Types of IRB Review
Human Subjects Research

Exempt from Review

Applies to research that is generally ***free of foreseeable risk***

Part A: All items must apply

- does *NOT* involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as participants
- does *NOT* involve the collection or recording of behaviors, which if known outside the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation
- does *NOT* involve the collection of information regarding sensitive aspects of the participants' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior)
- does *NOT* involve deception
- does *NOT* involve participants under the age of 18

Part B: At least one item applies

The research:

- will be conducted in established or commonly accepted educational settings and will involve normal educational practices
- will involve the use of anonymously collected data from educational tests, survey procedures or observation of public behavior
- will involve the collection or study of existing anonymous‡ data, documents, records, pathology specimens, or diagnostic specimens that are publically available or recorded by the investigator in a de-indentified fashion
- will involve taste or food quality evaluations or consumer acceptance studies and the tested products are wholesome foods without additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the USDA

Expedited Review

Applies to research that presents ***no more than minimal risk***† *to subjects*

Part A: The research

CANNOT involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as participants.

Part B: At least one item applies

The research:

- involves the **anonymous**‡ collection or recording of behavior, which if known outside the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, reputation, or be stigmatizing to the participant.
- involves the **anonymous**‡ collection of information regarding sensitive aspects of the participant's behavior, e.g., drug or alcohol use, illegal conduct, sexual behavior
- involves scientifically justified deception **AND** de-briefing procedures are immediate and are outlined in detail
- involves the use of educational tests, survey procedures, or observation of public behavior that is *NOT* collected anonymously, **AND** the identification of subjects would *NOT* put them at risk of criminal or civil liability, or be socially or economically damaging
- involves the collection of biological specimens for research purposes by noninvasive means or the collection of data through noninvasive procedures (not involving sedation or general anesthesia) routinely employed in clinical practice excluding x-rays or microwaves
- involves the collection of blood samples by finger stick, heel stick, ear stick or venipuncture from healthy adults ($\geq$ 110 lbs) and the draw is $\leq$ 550 ml in an 8-wk period

Full IRB Review

Applies when research presents ***more than minimal risk***† *to subjects*

When any one of these items apply

The research:

- involves prisoners, fetuses, children (less than 18 years of age), pregnant women, the seriously ill, or mentally or cognitively impaired adults as participants
- involves the **non-anonymous** collection or recording of behavior, which if known outside the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, reputation, or be stigmatizing to the participant
- involves the **non-anonymous** collection of information regarding sensitive aspects of participant's behavior, such as drug or alcohol use, illegal conduct, or sexual behavior;
- involves scientifically justified deception **AND** full debriefing of the subject is **NOT** carried out immediately
- involves procedures which present **more than minimal risk**† to the participants
- research that does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status

† More than minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

‡ If participant names or identifiers are recorded and attached directly or indirectly via codes to data, then the data are not anonymous. However, participant names can be recorded for the purpose of verifying or awarding participation without compromising anonymity, provided there is no way of linking the specific names to the data collected.

For more details visit: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

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