1. PURPOSE

The procedure describes the review of specific types of research that require additional considerations by the IRB.

2. PROCEDURE

The categories of research defined in this procedure involves either methodologies that might require additional considerations or for which there are federally mandated determinations that the IRB is required to make and document. These categories of research may include, but are not limited to:

- Clinical research involving devices.
- Genetic research.
- Prospective research in emergency settings.
- Emergency use of an investigational article.
- Medical records and chart review.
- Residual body fluids, tissues, and recognizable body parts.
- Tissue Banking.
- International research.
- Radiation materials.
- Research involving prisoners.

3. SPECIFIC PROCEDURES

3.1 Genetic Research

Genetic research may require special considerations. At first consideration, much genetic research may appear to meet the criteria for expedited review. This includes:

- Pedigree studies, which look for a pattern of inheritance of a gene.
- Positional cloning studies, which are conducted to identify particular genes.
- Diagnostic studies, which gather samples to develop techniques to determine the presence of specific DNA or RNA mutations.

However, some of these studies may create a vulnerable population and human subjects' autonomy may be compromised. Therefore, the full IRB may review these studies to consider questions such as:

- Will the samples be made anonymous to maintain confidentiality? If not, to what extent will the results remain confidential and who will have access to them?
- Will the samples be used for any additional studies not made explicit at the time of donation, or will the samples be destroyed after a specified, one-time use?
- Will the donor be informed of any and all results obtained from his or her DNA or RNA?
- Will the sample be sold in the future?
- Will the donor be paid for his/her sample now or in the future?
- Will the donor be informed of the results of the entire study?
- Will family members be implicated in the studies? If so, they are human subjects.

Gene therapy research (administration of recombinant vectors), which is carried out to develop treatments for genetic diseases at the DNA level, presents obvious and not so obvious questions,

including considerations of delivery methods, target population, required follow-up. Such protocols may require use of external consultants to provide independent guidance to the IRB. If the project involves gene therapy to human subjects for other than clinical purposes, the study must be reviewed and approved by the National Institutes of Health Recombinant DNA Advisory IRB prior to IRB approval. Monitoring must be adequate, and a Data Safety Monitoring Plan (DSMP) will be required.

Because there is still little regulatory guidance and relatively few ethical precedents, genetic research will require close scrutiny, and may require additional input of experts in this area.

3.2 Medical Records and Chart Review

Studies involving the use of existing publicly or privately held records may qualify for exempt status or expedited review. If the nature of the research could reasonably put human subjects' confidentiality at risk, the study may be reviewed by the full IRB. Studies that involve only chart and record review can sometimes pose significant risk to human subjects.

The most common breach of confidentiality is exposure of possible information without the knowledge or consent of the human subject. Such studies may also lead to recruitment of human subjects into future non-therapeutic studies, which may provoke the human subject to ask how his/her record was revealed to someone not part of his/her therapeutic team. The present procedure is to require IRB review of studies involving chart review or data collection and analysis.

If identifiers were to be recorded, the research would require IRB review to ensure that, among other things, procedures for protecting privacy and confidentiality are adequate. For example, a PI studying cancer risk factors may propose to go on to contact the human subjects (if still living) or family members (if the subject is deceased) to gather additional information, which may or may not be subject to the federal regulations.

3.3 Residual Body Fluids, Tissues and Recognizable Body Parts

Body fluids and tissues: Research on existing tissue ("on the shelf" or frozen) without identifying information (e.g., names, initials, hospital number, etc.) may be submitted to the IRB for exempt or expedited review.

3.4 Tissue Banking

In addition to the usual information contained in a human research protocol and an IRB submission, the IRB expects the PI to maintain a written plan for operating and managing a tissue bank.. The IRB must be able to evaluate the procedures to ensure confidentiality and protection of the participants. The proposal and informed consent should address the following items:

- How the specimens/tissue will be obtained, processed and stored?
- How the specimens/tissue will be labeled?
- How the clinical data will be associated with the specimen/tissue, and how the clinical data will be collected?
- What identifying information will be collected?
- How identifiers will be linked to specimens/tissue?
- What steps will be followed to maximize the confidentiality of linked identifiers?

- How specimens/tissue will be distributed?
- How the secondary distribution of specimens/tissue will be controlled?
- How the human subjects' rights will be protected with any future use of specimens/tissue not previously approved by the IRB?
- If results will be shared with human subjects, how will they be shared?
- How to withdraw and who to contact if they choose to withdraw later on.
- If tissue banking is a sub-component to a larger study, the applicable consent language must be under a separate heading for tissue banking, or can be in a separate consent entirely. All tissue banking elements should be discussed together in the consent.

3.5 Radiation Materials

- In addition to IRB approval, the PI may be required to obtain approval from the Radiation Safety Committee.

3.6 International Research

- Studies being conducted internationally will be reviewed according to federal regulations. Although, federal regulations governing research on human subjects cannot be imposed on cultures in other nations, it is the expectation of the IRB that ethical standards will be upheld and subjects provided with the same level of protection as human subjects in the United States.

4. RESPONSIBILITY

IRB staff is responsible for maintaining up-to-date review tools for review of research pertaining to these categories based on new and evolving applicable regulations and guidelines.

The IRB Chair or IRB staff is responsible for ensuring the IRB members are well versed in new and evolving regulations and guidelines pertaining to these categories, for selecting Primary and Secondary Reviewers with appropriate expertise to conduct the reviews of such research and for securing appropriate consulting expertise as needed for selected reviews.

Chair and Reviewers are responsible for conducting appropriate review of research planned for these categories in consultation with any appropriate experts and resources.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 812.66
21 CFR 50.24
45 CFR 46.101, 46.103
https://www.fda.gov/files/about%20fda/published/Exception-from-Informed-Consent-Requirements-for-Emergency-Research.pdf

6. REFERENCED DOCUMENTS

None

REVISION HISTORY

Revision Number	Version Date	Approved By	Date Approved
2.0	8/26/2020	Avera Institutional Official	9/23/2020
• Added in Radiation Materials and International Research. • Removed that a separate consent form must be used to obtain permission for tissue banking, because this may be included within a study consent. If it is included within a larger study, the whole section regarding tissue banking should be under a separate heading, and include all elements in one section of the consent. • Other minor administrative updates. • Removed some of the regulations that do not directly apply to this procedure.			
1.0	August 2016	Director HSRP / August 2016	