Frequently Asked Questions

What is the IRB's FWA number?

KDHE has a federal-wide assurance through the federal Department of Health and Human Services (IORG #: IORG0000646; IRB #: IRB00000986).

What common mistakes are found in IRB applications and how can I avoid them?

Make sure that all the required paperwork is submitted and complete. Many people fail to provide enough detail in the study protocol, particularly on how they will safeguard the data and destroy it after it is no longer used. Make sure to also submit human subjects training certification for the principal investigator and any co-principal investigators.

Does "exempt" mean that my project does not need IRB review?

Investigators may request Exemption for a proposed project by completing the New Project Request Form and indicating that an Exemption is requested. Per KDHE IRB Policy, all projects requesting an IRB determination of Exemption can submit their application through the expedited review process. Applications qualifying for expedited review are accepted and reviewed on a continuing basis.

What are the different types of Exemptions that the KDHE IRB will allow?

Projects seeking to obtain an Exemption determination must still request review by the KDHE IRB; only the KDHE IRB may make a determination on whether a project is Exempt.

Exemptions outlined by the Office of Human Research Protections (OHRP) include all of the following;

a) Educational Exemption (Exemption #1)
   (1) What it is? Research conducted in established educational settings (*e.g.*, classrooms, after-school programs, or online education) that involves normal educational practices (*e.g.*, research on instructional techniques or classroom management). The research must not be likely to adversely impact students' opportunity to learn, required educational content, or the assessment of educators who provide instruction.
   (2) IRB Review Required. Limited IRB review required (can use the expedited review mechanism). Limited IRB review is applicable where information recorded is both sensitive and identifiable. The review will make a determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data. Continuing limited IRB review is not required.

b) **Surveys, Interviews, Educational tests, and Observation of Public Behavior** (Exemption #2)
   (1) What it is? Research **that only includes** interactions involving education

tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including audio/visual means). This exemption does not apply to research involving interventions. Information must be recorded in a non-identifiable manner and cannot be linked back to subjects easily, not sensitive and there is a low risk of harm if the information is disclosed, or if identifiable information that may be sensitive is collected the IRB must review privacy and confidentiality protections.

(2) IRB Review Required. Limited IRB review required (can use the expedited review mechanism). Limited IRB review is applicable where information recorded is both sensitive and identifiable. The review will make a determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data. Continuing limited IRB review is not required.

(3) What is not allowed?

i. Interventions;
ii. Collection of biospecimens;
iii. Linking to additional personally-identifiable data; and
iv. Research with children (except for educational tests or some public observation).

c) **Benign Behavioral Intervention** (Exemption #3)

(1) What it is? A benign intervention is defined as one that is brief in duration, harmless, not physically invasive, painless, not embarrassing or offensive, and not likely to have a lasting adverse impact. The subjects must be adults who can consent for themselves. Data must be collected through interpersonal interaction (verbal or written responses), which may be recorded through audio/visual means. Information must be recorded in a non-identifiable manner and cannot be linked back to subjects easily, not sensitive and there is a low risk of harm if the information is disclosed, or if identifiable information that may be sensitive is collected the IRB must review privacy and confidentiality protections.

(2) IRB Review Required. Limited IRB review required (can use the expedited review mechanism). Limited IRB review is applicable where information recorded is both sensitive and identifiable. The review will make a determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data. Continuing limited IRB review is not required.

(3) What is not allowed?

i. Research with children;
ii. Deception (unless Comprehensive IRB Review has been obtained);
iii. Biomedical research
iv. Physiological data collection methods.

d) **Secondary Research** (Exemption #4)

(1) What it is? Research involving the collection or study of retrospective or

prospective data, documents, records, or pathological or diagnostic specimens if the sources are publicly available and the information is recorded so that individual subjects cannot be identified. This use of specimens has been expanded to include maintenance of identifiers if all study data is PHI.

(2) IRB Review Required. An IRB determination of exemption is required (can use the expedited review mechanism).

e) **Public Benefit/Service Program Research** (Exemption #5)

(1) What it is? Research designed to study, evaluate, improve, or otherwise examine public benefit or service programs. Demonstration projects that are conducted or supported by a federal agency. A list of projects covered by this exemption must be published by the federal agency supporting the research.

(2) IRB Review Required. An IRB determination of exemption is required (can use the expedited review mechanism).

f) **Taste/Food Quality Evaluation & Consumer Acceptance** (Exemption #6)

(1) What it is? Research involving if wholesome food without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA, EPA, or USDA.

(2) IRB Review Required. An IRB determination of exemption is required (can use the expedited review mechanism).

g) **Storage/Maintenance of Identifiable Data/Biospecimens Obtained with "Broad Consent"** (Exemption #7)

(1) What it is? Allows for storage of data and/or specimens in a repository with identifiers maintained if they were collected under an approved IRB protocol with "Broad Consent" for future secondary use research. Broad Consent must be tracked and denials must be honored for other research at the institution.

(2) IRB Review Required. The KDHE IRB will not allow this exemption.

h) **Use of Identifiable Data/Biospecimens Obtained with "Broad Consent"** (Exemption #8)

(1) What it is? Allows for secondary research use or analysis of identifiable data and/or biospecimens that were collected under an approved IRB protocol with "Broad Consent". Broad Consent must be tracked and denials must be honored for other research at the institution.

(2) IRB Review Required. The KDHE IRB will not allow this exemption.

For more information on Exemptions 1, 2, 3 and 5:
https://www.youtube.com/watch?v=APRVsvKsPrM

Do I need IRB review if my project is not funded?

If your project meets the criteria for IRB review outlined on the IRB homepage, regardless of funding, then it will need IRB review.

Do I need KDHE IRB review if my project requires IRB review by another institution?

IRB oversight for most federally-funded collaborative research projects located in the U.S. will be required to use a single IRB (commercial, academic, or hospital-based) starting January 20, 2020 (i.e. have a single IRB of record).

What are the potential decisions that the KDHE IRB might make about my project?

Decisions by the IRB will be one of the following:

a) **Exempt.**
b) **Approved.** Must include statement of any provisos, special circumstances, or limitations that the IRB believes have been mutually understood and accepted. This may not be used when substantive changes to protocols or consent forms are required. However, minor changes to the protocol and consent forms may be reviewed and approved by the study liaison. This decision requires no further action by the IRB for research to begin.
c) **Deferred Approval.** When the IRB requests substantive clarifications or modification regarding the proposal that are relevant to the determinations made by the IRB, then IRB approval of the proposed research should be deferred pending review of the modifications.
d) **Disapproved.** Must include statement of reasons for disapproval and explanation on how the decision can be appealed. Disapproval will imply irreconcilable differences between the IRB and the researcher. Examples of such differences would include the following:
   (1) Research outside the scope of the institution;
   (2) Research outside the scope of the IRB to review; or
   (3) The researcher is unable or unwilling to make changes in the protocol of a nature which would protect human subjects to an extent which satisfies the IRB.
e) **Delayed.** Incomplete information available for review (includes statement of documentation which must be complete before review can proceed).

How often does my project need IRB review?

Investigators should promptly report any proposed changes in a research activity and ensure that such changes in approved research may not be started without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject. The following should be promptly reported the KDHE IRB, as well as any federal agency with oversight of the project:

a) Any unanticipated problems involving risks to human subjects or others;
b) Any instance of serious or continuing noncompliance with these policies or the

requirements of the KDHE IRB; or

c) Any suspension or termination of IRB approval. **Suspension** may be defined as the action of temporarily suspending a researcher or research protocol that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to human subjects. **Termination** may be defined as the action of halting a research protocol which is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to human subjects. Only suspensions and terminations of an IRB approval of research are required to be reported to a federal agency.

Continuing Review

Once approved, some types of research must be reviewed no less often than annually. At the time of initial approval, the IRB will notify the researcher of the duration of approval. The researcher must ensure that he or she schedules a continuing review with the IRB or the designated IRB liaison prior to the expiration of approval. The researcher shall submit a brief report that includes the following:

a) A review of study progress including number of subjects enrolled;
b) Adverse or unanticipated events which may reflect on the risk to participants and any withdrawals from study;
c) Complaints received about the study;
d) Modifications to protocol, study instruments, or consent form(s). The IRB may request that a source other than the principal investigator submit that no material changes have occurred since the previous IRB review;
e) Any new results from this study or other studies which may reflect upon the risk to the participants; and
f) Attestation that pertinent data has been destructed per IRB requirements for project approval.

Continuing Review Not Required in Certain Circumstances

Effective on January 21, 2019, Continuing Review will no longer be required for certain types of studies, including:

a) Most studies that were approved after January 21, 2019 and were approved under a Limited IRB Review for Exemptions 2 and 3.
b) Studies (regardless of review path) that have completed subject intervention/interaction and in which activity is limited to either final analysis of identifiable data/biospecimens or involve accessing follow-up clinical data from procedures that subjects undergo as part of clinical care.

Even when continuing review is not required, investigators remain responsible for updating the IRB about adverse events and other unanticipated problems, seeking IRB

approval for changes to personnel, protocol amendments, recruitment materials, and informing the IRB when the research is complete.

Where and how long should the project-related documents be stored after my project is closed?

Records related to research that is conducted should be retained for at least 3 years after the project is complete.