory definition of research.

Intent to publish (although not automatically an indication of intent to do research) might signify that generalizable results are anticipated and is taken into consideration when making a determination of research.

Any research, inclusive of surveys that involves minors, prisoners, clinical populations; inclusive of any clients in any therapeutic setting/relationship with a potential researcher; and any other vulnerable populations, such as older adults, should undergo IRB review. A completed proposal, including an informed consent form and debriefing statement, should be provided. If data can be linked to a participant's identity, and thus, there is lack of anonymity or confidentiality and/or if there is explicit or implicit coercion, inclusive of a therapeutic relationship, IRB review would be required. § 46.117.

Note: the researcher needs to ensure the rights of any elder population member who may be under conservatorship (i.e., a family member who is legally responsible for decision-making) are upheld. Informed consent must be obtained from both parties. In addition, for minors in cases where informed consent is required, both the parent/guardian and child should sign the consent form.