

Exempt & Expedited Reviews

February 2017 IRB Member Training



Introduction

- ▶ Studies that are minimal risk
- ▶ Meet certain criteria ("categories")
- ▶ Extensive screening by ORA staff
- ▶ Reviewed by a designated member of the IRB (usually IRB Director or Chair)
- ▶ Exempt = Do not require continuing IRB review, unless significant changes are made that require re-assessment of the protocol
- ▶ Expedited = Require modifications and continuing reviews

Exempt vs. Expedited Overview

Exempt

- ▶ Research on commonly accepted educational practices, conducted in a standard school setting
- ▶ Anonymous survey, interview, observation etc. studies
- ▶ Survey, interview, observation etc. studies that are not "sensitive"
- ▶ Analysis of existing, de-identified or publically available data

Expedited

- ▶ Minimal risk clinical trials that do not involve an investigational products
- ▶ Routine procedures (e.g. blood draws), considering health of population
- ▶ Non-invasive data collection (e.g. MRI, EEG)
- ▶ "Sensitive" interviews/surveys
- ▶ Analysis of identifiable data

Expedited Biomedical/Clinical Studies

Clinical studies of drugs and medical devices only when:

- ▶ Drugs: An investigational new drug (IND) application is not required.
- ▶ Devices:
 - ▶ An investigational device exemption (IDE) application is not required, OR
 - ▶ The medical device is cleared/ approved for marketing and is being used in accordance with its cleared/approved labeling.

Noninvasive procedures routinely employed in clinical practice

- ▶ Medical devices must be cleared/ approved for marketing. Examples include:
 - ▶ Sensors applied to body or at a distance & do not involve significant energy into subject or invasion of privacy;
 - ▶ Weighing / testing sensory acuity;
 - ▶ MRI without contrasting agents;
 - ▶ ECG, EEG, thermography, detection of naturally occurring radioactivity, electroretinography (ERG), ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - ▶ Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate, given the age, weight, and health of the individual.
- ▶ Excludes: Procedures with x-rays, microwaves, anesthesia, & sedation

Expedited Biomedical/Clinical Studies

- ▶ Collection of blood samples **by finger stick, heel stick, ear stick, or venipuncture** as follows:
 - ▶ From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn **may not exceed 550 ml in an 8 week period** and collection **may not occur more frequently than 2 times /week**; or
 - ▶ From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn **may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period** and collection **may not occur more frequently than 2 times /week**.
- ▶ Prospective collection of biospecimens for research by noninvasive means.
 - ▶ For example, hair and nail clippings, deciduous teeth, excreta and external secretions, saliva, placenta removed at delivery, amniotic fluid obtained at the time of rupture of the membrane prior to or during labor, dental plaque and calculus, cells collected by buccal scraping or swab, skin swab, or mouth washings, sputum collected after saline mist nebulization.

Survey & Similar Research

- ▶ Review level depends on the 1) sensitivity and 2) anonymity of the data.
- ▶ Sensitive information is defined as information that could reasonably place the subjects at risk of criminal or civil liability or be damaging to financial standing, employability, or reputation.
- ▶ The study qualifies for exemption, category 2 if the study does not collect sensitive information, or if the study is completely anonymous.
 - ▶ Survey, interview, and observations with children do not qualify for exemption unless the study meets criteria for exemption for educational research, or if it involves observation of public behavior.
- ▶ The study qualifies for expedited, category 7 if the study does generate potentially sensitive identifying information, but appropriate privacy and confidentiality plans are in place
 - ▶ Studies that collect sensitive, identifiable data may still be referred to the convened board

Dataset Research

Studies involving the use of data or specimens that have been or will be collected for non-research purposes

- ▶ Existing data (retrospective) and collected / recorded by the investigator in a way that subjects cannot be identified or linked to identifiable information, the study can qualify for exempt Category 4:
 - ▶ Secondary analysis of de-identified data or data with indirect identifiers (i.e. limited dataset) previously collected for research or clinical purposes.
 - ▶ Limited datasets: Contains elements of dates and/or city/state/zip code information; may require a data use agreements (DUA) for data that is not publicly available
- ▶ If identifiable information will be collected/used, the study will qualify for expedited Category 5.
 - ▶ Expedited Category 5 mostly applies to studies involving the clinical setting and PHI.
 - ▶ Retrospective & prospective medical record reviews may be conducted with waivers of informed consent & HIPAA authorization if criteria for waivers are met.
 - ▶ If criteria for waivers are not met, consent / HIPAA authorization required, with some exceptions.
- ▶ Material transfer agreements (MTA) and DUAs may be needed for research reviewed under both categories if data/specimens are being shared to or received from another entity.

Waivers of Informed Consent and HIPAA Authorization

Expedited research is sometimes conducted under waivers of informed consent, written documentation of consent and HIPAA authorization providing select criteria are met.

▶ Criteria for Waiver of Informed Consent

- ▶ Study poses no greater than minimal risk
- ▶ Waiving consent does not impact subjects rights or welfare
- ▶ There is a mechanism for returning pertinent information to subjects
- ▶ The study cannot be practicably conducted without the waiver

▶ Criteria for Waiver of Written Documentation of Consent

- ▶ Only record linking subject and study would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether or not he or she wants documentation linking him or her with the research.
- ▶ Research is no more than minimal risk and involves no procedures for which written consent is normally required (e.g. a telephone survey).
- ▶ The IRB may require the investigator to provide participants with a written statement regarding the research.

▶ Criteria for Waiver of HIPAA Authorization:

- ▶ There is an adequate plan to protect PHI for improper use and disclosure
- ▶ There is an adequate plan to destroy PHI at the earliest opportunity
- ▶ There is an assurance that PHI will not be reused or disclosed without IRB permission
- ▶ The minimum necessary PHI will be collected to conduct the research

Case Study

- ▶ Primary Objective: investigate whether a nutritional intervention to adolescents and their parents can reduce their level of externalizing behavior problems.
- ▶ Design: 2 x 2 randomized placebo-controlled trial
- ▶ Participants: Parents and children (aged 11+)
- ▶ Research Site: Island of Mauritius
- ▶ Procedures:
 - ▶ Administration of fruit juice containing Omega-3 (or placebo juice) for 6 months
 - ▶ Questionnaires/Structured Interviews/ Intelligence testing
 - ▶ Measuring height, weight, heart rate, blood pressure
 - ▶ Blood collection via fingerprick

References

- ▶ Exempt Research Categories: [www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101\(b\)](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101(b))
- ▶ Expedited Review Categories: www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998
- ▶ Waiver of Consent: www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116
- ▶ Waiver of HIPAA Authorization: www.hhs.gov/hipaa/for-professionals/privacy/guidance/research/index.html