

University of Kentucky
Guidance to Criteria for Institutional Review Board (IRB) Approval

All research proposals that intend to enroll human subjects must meet federally mandated criteria before the research can be initiated. The criteria are based on federal regulations and the ethical principles discussed in the Belmont Report. In addition, other criteria unique to the University of Kentucky (UK) human research protections programs apply.

The UK IRB initial review application which includes a General Information Sheet, research description, and an informed consent form template are available online by following the applicable links through the Office of Research Integrity (ORI) Forms/Applications web page: <http://www.research.uky.edu/ori/human/HumanResearchForms.htm>. A sample continuation review report is located on the same page and under *Continuation Review* on the IRB Review Types web page: <http://www.research.uky.edu/ori/human/IRBReviewTypes.htm#CR>. The IRB forms are designed to address these criteria and thereby, assist the IRB in collecting enough information to make a determination of approval.

Before issuing approval, IRB reviewers complete criteria approval checklists which serve as a guide in applying the following criteria.

A. Risks to subjects are minimized:

- By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
- Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes, and
- By addressing the likelihood of harm and magnitude of harm encompassing physical, psychological, social, economic, and/or legal risks to the subjects.

B. Risks to subjects are reasonable in relation to:

- anticipated benefits, if any, to subjects, and
- importance of the knowledge that may reasonably be expected to result.

In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

The IRB also considers the professional qualifications and resources of the research team as identified in the study personnel listing on the General Information Sheet (GIS) to ensure appropriate expertise is represented.

In the IRB application, additional information is obtained from the investigator on the Food and Drug Administration (FDA) status of the project (e.g., approved, Phase I, Phase II, Phase III); the available animal toxicity and side effect data; and the short-term and long-term risks to which human subjects will be exposed during the course of research. Where appropriate, the IRB reviews provisions for monitoring the data collected to ensure the safety of the subjects.

For further information, see UK Assessing Research Risks Guidance document.

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C. Selection of subjects is equitable.

In making this assessment, the IRB takes into account the purposes of the research and the setting in which the research will be conducted and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, fetuses, neonates, adults with impaired consent capacity, or economically or educationally disadvantaged persons.

D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative unless this requirement is waived by the IRB.

Informed consent is a process. To minimize coercion, the IRB considers the circumstances under which consent is obtained including but not limited to: timing; relationship between prospective subject and individual obtaining informed consent; language used to recruit prospective subjects; and qualifications of individuals obtaining informed consent. Also, informed consent, whether oral or written, may not include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. Compensation language to accommodate industry sponsored research protocols may be considered on a case-by-case basis.

For further information, see the Informed Consent SOP, the IRB initial review application, and the Principal Investigator's Guide to Identification and Recruitment of Human Subjects.

E. Informed consent will be appropriately documented as required by local, state and federal regulations unless the requirement is waived by the IRB.

Documentation of informed consent is also important. The Informed Consent SOP includes guidance for reviewing the informed consent document as does the informed consent form template included in the IRB application. The IRB informed consent form template is designed to ensure that documentation of informed consent includes federally mandated basic and additional elements of informed consent.

No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

See the Informed Consent SOP and the IRB initial review application for further information.

F. When the study is greater than minimal risk, clinical research, or a NIH funded/FDA regulated clinical trial, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

The IRB reviews if applicable:

- Procedures for promptly detecting harm and mitigating potential injuries.

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- Implementation of monitoring procedures and frequency.
- Procedures to ensure adequate feedback of information to researchers and medical decision-makers.
- Procedures for ensuring appropriate reporting of findings to the IRB.
- Procedures for reporting temporary or permanent suspensions of a study to the appropriate entity (i.e. funding agency) and the criteria for suspension or termination of the study.
- Any quality control measures to ensure protocol adherence.
- Procedures and plans for communications such as protocol modifications, data safety monitoring reports and unanticipated problems between sites when research is part of a multicenter study in which UK is the coordinating institution or a UK investigator is the lead investigator.

See also Data and Safety Monitoring Plan SOP.

G. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

The IRB reviews, if applicable:

- The methods used to identify and contact potential human subjects.
- The settings in which an individual will be interacting with an investigator.
- The appropriateness of all personnel present for research activities.
- The methods used to obtain information about subjects.
- The nature of the requested information.
- Information that is obtained about individuals other than the “target subjects,” and whether such individuals meet the regulatory definition of “human subject” (e.g., a subject provides information about a family member for a survey).
- Privacy guidelines developed by relevant professional associations and scholarly disciplines (e.g., oral history, anthropology, psychology).
- How to access the minimum amount of information necessary to complete the study.
- The long-range plan for protecting the confidentiality of research data, including a schedule for destruction of identifiers associated with the data.
- The consent form and other information presented to potential research subjects to ensure limits to confidentiality are clearly and adequately described.
- The informed consent process and the informed consent document, and if applicable the HIPAA authorization form, to ensure that subjects are informed regarding who will have access to the subject’s information and under what circumstances data may be shared (i.e., government agencies, sponsors).

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See also Privacy vs. Confidentiality, What's the Difference?, the Certificate of Confidentiality Summary Sheet, the Family Educational Rights and Privacy Act document, and HIPAA documents for additional guidance.

H. When appropriate, additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.

When some or all of the subjects, such as children, prisoners, adults with impaired consent capacity, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or for subjects found at international sites, IRB consider whether additional safeguards have been included in the study, to protect the rights and welfare of these subjects.

See Protection of Vulnerable Subjects SOP and Protocol Specific Training materials included in the IRB Survival Handbook.

I. The IRB requires that the Department Chairperson sign the Signature Assurance sheet:

By signing the Assurance Statement, a Department Chairperson signifies that: the study has scientific validity; the research staff is qualified to perform research activities; adequate facilities and resources are available; investigators who are also sponsors are knowledgeable about additional regulatory requirements; investigator has access to subject population and ancillary resources; and the Department Chairperson or authorized designee will mentor the investigator as needed.

See the "What does the Department Chairperson's Assurance Statement on the IRB application mean?" document.

J. Additional review by other committees may be required for review of proposed medical research:

- Institutional Biosafety Committee (IBC);
- Markey Cancer Center (MCC);
- Radioactive Drug Research Committee (RDRC);
- Radiation Safety Committee (RSC).

K. Advertisements and Recruitment Incentives:

The IRB reviews the recruitment procedures and materials according to FDA recommendations found in the FDA Information Sheets and the UK A Principal Investigator's Guide to Identification and Recruitment of Human Subjects for Research document.

L. Payment and/or cost to Research Subjects :

At a minimum, the IRB considers the following for appropriateness when applicable:

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- Proposed payment(s) to research subjects as outlined in the informed consent document and research description of the IRB application.
- How the payment(s) will be prorated to compensate the subjects' time for participation, or if the subject withdraws before completion of the study.
- Costs for care, drugs/devices, or any research procedures that will be the subject's responsibility as a consequence of participating in the research.

M. Approval from external institutions:

The IRB ensures that written approval is obtained from an authorized official of any institution external to the University from where subjects may be recruited or research procedures conducted.

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