IRB Review
A compilation of 'need to know' updates for UK Institutional Review Board (IRB) members, investigators and others involved in human subject research

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UNIVERSITY OF KENTUCKY Office of Research Integrity

NIH Genomic Data Sharing Policy

The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy [http://gds.nih.gov/]published on August 27, 2014 sets forth expectations that ensure the broad and responsible sharing of genomic research data. The GDS Policy applies to all NIH-Funded research that generates large-scale human or non-human genomic data as well as the use of the data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism (e.g., grant, contract, cooperative agreement, or intramural support).

For studies initiated after the effective date of the GDS Policy, NIH expects investigators to obtain participants' consent for their genomic and phenotypic data to be used for future research purposes and to be shared broadly. The consent should include an explanation about whether participants' individual-level data will be shared through unrestricted- or controlled-access repositories.

For studies proposing to use genomic data from cell lines or clinical specimens that were created or collected after the effective date of the Policy, NIH expects that informed consent for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified.

Additional information is available under the 'Genetic Research' heading of the IRB Survival Handbook www.research.uky.edu/ori/IRB-Survival-Handbook.html

Recruitment Q & A

Do I need to submit a protocol modification to the IRB if I want to try out a new recruitment strategy?

Yes, if the strategy is different from what is currently approved in the protocol and/or research description (Form B). To request IRB approval of a new strategy, submit a Modification Request Form along with two copies (one clean copy and one with changes indicated) of the revised Research Description including new strategies under item #5 Subject Recruitment Methods and Privacy. Attach applicable materials such as advertisements. Secure UK Public Relations review for any print or media advertisements to the public.

Including a range of possible recruitment methods in the initial IRB submission can reduce the need for requesting modifications should you choose to implement new strategies or "contingency" plans.

The UK Center for Clinical and Translational Science (CCTS) Participant Recruitment/Marketing Services offers recruitment services upon request by UK researchers (e.g., print advertising, outreach events, participant registries). The CCTS provides sample language for inclusion in the research description, which itemizes all of the various recruitment strategies they assist with.

Retrospective and Prospective Record Review: IRB implications

The method used in conducting record reviews for human research studies has implications related to the type of IRB review and informed consent requirements.

Review Type

A **retrospective record review** involving little to no risk to subjects may be eligible for **Exempt Review** if the IRB determines all of the following criteria are met: **(Exempt Category 4)** *Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.*

The term "**existing**" is interpreted by the Office for Human Research Protections (OHRP) to mean that all of the data, documents, records, etc., used in the research are in existence prior to IRB review and were collected for purposes other than the proposed research. The IRB reviewer must assure that the investigator has shown that all of the data to be collected under this category are currently in existence at the time of IRB review.

- **Retrospective medical chart review** - evaluates data that is existing at the time the protocol is submitted to the IRB for initial approval.
- **Prospective medical chart Review** –evaluates data that **does not yet exist** at the time the protocol is submitted to the IRB for initial review.

Retrospective and prospective record reviews may qualify for **Expedited Review** if they present no more than minimal risk to human subjects, and meet the following criteria: **(Expedited Category 5)** *Research involving materials (data, records, etc.) that have been collected or will be collected solely for non-research purposes.*
The expedited review procedure may not be used where identification of the subjects and/or their responses would 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.

Additional information regarding IRB review type may be found at
www.research.uky.edu/ori/human/IRBReviewTypes.htm

Informed Consent

Standard requirements for **informed consent** (or waiver/alteration of consent) apply regardless of the type of review utilized by the IRB. The ethical principle of Respect for Persons mandates that subjects enter into research voluntarily and with adequate information. Informed consent may only be waived or altered in specific circumstances where the regulatory criteria and ethical considerations are met.

In order for the IRB to approve a waiver of consent process, the IRB must be satisfied that the following criteria are met:

A. The research involves no more than minimal risk to the subjects;
B. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
C. The research could not practicably be carried out without the waiver or alteration; and
D. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The IRB may determine that written consent is required if the investigator is unable to justify why it's impracticable to conduct the research without a waiver. For **prospective record reviews**, investigators are likely to have access and opportunity to complete an informed consent process with prospective subjects.

Research subject to HIPAA regulations must also obtain a HIPAA Authorization from the subjects or must qualify for a Waiver of HIPAA Authorization. A Waiver of Authorization does not mean the research is exempt from all HIPAA's privacy regulations. It only means that a signed Authorization form is not required because specific waiver criteria have been met. HIPAA is designed to protect the use and disclosure of individually identifiable health information.

See the following links in the IRB Survival Handbook for additional information on informed consent and HIPAA in research www.research.uky.edu/ori/IRB-Survival-Handbook.html#Informed and www.research.uky.edu/ori/HIPAA/main%20page.htm#Anchor-Medical