IRB SOP 20.0 Flexible IRB Review, 2018 requirements

1. Purpose:

This SOP outlines how projects that do not fall under the common rule are reviewed and approved by the KUMC IRB.

2. Procedure:

20.1 Background and Ethical Principles

I. All human subjects research reviewed at KUMC, regardless of research type, will be guided by the core ethical principles of respect for persons, beneficence and justice.

II. KUMC applies federal regulations to research that is conducted or supported by any federal agency. For research not conducted or supported by a federal agency, KUMC has the flexibility to apply human subjects protections commensurate with risk. Investigators conducting minimal risk research that is not conducted or supported by a federal agency can request flexible IRB review.

III. When federal regulations do not apply, KUMC provides equivalent protections for research participants. Equivalent protections include the requirement for IRB approval, expertise of the reviewers, human subjects training and financial disclosures from study teams, agreement by participants for research involving direct interactions, provisions for confidentiality and security if data are identifiable, HIPAA protections when applicable, and reporting of unanticipated problems to the IRB.

20.2 Definitions

I. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

II. Federally funded or supported is defined at KUMC as any of the following:

   A. Funded by a direct federal grant
   B. Funded through a sub-award or pilot grant associated with federal dollars
   C. Includes personnel on a federally-funded training grant
   D. Research conducted under a no-cost extension
   E. Data will be used to support an application for FDA approval or a grant application (e.g., data
collection in response to a scored grant submission with plans to re-submit)
F. Involves an FDA-regulated product or dietary supplement
G. Involves registries about FDA-regulated products
H. Conducted under a contract that requires the investigator to adhere to federal human subjects regulations (e.g., 45 CFR 46, 34 CFR 97 or other references to the HHS Common Rule)
I. Involves any services that could be billed to a federal program

III. Flexible IRB review means a review and oversight process that applies human subjects protections commensurate with risk while reducing administrative burdens for researchers and the IRB. Flexible IRB review allows abbreviated IRB applications and consent forms, streamlined review by IRB Chair or staff members and elimination of the continuing review requirement.

20.3 Eligibility for Flexible IRB Review
I. Research studies are eligible for flexible IRB review if they meet the following criteria:
   A. Minimal risk research, as defined above;
   B. Does not involve federal funding or support, as defined above; and
   C. Does not involve reliance on KUMC's IRB by collaborating institutions or organizations that apply federal regulations to all research regardless of funding source.

II. In the course of requesting flexible review, the principal investigator will provide attestation that the research meets all eligibility criteria. IRB review will be conducted based on the attestation.

20.4 Types of Research
I. Flexible review may be applied to specified studies involving behavioral activities, analysis of data or specimens or studies involving biomedical activities.
   A. The research may involve randomization, if disclosed to participants.
   B. The research may involve deception, if the participant agrees and the IRB approves the debriefing script.
   C. The research may be audiotaped, if the participant agrees and identities are not shared.
   D. Research that involves hospital services may be subject to further administrative review and approval.

II. Behavioral activities may include:
   A. Research conducted in established or commonly accepted educational settings, involving normal educational practices.
      1. The research must not adversely impact students' opportunity to learn required educational content.
      2. The research must not adversely impact the assessment of educators who provide instruction.
      3. An information sheet or abbreviated consent document may be used.
   B. Benign research on perception, cognition, motivation, communication, social behavior, behavioral games or minimal risk performance tasks.
      1. The term "benign" describes activities that are not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive.
2. An information sheet or abbreviated consent document may be used.

C. Surveys, interviews or focus groups with adults or children and covering benign topics.
   1. The term "benign" describes topics that are not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive.
   2. An information sheet or abbreviated consent document may be used.

D. Minimal risk behavioral tests, performance tasks, surveys, interviews or focus groups that involve participants with cognitive impairment, potentially sensitive topics or use of videotaping if appropriate consenting and data protections are in place.

E. Observations of public behavior

III. Analysis of data or specimens may include:

A. Secondary research using identifiable information or specimens collected for non-research purposes
   1. HIPAA requirements must be met (authorization, BAA or waiver of authorization)
   2. Data storage and transfer (if any) must meet institutional security standards

B. Secondary research using identifiable information or specimens collected for research purposes
   1. The new purpose for analysis must not be precluded by the original consent
   2. HIPAA requirements must be met (authorization, BAA or waiver of authorization)
   3. Data storage and transfer (if any) must meet institutional security standards

IV. Biomedical studies may include activities listed below provided participants are adults, research results are not clinically relevant; results are not placed in the participant's medical record; and results are not returned to participants.

A. Non-invasive procedures, such as ultrasound, MRI without contrast, Doppler, MEG, EEGs, ECGs, eye tracking

B. Moderate exercise in healthy adult participants only

C. Non-invasive collection of biospecimens

D. Non-invasive tests (body composition, BP, pulse)

E. Collection of blood for research purposes only, from heel stick, ear stick, finger stick or indwelling catheter already in place for clinical purposes, provided:
   1. Total amounts in healthy adults do not exceed 550 ml in an 8 week period; frequency and volumes are consistent with standard clinical practice
   2. For other adults and children, considering the age, weight and health of participants and collection procedure, the total amount drawn does not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and does not occur more frequently than two times per week.

F. Skin biopsies without sutures

G. Additional collection of blood, CSF, bone marrow, GI biopsy samples or cervical biopsy samples during clinically indicated procedures, provided the additional collection does not significant extend anesthesia, sedation or operating room time

H. Collection of data from a single exposure to ionizing radiation (e.g., a standard chest x-ray or standard dexa scan, <100 mrem/yr (1 Sv); adult participants only.
20.5 Submission process

I. Research that qualifies for flexible IRB review is submitted in the electronic IRB system.

II. The request should be accompanied by the following documentation:

A. Behavioral study activities or biomedical study activities:
   1. Request for Flexible IRB Review application form
   2. Study protocol
   3. Administrative Certification, when required by the department
   4. Additional documents as applicable:
      a. Information sheet, letter of invitation or consent form
      b. Data collection sheet
      c. Proposed interview, survey questions, or focus group facilitation guide
      d. Recruitment materials

B. Secondary research involving data or specimens:
   1. Protocol and Application for Secondary Research. This form combines both protocol and IRB application elements.
   2. Administrative Certification, when required by the department
   3. Data collection sheet

20.6 Agreement by participants

I. Research conducted under flexible IRB review must obtain agreement from participants when the research involves direct interactions. Information sheets, letters of invitation or consent documents must provide sufficient detail to allow participants to make an informed choice.

II. For all studies, participants must be provided with the following information:

A. Investigator name and identification that the research is being conducted by KUMC
B. Brief statement of study purpose
C. Statement about voluntariness and freedom to withdraw at any time
D. Explanation about why persons were selected (unless evident from the purpose statement)
E. Details about study activities
F. Time commitment
G. Investigator contact information
H. IRB contact information

III. Additional elements, as applicable to the research, may include:

A. Explanation about which parties will have access to identifiable information
B. Statement about how the research team will ensure data security, e.g., a secure database and access only by study team members
C. Explanation of plans to share data outside KUMC, if applicable
D. As needed, location of study procedures
E. Physical discomfort or risks that may not be obvious to subjects
F. Benefits that participants might experience, if any
G. Freedom to decline any survey or interview questions
H. Costs of participation or payments, if applicable
   I. HIPAA language (for research involving information that comes from or goes into a medical record)
J. Statement that participants will receive a copy of the information/consent (for paper documents)
K. Signature of participant:
   1. Signature is required for studies that access or create protected health information
   2. Signature is required for studies that involve videotaping.
   3. The IRB may waive the signature requirement for studies without risk, for circumstances where participation is sufficient evidence of agreement or for studies addressing sensitive topics.

IV. Some flexible review projects may not have foreseeable risks and may not provide any benefit to participants. Consideration of alternative procedures or treatments might not be applicable. When not relevant, discussion of these topics can be omitted from the information sheet or consent document.

20.7 Review of studies
I. IRB staff will confirm that study team members have current training in human subjects protection and a current conflict of interest disclosure. Final IRB approval will be held until this requirement is met.
II. Research qualifying for flexible review is subject to additional evaluations of conflicts of interest, radiation safety, HIPAA privacy and data security when applicable. Conditions of these ancillary reviews must be fulfilled prior to IRB approval.
III. Research qualifying for flexible review can be reviewed and approved by the IRB Chair, IRB members with relevant expertise, HRPP Director or IRB staff members who have been trained on the institution's policy. Reviewers can request expert consultation from IRB members.
IV. The reviewer will confirm:
   A. The research qualifies for flexible IRB review
   B. The study is appropriately designed
   C. Any risks have been minimized
   D. When required, information provided to participants meets the standards discussed above in 20.6.
V. The reviewer can make one of three determinations:
   A. Approved
   B. Modifications required to secure approval
   C. Ineligible for flexible IRB review.
VI. Studies determined to be ineligible for flexible IRB review must be re-submitted for exempt, expedited or convened-board reviews.

20.8 Study approval
I. IRB approvals are documented with an approval letter generated by the electronic IRB system.
II. Research under flexible IRB review is not subject to continuing review requirements.
20.9 Investigator responsibilities after IRB approval

I. During the conduct of the study, the principal investigator is responsible to obtain prior IRB approval for:
   A. Changes to study design
   B. Any changes to the protocol,
   C. Edits to information sheets or consent documents
   D. Additions of study personnel

II. The principal investigator is responsible for notifying the IRB if there is a change in funding or any other change in status that would cause the project to no longer qualify for flexible review. In such case, the investigator must submit a modification to the project in the electronic IRB system. The study will be re-reviewed in accordance with federal regulations.

III. The investigator is responsible for notifying the IRB if any reportable events occur. Reportable events are outlined in SOP 5.3 and 17.1

IV. The investigator is responsible for closing the study in the electronic IRB system upon completion of the project.

Attachments:

Approval Signatures

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<thead>
<tr>
<th>Approver</th>
<th>Date</th>
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<tbody>
<tr>
<td>Steffani Webb: Vice Chancellor for Administration</td>
<td>12/10/2019</td>
</tr>
<tr>
<td>Lisa Hoebelheinrich: Chief Compliance Officer</td>
<td>12/10/2019</td>
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<tr>
<td>Annie Fors: QA Director</td>
<td>12/4/2019</td>
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<tr>
<td>Karen Blackwell: Director HRPP</td>
<td>11/26/2019</td>
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<tr>
<td>Kyle Stephens: Assistant Director</td>
<td>11/22/2019</td>
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Applicability

KU Medical Center, KU SoM Wichita