IRB Handbook
2025

KANSAS HEALTH SCIENCE UNIVERSITY

KANSAS COLLEGE *of* OSTEOPATHIC MEDICINE

Office of Research
Kansas College of Osteopathic Medicine
Kansas Health Science University
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Contents

1. IRB RESEARCH & PRIVACY BOARD POLICY

Policy Statement

All research conducted by members of Kansas Health Science University (KHSU)-Kansas College of Osteopathic Medicine (KansasCOM) utilizing institutional resources or involving identifiable private information must adhere to the ethical principles outlined in the Belmont Report and comply with applicable state and federal laws, including 45 CFR Part 46 and FDA human subjects protection regulations.

KHSU-KansasCOM will maintain an **Institutional Review Board (IRB)** to ensure the protection of human research subjects, regardless of the study's funding or location. The IRB, through its **Privacy Sub-committee**, will confirm proper HIPAA authorization or assess the waiver of this requirement with documentation of its decisions. An **Institutional Official (IO)** will oversee the IRB and ensure compliance with all legal and regulatory obligations.

Purpose

The purpose of this policy is to establish the framework for the IRB and Privacy Sub-committee to ensure the ethical conduct of research involving human subjects while safeguarding the privacy and confidentiality of research participants.

This IRB is responsible for the review, approval, and oversight of research activities to ensure compliance with federal, state, and institutional regulations regarding human subjects protection and the protection of private and sensitive information.

Applicability

This policy applies to all KHSU-KansasCOM faculty, staff, students, IRB members, participating investigators, and research team members.

This policy applies to all research involving human subjects conducted under the auspices of KHSU-KansasCOM, including studies that involve the use, collection, storage, and sharing of **Personally Identifiable Information (PII)**, **Protected Health Information (PHI)**, or other sensitive data.

Authority

No human subjects research may commence until all required Institutional approvals (including IRB approval) are obtained. The results from studies conducted without obtaining prior IRB approval cannot be represented as having such approval.

Representatives from the administration may choose to review and disapprove the implementation of a research protocol that has been approved by the IRB. Those representatives may include the President and/or the President's designees. However, no one at KHSU-KansasCOM may approve or permit the implementation of any research protocol involving the use of human subjects that the IRB has not also approved.

Definitions

KHSU-KansasCOM references definitions provided in the Code of Regulations (CFR) Common Rule and the definitions for HIPAA and Privacy.

Policy

All research conducted by members of the KHSU-KansasCOM community, using KHSU-KansasCOM facilities or resources, or involving the use or disclosure of identifiable private information created

or maintained by KHSU-KansasCOM shall be guided by the ethical principles of respect for persons, beneficence, and justice as described in the Belmont Report, and performed in compliance with applicable State and Federal law, including 45 CFR Part 46, when applicable, and FDA's human subjects protection regulations at 21 CFR Parts 50 and 56, when applicable.

Any research that involves KHSU-KansasCOM receiving, accessing, PII and/or PHI will be reviewed and approved according to the federal privacy regulations (the "Privacy Rule") under the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "HIPAA").

KHSU-KansasCOM shall maintain an IRB to review research protocols involving human subjects as part of its commitment to the principles and guidelines outlined in the Belmont Report. The IRB is an autonomous administrative body established to protect the rights, welfare, and privacy of human research subjects participating in research activities. The IRB will review all research conducted by or under the auspices of KHSU-KansasCOM involving human subjects regardless of funding source, status, or study location.

Where KHSU-KansasCOM will access, receive, or use PII and/or PHI (other than a Limited Data Set) from a Covered Entity, the Privacy Sub-committee of the IRB shall confirm that an appropriate and valid HIPAA Authorization will be obtained from Research participants or will assess the criteria for whether it is appropriate to waive the HIPAA Authorization requirement, in whole or in part. The Privacy Sub-committee shall document its approval of either the HIPAA Authorization template or its decision to waive, in whole or in part, the HIPAA Authorization requirement.

KHSU-KansasCOM shall designate an IO who shall have overall responsibility for the IRB. The IO shall be legally authorized to represent the Institution. The IO and IRB shall work to ensure that all research complies with state and federal requirements, including, but not limited to, 45 CFR part 46 and HIPAA.

2. INSTITUTIONAL ROLES & RESPONSIBILITIES

Institutional Official (IO)

The President of KHSU-KansasCOM shall appoint an IO, who shall be legally authorized to act on behalf of the institution regarding the IRB. In accordance with Office of Human Research Protection ("OHRP") guidelines, the IO should be at a level of authority higher than the department chair, division director, etc. The appointment shall be indefinite without a given term limit. The IO serves as the primary contact at KHSU-KansasCOM for OHRP and other federal regulatory agencies.

IRB Chair

The IRB must be perceived to be fair, impartial, and immune to pressure by the administration, the investigators whose research plans are brought before it, and other committees and departments. The IO appoints and evaluates the IRB Chair. Any change in appointment, including reappointment or removal, requires written notification. IRB Chair responsibilities include:

- Managing the IRB and the matters brought before it with fairness and impartiality and in accordance with the policies and procedures in this handbook.
- Conducting IRB meetings and expedited reviews.
- Serving as a signatory for correspondence generated by the IRB.
- Taking immediate action to suspend a study or studies if subjects may be at risk of harm, when serious noncompliance may have occurred, or for any other reason where such action

would be deemed appropriate. Such action requires subsequent notice to and review by the convened IRB.
- Delegating duties to other experienced IRB members, such as expedited reviews and other IRB functions.
- Advising the IO about IRB operations, including IRB member performance.
- Collaborating with the Director of Research and Scholarly Activity on matters pertaining to the ethical conduct of human subject research at KHSU-KansasCOM.
- Submitting, implementing, and maintaining an approved Federal Wide Assurance ("FWA") with OHRP.
- Overseeing and maintaining training requirements for IRB members and KHSU-KansasCOM investigators.

Director of Research and Scholarly Activity

The Director of Research and Scholarly Activity is responsible for facilitating ethical research. This includes:

- Overseeing the research program at KHSU-KansasCOM.
- Advising the IO regarding research at KHSU-KansasCOM.
- Developing, managing, and evaluating policies and procedures that ensure compliance with applicable laws and regulations.
- Monitoring applicable law, regulation, and policy as it pertains to research.
- Providing regulatory guidance to the IRB Chair and members as appropriate.

Principal Investigator (PI)

A PI is the individual charged with responsibility for a specific research activity. PIs are responsible for ensuring applicable laws, regulations, and policies are adhered to during the conduct of the research, including this IRB policy.

A co-principal investigator (co-PI) is similarly responsible for compliance of activities within applicable laws, regulations, and policies. However, KHSU-KansasCOM will recognize only one PI for any given study for administrative purposes.

Eligibility

- All regular, full-time KHSU-KansasCOM faculty members in good standing are eligible to serve as PIs or co-PIs.
- Non-Teaching Administrative and Professional faculty members in good standing are eligible to serve as PIs or co-PIs.
- All active adjunct KHSU-KansasCOM faculty members in good standing are eligible to serve as PIs or co-PIs with the written approval of their faculty supervisor and supervising dean.
- All KHSU-KansasCOM students in good standing are eligible to serve as co-PIs with the written approval of a faculty supervisor who serves as the PI for the project.

Principal Investigator Responsibilities

Principal Investigators at KHSU-KansasCOM must:

- Provide accurate and complete information in their IRB submission through the Cayuse Human Ethics platform.
- Certify applications to the KHSU-KansasCOM IRB for all proposed research, including proposed research that the investigator believes to be "Exempt Research."

- Ensure that no research involving human subjects, including subject recruitment, will begin without IRB approval.
- Ensure that the proposed research, the conduct of the entire study, and the conduct of all research team members meet the standards set forth in the Common Rule.[1]
- Ensure compliance with the principles of beneficence, respect for persons, and justice as articulated in the *Belmont Report*.
- Ensure the scientific merit of the proposed study.
- Verify that adequate human, financial, and technical resources have been secured for the study.
- Ensure compliance with all applicable laws, regulations, and internal policies.
- Scrupulously adhere to the approved protocol.
- Accept responsibility for the study conducted under their auspices.
- Seek appropriate approval before making any protocol changes.
- Report any adverse events or unanticipated problems.
- Notify the IRB immediately upon the identification of any potential conflicts of interest.

Research Team Members

Persons who may have access to individually identifiable data or interact with human subjects should be listed as research team members. Research team members are considered "investigators" under 45 CFR Part 46. Exceptions may be necessary under certain limited conditions. Some examples of exceptions may include non-key personnel who assist with study activities that are not associated with the scientific development of the project and do not assist with data analysis or individuals who are members of the community or lay parties assisting with community-based participatory research. Regardless of whether a team member is listed as key personnel, the PI is responsible for ensuring all research team members are qualified to perform their respective tasks in accordance with laws, regulations, and policies.

3. INSTITUTIONAL REVIEW BOARD (IRB)

IRB Responsibilities

The KHSU IRB shall:

- Approve, require modifications to secure approval, or disapprove all research conducted by or under the auspices of KHSU-KansasCOM involving human subjects regardless of funding source, status, or study location.
- Require that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements have been satisfied and approved by the IRB. The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.
- Conduct continuing review of research at intervals appropriate to the degree of risk of the research, but not less than once per year.

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[1] As a matter of federal law, only federally funded, conducted, or supported studies are required to comply with the Common Rule. However, as a matter of KHSU-KansasCOM policy, all KHSU-KansasCOM Research will be reviewed and approved according to the standards and requirements set forth in the Common Rule.

- Suspend or terminate approval of research not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to participants.
- Through its Privacy Subcommittee, ensure compliance with requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191, including the Privacy Rule.

IRB Member Responsibilities

- Maintain the confidentiality of all IRB discussions and research reviewed by the IRB.
- Remain free from the influence of financial and other organizational interests.
- Completing member education and training, both initial and on-going.
- Conducting and documenting reviews in a timely fashion.
- Recusing self from reviewing or voting on research when the member has a conflict of interest.

Membership

The IRB shall have at least five (5) members with varying backgrounds to promote a complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence) and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall, therefore, include persons knowledgeable in these areas. If the IRB reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

The IRB shall include at least one (1) member whose primary concern is in a scientific area and at least one member whose primary concern is in a nonscientific area.

The IRB shall include at least one (1) member who is not otherwise affiliated with the Institution and who is not part of the immediate family of a person who is affiliated with the Institution.

Privacy Subcommittee Membership

- Members must have varying backgrounds and appropriate professional competencies as necessary to review the effect of the research protocol on individuals' privacy rights and related interests.
- The Subcommittee must have at least one (1) member who is not affiliated with the covered entity or with any entity conducting or sponsoring the research and who is not related to any person who is affiliated with such entities.
- Members may not have conflicts of interest regarding the projects they review.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

KHSU-KansasCOM shall maintain and update accurate lists of all KHSU-KansasCOM IRB members identified by name, earned degrees, representative capacity, indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant.

IRB Members Appointment and Evaluation

The President of KHSU shall appoint members from among nominations endorsed by the IO. Members serve three (3) year terms, with the inaugural membership staggered in 1, 2, and 3-year terms to ensure continuity of membership over time. Members may serve an unlimited number of terms.

The IRB Chair will review the performance of IRB members. The IRB Chair may remove members who do not fulfill the membership responsibilities. Members have the right to appeal such a decision to the IO.

4. IRB MEETING PROTOCOLS

Meetings

Meetings will be regularly scheduled, to be determined by the IRB annually, and informed by the volume of historical and anticipated requests. Special meetings may be called at the discretion of the IRB Chair.

Meeting Materials

The required materials must be distributed to members at least one week prior to the convened meeting for items included in the IRB agenda. Meeting materials should consist of the agenda, minutes from the previous meeting, and any study submissions for review.

All IRB members receive and are expected to review all study submissions and meeting materials. However, some members may be assigned primary or secondary reviewer status to ensure each study has an IRB member with key responsibility for leading those study discussions.

All members of the IRB will be apprised of all exempt or expedited review approvals via written reports provided on a regular schedule as determined by the Chair. Any IRB member can request to review the full protocol of any given study.

Quorum

A quorum is determined by a simple majority of the voting members but must include at least one (1) member who is in a non-scientific area. For FDA-regulated proposals, at least one (1) member of the quorum must be a licensed physician. IRB members who have received all the necessary meeting materials at least one week in advance may be considered present so long as they are able to fully engage and interact (typically hearing and speaking for conventionally-abled persons) by attending in person or by attending via electronic means.

The Chair is responsible for assuring that a quorum is present before calling the meeting to order and that the quorum is maintained until the meeting is adjourned. If a quorum is not maintained, the pending action item(s) must be deferred until a quorum is established or until the next meeting.

Meeting Procedures

1. The IRB Chair (or acting chair) will call the meeting to order once a quorum is established.
2. The IRB will review the agenda and discuss and approve minutes from the previous meeting. Once the minutes are approved, they are considered final.
3. The Chair will query the members present about any conflicts of interest with items on the agenda and remind members about the importance of confidentiality. Members with conflicts of interest will recuse themselves during any discussions or votes, and will leave the meeting during the time in which the item under conflict is discussed and voted upon. The Chair will refrain from making motions to the extent possible. In the event that the Chair is serving as the primary reviewer of a proposal under discussion, an acting chair will serve as chair during the review of that proposal.
4. The IRB may, at its discretion, invite investigators and research team members to answer questions about their proposed or ongoing research. Guests will be asked to leave for the IRB discussion and vote on the applicable research proposal.
5. Minutes will be recorded and must contain sufficient detail to show the following:
    - Attendance (names of members or alternates present, names of members or alternate members participating through videoconference or teleconference, and documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions), names of consultants, investigators, and other guests present).
    - There was a quorum throughout the meeting.
    - Business items that were discussed and any education provided.
    - Actions taken, including separate deliberations, actions, and votes for each research study undergoing review by the convened IRB.
    - Vote counts on these actions (total number voting, number voting for, number voting against, number abstaining, number of those recused).
    - Basis or justification for actions disapproving or requiring changes in research.
    - Summary of controverted issues and their resolution.
    - Approval period for initial and continuing reviews, including identification of research that warrants review more often than annually and the basis for that determination.
    - Risk determination for initial and continuing reviews and modifications when the modification alters the prior risk determination.
    - Justification for deletion or substantive modification of information concerning risks or alternative procedures contained in the approved sample informed consent document.
    - Study-specific findings support that the research meets each of the required criteria when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain informed consent altogether.
    - Study-specific findings support that the research meets each of the required criteria when the requirements for documentation of consent are waived.
    - Study-specific findings support that the research meets each of the criteria for approval for vulnerable populations under any applicable subparts.
    - Significant risk/non-significant risk device determinations and the basis for those determinations.

- Determinations of conflict of interest and acceptance or modification of conflict management plans.
- Identification of any research for which there is a need for verification from sources other than the investigator that no material changes are made in the research.
- Review of interim reports, e.g., unanticipated problems or safety reports; modification requests; report of violation/deviations; serious or continuing non-compliance; suspensions/terminations, etc.
- A list of research approved under expedited review procedures since the time of the last such report.
- An indication that when an IRB member or alternate has a conflicting interest with the research under review, the IRB member or alternate was not present during the final deliberations or voting.
- Key information provided by consultants will be documented in the minutes or report provided by the consultant.

IRB Records

The IRB shall maintain documentation of IRB activities, including the following:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.
- Records of all Privacy Subcommittee findings.
- Minutes of IRB meetings.
- Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in 45 CFR 46.109(f)(1).
- Copies of all correspondence between the IRB and the investigators.
- Copies of all conflict of interest forms submitted by investigators.
- Documentation of Human Subjects Protection Training (CITI) for all active investigators.
- A list of IRB members.
- Written procedures for the IRB.
- Statements of significant new findings provided to subjects, as required by 45 CFR 46.116(c)(5).
- The rationale for an expedited reviewer's determination under 45 CFR 46.110(b)(1)(i) that research appearing on the expedited review list published by the Secretary of HHS is more than minimal risk.
- Documentation specifies the responsibilities that each institution and organization operating an IRB will undertake to ensure compliance with the requirements of this policy, as described in 45 CFR 46.103(e).

Records shall be retained for at least three (3) years, and records relating to research conducted shall be retained for at least three (3) years after completion of the research. Records may be maintained in printed or electronic form.

Meeting Modalities

All human subjects research involving more than minimal risk will be reviewed at a full board meeting, which may be in person, electronic, or hybrid. Meetings will follow a regular schedule as determined by the Chair. Special meetings may be called at any time by the Chair or IO.

An absent reviewer can submit their written comments for presentation at the convened meeting for consideration. Still, these opinions may not be counted as votes or used to qualify as a quorum for the convened meeting.

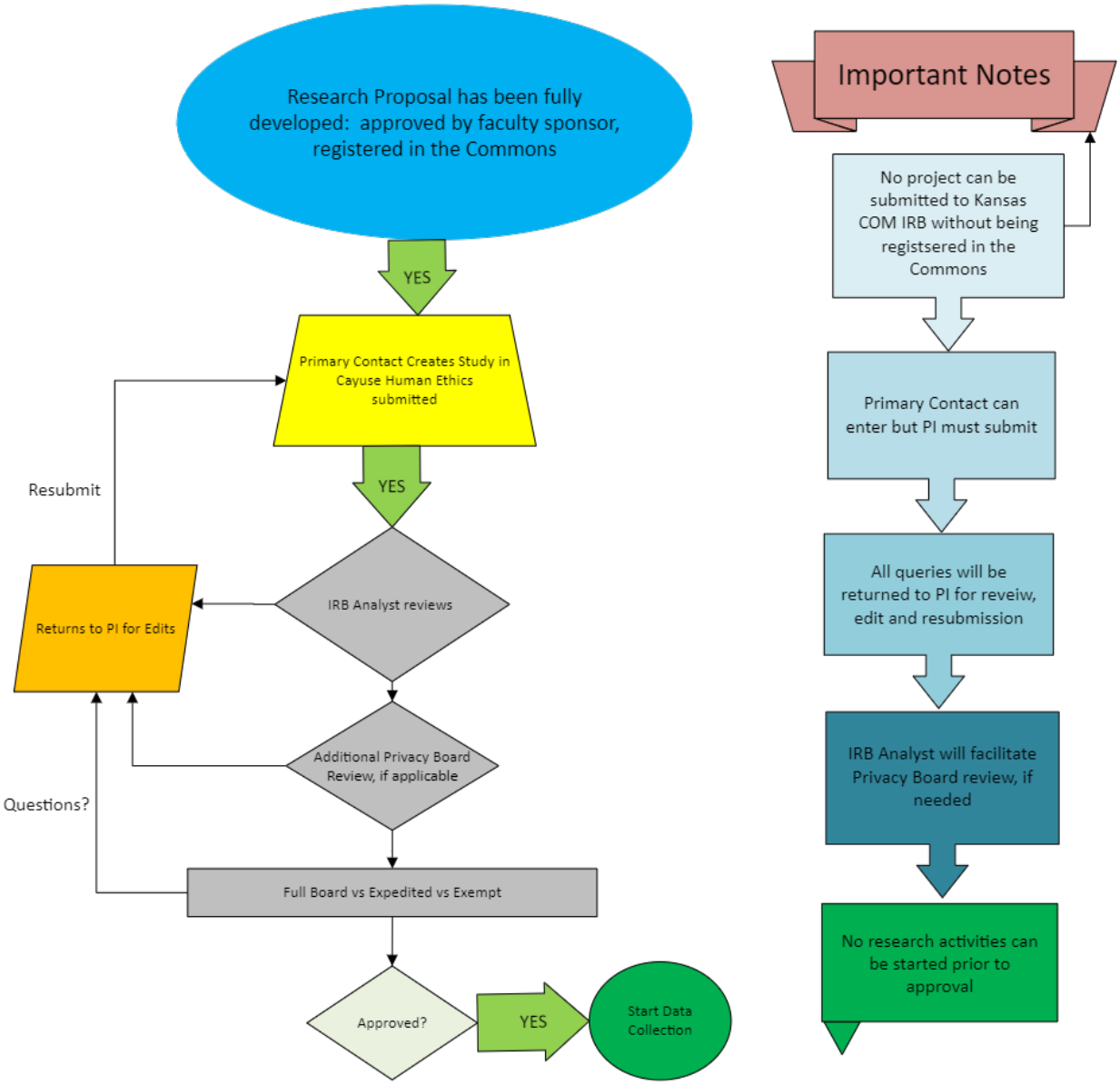
5. IRB PROCEDURES

Criteria for IRB Approval of Research

To approve research covered by this policy, the IRB shall determine that all the following requirements are satisfied:

1. Risks to subjects are minimized by using procedures consistent with sound research design and do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider the possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) among the research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involve a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required, by 45 CFR 46.116.
5. Informed consent will be appropriately documented or appropriately waived in accordance with 45 CFR 46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
9. Any research study or activity that involves access to, receipt of, or request for PHI from a Covered Entity must include a copy of the protocol and specify whether the researcher is relying on a HIPAA Authorization or seeking a waiver or alteration of the HIPAA Authorization requirement from the Privacy Board.

Submission Workflow



Submission Procedures

Initial Submission

All research applications shall include the following materials to be considered complete and ready for preliminary review ten [10] business days prior to inclusion on the IRB agenda:

- Completed IRB submission on the Cayuse Human Ethics platform[2].
- Human Subjects Protection Training (CITI) certificates.
- Conflict of Interest forms.
- Proposed consent/assent forms.
- Proposed data collection instruments, if applicable.
- Proposed recruitment materials, if applicable.
- Letters of support or permission from external sites, if applicable.
- Approval documentation from any external IRB, if applicable.
- Letter of support from faculty supervisor, if applicable.

If an investigator is submitting for the first time or is not well-versed in the submission procedures, consultations can be arranged with IRB staff.

Renewals

Renewals receive the same level of review as was used for the initial submission.

Modifications

Modifications shall be classified as minor or major by the Analyst (in consultation with the IRB Chair). Minor modifications (including modifications to projects requiring Full Board Approval) are approved through an Expedited process. However, the Analyst and Reviewer may not be the same person. Major modifications require the approval process appropriate to the project.

Incident Reports

Incident Reports are filed through Cayuse and always require consideration by the Full Board. If the incident report indicates a danger to subjects or researchers, the IRB Chair has the authority to take all appropriate actions, including suspending all activities on the project.

IRB Analyst

An IRB analyst shall review all submissions and may request additional information or clarification from the PI. The PI and/or their faculty supervisor (if appropriate) will be informed of any perceived issues that will need to be rectified prior to bringing the application forward to the IRB for review. If any proposed study or research activity involves the use, disclosure, or creation of PHI, the analyst will submit the proposal to the Privacy Subcommittee for review and approval. The analyst will make an initial recommendation for the level of review for the submission.

[2] *All proposed research must be submitted in an IRB application, regardless of whether the investigator believes the research falls within the definition of Exempt Research. Investigators should include a statement justifying why the investigator believes the proposed research is considered Exempt Research within the IRB application for such proposed research.*

IRB Reviewer

After a submission has passed the IRB analyst, a proposal shall be assigned to a member of the IRB for review. A secondary reviewer may also be assigned. The reviewer shall:

- Complete an in-depth review of the proposed research.
- Confirm an analyst's recommendation for the level of review. The reviewer may recommend a different level of review.
- The reviewer may request additional information from the PI.
- Approve, disapprove, or require changes for exempt status and report on this decision at the next IRB meeting.
- Approve submissions for expedited review and report on this decision at the next IRB meeting. If the reviewer cannot approve an Expedited submission, the submission will go to the full board for review.
- Summarize approvals granted for exempt or expedited proposals at the IRB Meeting.
- Present full board submissions at the IRB meeting.
- Complete all the IRB reviewer processes on the Cayuse Human Ethics platform.

Levels of IRB Review and IRB Review Standards

There are three levels of IRB Review: Exempt, expedited, and full board review.

Exempt (45 CFR 46.104)

The KHSU-KansasCOM IRB considers KHSU-KansasCOM students to be a unique population, and as such, research projects involving students as subjects are not eligible for exempt status.

Exempt research involving no more than minimal risk, as federally defined, and fits one of the exemption categories in 45 CFR 46.104(d).[3]:

1. Research conducted in established or commonly accepted educational settings.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at certain criteria are met.
3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses if certain criteria are met.
4. Secondary research for which consent is not required.
5. Secondary research uses of identifiable private information or identifiable biospecimens if certain criteria are met.
6. Research and demonstration projects that are conducted or supported by a federal department or agency or otherwise subject to the approval of the department.
7. Taste and food quality evaluation and consumer acceptance studies.
8. Storage or maintenance for secondary research for which broad consent is required (requires limited IRB Review).

Secondary research for which broad consent is required. (*Requires* limited IRB review).

[3] *The categories are edited for brevity. Refer to 45 CFR 46.104(d) for a full description.*

The KHSU-KansasCOM IRB is responsible for determining whether the proposed research falls within the definition of exempt research. Investigators may not make this determination independently.

Documentation of exemptions shall be maintained in the Cayuse Human Ethics platform. Exempt determinations shall be included at each regularly scheduled IRB meeting, and any discussion shall be documented in the minutes.

In conducting a limited IRB review of exempt research, the IRB shall make the following determinations:

- Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of 45 CFR 46.116.
- Broad consent is appropriately documented, or waiver of documentation is appropriate, in accordance with 45 CFR 46.117.
- If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Expedited Review (45 CFR 46.110)

The KHSU-KansasCOM IRB shall follow federal regulations and guidelines regarding expedited reviews. Expedited reviews apply to proposals that involve no more than minimal risk and fit into one of these categories:

- Research that appears on the list published, maintained, and periodically updated by the Secretary of the Department of Health and Human Services, as authorized in 45 CFR 46.110[4] :

    1. Clinical studies of drugs and medical devices when certain conditions are met.
    2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
    3. Prospective collection of biological specimens for research purposes by noninvasive means.
    4. Data collection through noninvasive procedures (not involving general anesthesia or sedation) is routinely employed in clinical practice, excluding procedures involving X-rays or microwaves.
    5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes.
    6. Collection of data from voice, video, digital, or image recordings made for research purposes.
    7. Research on individual or group characteristics or behavior.
    8. Continuing review of research previously approved by the convened IRB (under certain conditions).
    9. Continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened

[4] *These categories have been edited for the sake of brevity. For full details, please refer to the HHS website: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html*

meeting that the research involves no greater than minimal risk and no additional risks have been identified.

- Minor changes in previously approved research during the period for which the approval is authorized.
- Research for which limited IRB review is a condition of exemption under § 46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8).

Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the IRB Chair from among members of the IRB. IRB members who serve as designees to the IRB Chair for expedited review will be matched as closely as possible with their field of expertise to the study.

When reviewing research under an expedited review procedure, the IRB Chair or designated IRB member(s) will receive and review all documentation that would normally be submitted for a full board review. This requirement applies to all categories of submissions, including initial reviews, continuing reviews, and modifications. The same criteria of approval apply to reviews conducted via expedited review as to those conducted by the convened board. If the research does not meet the criteria for expedited review, then the reviewer will indicate that the research requires full review by the IRB, and the research study will be placed on the next available agenda for an IRB meeting.

The reviewer may exercise all the authorities of the IRB except that the reviewers may not disapprove of the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure by the full board.

Documentation of expedited reviews shall be maintained in the Cayuse Human Ethics platform. Expedited decisions should be included at each regularly scheduled IRB meeting, and any discussion shall be documented in the minutes.

Full Board Review (45 CFR 46.109)

Except when an expedited review procedure is used, the IRB will conduct initial and continuing reviews of all non-exempt research at convened meetings at which a quorum of the members is present. The appointed IRB leads the IRB in the discussion of the proposed research by summarizing the proposed research and leading the IRB through the regulatory criteria for approval. All members present may ask questions and make suggestions. After the discussion is complete, each board member shall cast a vote to:

- Approve.
- Approve with conditions.
- Defer to a later IRB meeting.
- Disapprove.

The IRB decision shall be based on a simple majority of the members present and able to vote.

Continuing Review

The IRB shall conduct a continuing review of research at intervals appropriate to the degree of risk, not less than once per year, except as described below.

Unless the IRB determines otherwise, continuing review of research is not required if the research is:

- Eligible for expedited review.

- Exempt research.
- Has progressed to the point that it only involves one or both of the following, which are part of the IRB-approved study:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens.
    - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

The date by which continuing review must occur will be recorded in the IRB minutes or other IRB records and communicated in writing to the investigator. Email notifications are automated through the Cayuse Human Ethics platform. It is the PI's responsibility to ensure that the continuing review of ongoing research is approved prior to the expiration date. By federal regulation, no extension to that date can be granted.

Investigators must submit the following for continuing review:

- The current protocol and IRB application.
- The current consent document.
- The most recent report(s) from the DSMB or DMC, if applicable.
- The most recent multi-site progress report, if applicable.
- Updated Financial Conflicts of Interest forms.
- Copy of any audits performed during the review period, if applicable.
- The continuing review status report.

To re-approve research at the time of continuing review, the IRB must determine that the regulatory criteria for approval continue to be satisfied. Because the research was previously found to satisfy the criteria for approval, the IRB shall focus its considerations at the time of continuing review on whether any new information is available that would affect the IRB's prior determination that the criteria for approval are satisfied. The IRB will pay particular attention to four aspects of the research:

- Risk assessment and monitoring.
- Adequacy of the informed consent process.
- Local investigator and organizational issues.
- Research progress.

As with the initial IRB review, at the time of the continuing review, the IRB may vote to take any of the following actions.

- Approve.
- Approve with conditions.
- Defer.
- Disapprove.

The IRB decision shall be based on a simple majority of the members present and able to vote.

If a research study receives approval with conditions at the time of the continuing review, the IRB will specify whether any conditions need to be satisfied before an investigator can continue particular research activities related to those conditions or requirements that must be adhered to until the conditions of approval have been satisfied.

Suspension or Termination of IRB Approval

The KHSU-KansasCOM IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB or regulatory requirements or has been associated with unexpected problems or serious harm to subjects.

When the IRB suspends approval of some or all research activities, the IRB will consider notification of subjects and any actions necessary to ensure that the rights, safety, and welfare of subjects are appropriately protected. The IRB shall notify the investigator in writing of suspensions and shall include a statement of the reasons for the IRB's actions and any requirements or conditions associated with the suspension (e.g., notification of subjects). The investigator shall be provided with an opportunity to respond in person or in writing. Suspensions of IRB approval must be reported promptly to the IO, sponsors, including federal department or agency heads, and federal oversight agencies according to applicable federal and organizational requirements.

When study approval is terminated by the IRB, in addition to stopping all research activities, the IRB will consider notification of subjects and any actions necessary to ensure that the rights, safety, and welfare of subjects are appropriately protected. The IRB shall notify the investigator in writing of a study termination and shall include a statement of the reasons for the IRB's actions and any requirements associated with the termination (e.g., notification of subjects). The investigator shall be provided with an opportunity to respond in person or in writing. Terminations of IRB approval must be reported promptly to the IO, sponsors, including federal department or agency heads, and federal oversight agencies according to applicable federal and organizational requirements.

Single IRB Review

Investigators engaged in cooperative research involving more than one institution may choose to limit their IRB review to a single IRB in accordance with Federal guidelines for sponsored multiagency research (45 CFR part 46.114). KHSU-KansasCOM may still elect to require an additional KHSU-KansasCOM IRB review to oversee activities taking place under KHSU-KansasCOM auspices.

6. CONSENT

In keeping with the ethical principles set forth in the *Belmont Report*, which require that participants, to the extent that they are capable, be given the opportunity to choose what shall or shall not happen to them, the IRB must consider the consent process proposed for each study. The consent process should consist of a dialogue between the participant and the investigator during which the participant is encouraged to ask questions about the study and or procedures prior to agreeing to participate. Therefore, simply giving the participant a consent form or reading an oral script does not constitute informed consent. The requirements for informed consent will depend on the nature of the research. All applications submitted to the IRB are required to include a description of the consent process to be used and a copy of the consent forms.

Broad Consent

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to informed consent.

Child Assent/Parental Consent

Generally, all research enrolling individuals under the age of 18 will require written permission from the minor's parent or legal guardian. Permission must be provided by at least one parent/legal

guardian, except in instances where the research presents more than minimal risk and offers no direct benefit to the subject. In such an instance, permission from both parents will be required unless one parent is deceased, unknown, incompetent, or not reasonably available.

The IRB may waive parental consent if the study is enrolling a population of children for which parental or guardian permission is not a reasonable requirement to protect the subject (for example, neglected or abused children), provided an appropriate mechanism for protecting the child is in place.

Additionally, the IRB must determine if appropriate provisions have been made to obtain the assent of the minor if they can reasonably be consulted. This assent is an indication that the child has agreed to participate in the research study. The IRB may waive the assent requirement if the child cannot reasonably be consulted due to age or condition and the requirements for a waiver have been met. If the IRB determines that the assent of the minor is required, research that will not directly benefit the child may not proceed without the assent of the minor. A separate assent form or an oral assent script can be prepared for this purpose. The assent form or assent script must explain the study at the age level and in language that the child can understand.

Non-English Speaking Participants

If non-English speaking participants will be enrolled in research, a translated version of the English language consent must be prepared and submitted. In addition, the qualifications of the individual who translated the document must be described.

Participants Who Cannot Read or Write

The written consent form may be read to the participant or their representative if the participant cannot read or write. The consent form should document the means by which the participant communicated their agreement to participate. An impartial third party should witness the consent process and sign the consent document.

Forbidden Language in Consent forms

Consent forms may not include language through which the subject is made to waive or appear to waive any legal rights or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Consent Templates

The IRB has prepared consent form templates, which include the required elements of consent as described in the Federal Regulations (45 CFR 46.116). The consent form template is available on the IRB website. The consent form should be typed in a 12-point font and should be written in a language that a person with an eighth-grade reading level can understand. Investigators may make changes to the template as long as each of the required elements is addressed.

7. ADVERTISEMENTS

The IRB must review and approve the exact wording and graphic appearance of all advertisements used to recruit subjects. Copies of all advertisements (flyers, newspaper ads, internet, emails, or other materials) must be included with each application. Advertisements to be used to recruit research participants must contain the following information:

- Identification as advertisement for research.
- The purpose of the research.

- A summary of the eligibility criteria.
- A brief summary of the study procedure.
- The anticipated time commitment (duration, number, and frequency of study visits).
- Location of the research activities.
- A description of the compensation to the participant, if applicable.
  ** Advertisements may not emphasize the amount to be paid (e.g., large or bold type)*
- The name of the person to contact for further.

Recruitment of KHSU-KansasCOM Faculty, Staff, or Students Participants

If a research proposal seeks to recruit KHSU-KansasCOM faculty, staff, or students via their KHSU-KansasCOM directory information, the request must first be approved by the IRB. The recruitment materials must include clear notice that the participation is being sought under the approval of the IRB as part of an approved research study and that participation is voluntary. The approved communication may be sent on behalf of the investigator from an official KHSU-KansasCOM account, and information for the PI will be included so prospective participants can contact them for additional information.

8. VULNERABLE POPULATIONS

Certain individuals, by nature of their age or mental, physical, economic, educational, or other circumstances, may be more vulnerable to coercion or undue influence than others. At the time of initial submission or when a proposed modification includes vulnerable subject populations, the IRB will consider the scientific and ethical reasons for including vulnerable subjects in research. When appropriate, the IRB may determine and require that additional safeguards be put into place for vulnerable subjects. When the IRB does not have the relevant expertise among its membership, expertise may be sought through consultants.

The IRB evaluates the proposed inclusion of vulnerable population(s) in the research and the safeguards proposed by the investigator, taking into consideration the following factors, as applicable to the research:

- Whether the inclusion of vulnerable populations is ethically and scientifically appropriate.
- Whether the proposed plans, including the settings and circumstances for the identification and recruitment of subjects, and for obtaining consent or parental permission, ensure equitable selection of subjects and promote voluntariness.
- Whether the proposed research confers any direct benefit, whether the benefit is available outside of the research, and whether access to the benefit may unduly influence participation by vulnerable populations.
- Whether any costs or plans for subject reimbursement or compensation may exclude or unduly influence participation by vulnerable populations.
- Whether the provisions for privacy and confidentiality adequately protect vulnerable populations.
- Other relevant considerations as appropriate for the population(s) and the circumstances of the research.

Pregnant Women, Human Fetuses, and Neonates

Research involving pregnant women, human fetuses, and neonates is regulated through 45CFR46 Part B.

Children

Research involving children is regulated through 45 CFR 46 Part C.

Prisoners

Research involving prisoners is regulated through 45 CFR 46 Part D.

Other Potentially Vulnerable Populations

Other potentially vulnerable populations include (but are not limited to) adults with diminished decision-making capacity, employees, students, refugees, undocumented workers, and mental health patients under involuntary holds.

9. REPORTING REQUIREMENTS

The PI shall submit an Incident Report through the Cayuse Human Ethics Platform in the event of any unanticipated problems, adverse events, or complaints by subjects. Any member of the community may report the occurrence of noncompliance, deviation from the research protocol, or other concerns. All reports will be evaluated and investigated by the IRB Chair to determine the level of seriousness and the appropriate institutional response.

Unanticipated Problems and/or Adverse Events

If necessary, the IRB may instruct the PI to discontinue all research activities until the investigation is complete. The IRB Chair, IO, and Director of Research and Scholarly Activity will be notified, as well as federal Department or Agency Heads (as appropriate). An examination of the incident, along with the purpose of the study, the consent form, the method of recruitment, and all other study-related materials, will be necessary to determine the best course of corrective action. The PI is required to submit documents that the IRB deems essential to complete this examination.

Serious Noncompliance

Noncompliance is defined as the failure to follow federal, state, or local regulations governing human subject research, institutional policies related to human subject research, or the requirements or determinations of the IRB. Noncompliance may be minor or sporadic, or it may be serious or continuing. Serious noncompliance is defined as noncompliance that, in the judgment of the convened IRB, creates an increase in risks to subjects, adversely affects the rights, welfare, or safety of subjects, or adversely affects the scientific integrity of the study. Willful violation of policies and/or federal regulations may also constitute serious noncompliance.

All incidents of noncompliance determined to be serious will be presented to the IRB, and the following steps will be taken:

- The IRB will discuss the incident to consider the potential risk to participants as well as whether the incident reflects continuing noncompliance and determine a corrective action plan.
- The corrective action plan will be sent in writing to the PI, the Director of Research and Scholarly Activity, and the IO.
- The appropriate regulatory agencies will be notified of the incident, as applicable.
- Documentation of the incident, the investigation, and the resolution will be maintained within the appropriate IRB file.

Non-Serious Issues

If an incidence is deemed to be non-serious in nature, the following steps will be taken.

- The IRB Chair will recommend a corrective action plan.
- The corrective action plan will be sent in writing to the Investigator.
- Documentation of the incident, results of an investigation, and the resolution will be maintained within the appropriate IRB file.

10. APPEAL OF IRB DECISIONS

When an IRB disapproves or defers a research study, the IRB will notify the PI in writing about the specific deficiencies and the modifications that are necessary for appropriate IRB approval. The IRB shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. Similarly, when research is suspended in part or in full, or terminated, the IRB will notify the PI in writing of the suspension or termination and the reasons for its decision. The PI may ask that the decision be reconsidered by submitting a request in writing to the IRB Chair. The request must contain the basis for the appeal, including any substantive new information that the Board did not have the opportunity to consider previously. The request will be reviewed at a convened IRB meeting, and the PI will be invited to attend the meeting. However, the PI will not be present when the IRB votes.

11. CONFLICTS OF INTEREST (COI)

Investigators

All members of a research team must rigorously guard against conflicts of interest. A conflict of interest can be defined as a set of conditions in which a researcher's judgment concerning a primary interest (e.g., subject welfare, integrity of research) could be biased by a secondary interest (e.g., personal or financial gain).[5] The IRB has several options for managing investigator conflict of interest, including the following:

- Requiring disclosure of the COI to subjects through the consent process.
- Prohibit conflicted investigators from having any involvement in the study
- Prohibit conflicted investigators from participating in key components of the study– for example, the consent process, evaluation of inclusion criteria, specific procedures, and overall data analysis.
- Require a person who is not connected in any way to the investigator or study sponsor to act as a subject advocate during the initial and ongoing consent process.

All members of a research team must complete a COI form as part of the submission process. Conflicts of interest would include (but not be limited to) an investigator or an investigator's spouse/domestic partner or first-degree relative of an investigator who:

[5]*Adapted from: Amdur, Robert J., and Elizabeth A. Bankert. Institutional Review Board: Member Handbook, Jones & Bartlett Learning, LLC, 2021. ProQuest Ebook Central, http://ebookcentral.proquest.com/lib/tcsesl/detail.action?docID=6407908. Created from tcsesl on 2022-07-22 18:44:35.*

- Holds a significant financial interest, defined as any equity (stock, stock options) interests exceeding $5,000, intellectual property rights, patents, or royalties related to the outcome of the study, in an entity that is funding a project under review.
- Holds a significant financial interest in an entity that competes with another entity that is funding a project under review.
- Acts as an officer or director of the entity that is funding a project under review.
- Accepts any significant gifts such as hotel accommodations, airline tickets, services, or property by any entity funding a project under review.

IRB Members

Conflicts of interest may arise from time to time among IRB members. IRB members and staff must disclose situations that involve conflict of interest. Conflicts of interest would include (but not be limited to) reviewing or managing projects involving an IRB member and/or the spouse/domestic partner or first-degree relative of an IRB member who:

- Is listed as a PI or co-PI on a project under review.
- Provides support on a project under review.
- Holds a significant financial interest, defined as any equity (stock, stock options) interests exceeding $5,000, intellectual property rights, patents, or royalties related to the outcome of the study, in an entity that is funding a project under review.
- Holds a significant financial interest in an entity that competes with another entity that is funding a project under review.
- Acts as an officer or director of the entity that is funding a project under review.
- Has an amorous or sexual relationship with any person in the role of PI, co-PI, or investigator.
- Accepts any significant gifts such as hotel accommodations, airline tickets, services, or property by any entity funding a project under review.

IRB members shall inform the IRB Chair of any COI and refrain from discussing or voting on a proposal in which the IRB member is conflicted.

12. TRAINING

IRB Members

Prior to participation in any IRB meetings, all IRB members must complete CITI Human Subjects Protection Training and other relevant training on human subjects protection, as appropriate. Documentation of completed training must be maintained. Training must be repeated at least every two years.

Investigators

Prior to submission of any study to the IRB, all research team members must complete CITI Human Subjects Protection training and documentation of completion must be included in the IRB application. Approval of research projects will not be issued until documentation of training has been received by the Office of the Director for Research and Scholarly Activity for all research team members. Training must be repeated at least every two years.

13. CASE STUDY AND REPORTS POLICY

Policy Statement

KHSU-KansasCOM does not require IRB review of Single Case Reports or Case Series Reports consisting of three or fewer cases because these activities do not meet the federal definition of research subject to IRB review. This condition is true so long as the subject's identity cannot be discerned and does not involve at-risk or special populations or vulnerable adults.

Purpose

The purpose of this policy is to communicate to students, faculty, and outside participants in research the role of the IRB regarding Case Studies, Single Case Reports, or Case Series Reports.

Applicability

This IRB Case Study Policy applies to all KHSU-KansasCOM students, faculty, participating investigators, and research team members.

This policy applies to research that falls under the auspices of KHSU-KansasCOM, including research that is conducted at the Institution, under the direction of any Institution employee or agent (including students) in relation to their Institutional responsibilities, by or under the direction of any Institution employee or agent (including students) that uses any facility or property belonging to the Institution, and/or involving KHSU-KansasCOM's private or proprietary information to identify or contact human persons.

Procedures

Single Case Reports or Case Series Reports consisting of three or fewer cases do not meet the federal definition of research and do not require IRB review.

Single Case Reports or Case Series Reports not subject to IRB review must not:

- Include any dates (save the year) regarding an individual, including birth, admission, discharge, or death dates.
- Include any reference to a geographic location smaller than a state or province.
- Include any HIPAA-protected or personally identifiable information.
- Include members of any vulnerable group, including Pregnant women, human fetuses, neonates, prisoners, children, or adults with diminished capacity to provide consent.

Single Case Experiments and Single Case Series resulting in generalizable data are not covered by this exemption and do fall under the jurisdiction of the IRB.

14. THE BELMONT REPORT

Ethical Principles & Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes [1] intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized, and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

A. Boundaries Between Practice and Research

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment, or therapy to particular individuals [2]. By contrast, the term "research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is “experimental,” in the sense of new, untested, or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project [3].

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

B. Basic Ethical Principles

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human

actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence, and justice.

1. Respect for Persons: Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

   An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show a lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment when there are no compelling reasons to do so.

   However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

   Some persons are in need of extensive protection, even to the point of excluding them from activities that may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequences. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

   In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, the application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions, they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. Beneficence: Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood, in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of

beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful, and in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will, in fact, benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer-term benefits and risks that may result from the improvement of knowledge and the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined, justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children -- even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that, on closer investigation, turn out to be dangerous. But, the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. Justice: Who ought to receive the benefits of research and bear its burdens? This is a question of justice in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal, and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and

benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation, and political representation. Until recently, these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries, the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940s, the Tuskegee syphilis study used disadvantaged, rural Black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

C. Applications

Applications of the general principles to the conduct of research lead to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. Informed Consent: Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

   While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension, and voluntariness.

   Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include the research procedure, its purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been

proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that (1) incomplete disclosure is truly necessary to accomplish the goals of the research, (2) there are no undisclosed risks to subjects that are more than minimal, and (3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension. The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration, or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity, and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provisions may need to be made when comprehension is severely limited – for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disabled

patients, the terminally ill, and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose, to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored unless the research entails providing them with a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

2. Assessment of Risks and Benefits: The assessment of risks and benefits requires a careful array of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about the proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist in the determination of whether or not to participate.

   The Nature and Scope of Risks and Benefits. The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to the possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Unlike "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to the probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harm to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may, on some occasions, be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against the risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

The Systematic Assessment of Risks and Benefits. It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation, and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability, and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risks. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations: (i) Brutal or inhumane treatment of human subjects is never morally justified. (ii) Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is, in fact, necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. (iii) When research involves a

significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject -- or, in some rare cases, to the manifest voluntariness of the participation). (iv) When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. (v) Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

3. Selection of Subjects: Just as the principle of respect for persons finds expression in the requirements for consent and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

   Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness; thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

   Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus, injustice arises from social, racial, sexual, and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to ensure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

   Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

   One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized, may continually be sought as research subjects, owing to their

ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience or because they are easy to manipulate as a result of their illness or socioeconomic condition.

[1] Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

[2] Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants), or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or group of individuals; thus, it is practice and need not be reviewed as research.

[3] Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies.

15. FEDERAL REGULATIONS (45CFR 46)

Subpart A. Basic HHS Policy for Protection of Human Research Subjects

§46.101 To what does this policy apply?

§46.102 Definitions for purposes of this policy.

§46.103 Assuring compliance with this policy--research conducted or supported by any Federal department or agency.

§46.104 Exempt research.

§46.105 [Reserved]

§46.106 [Reserved]

§46.107 IRB membership.

§46.108 IRB functions and operations.

§46.109 IRB review of research.

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

§46.111 Criteria for IRB approval of research.

§46.112 Review by Institution.

§46.113 Suspension or Termination of IRB Approval of Research.

§46.114 Cooperative Research.

§46.115 IRB Records.

§46.116 General Requirements for Informed Consent.

§46.117 Documentation of informed consent.

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.

§46.119 Research undertaken without the intention of involving human subjects.

§46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.

§46.121 [Reserved]

§46.122 Use of Federal funds.

§46.123 Early termination of research support: Evaluation of applications and proposals.

§46.124 Conditions.

Subpart B. Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research

§46.201 To what do these regulations apply?

§46.202 Definitions.

§46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

§46.204 Research involving pregnant women or fetuses.

§46.205 Research involving neonates.

§46.206 Research involving, after delivery, the placenta, the dead fetus, or fetal material.

§46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

§46.301 Applicability

§46.302 Purpose.

§46.303 Definitions.

§46.304 Composition of Institutional Review Boards where prisoners are involved.

§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

§46.306 Permitted research involving prisoners.

Subpart D: Additional Protections for Children Involved as Subjects in Research

§46.401 To what do these regulations apply?

§46.402 Definitions.

§46.403 IRB duties.

§46.404 Research not involving greater than minimal risk.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

§46.408 Requirements for permission by parents or guardians and for assent by children.

§46.409 Wards.

16. IRB TEMPLATES

A. Informed Consent Template

Consent to Participate in a Research Study

*[**General Note**: This model consent form may be used as a general template for researchers in drafting participant consent forms for specific research studies. Researchers may adapt this template to fit the needs of the specific research studies they are conducting, but they are responsible for ensuring the consent forms contain all necessary information and comply with relevant laws and regulations, including the Office for Human Research Protections' informed consent requirements (45 CFR 46.116). Required statements are included in black type.] "Investigator" may refer to the PI or another designated representative of the research project. "Participant" may refer to either the participant or a Legally Authorized Representative.*

Title of Study: *[insert study title]*

Principal Investigator*: [name of PI]*

Investigators: *[List all researchers involved in this study with their academic titles/degrees.]*

Contact Information: *[name, phone, email for whom to contact with questions. You may list separate contacts for whom to contact with questions about the project or this consent form and whom to contact in the event of a research-related injury. You must also provide this contact information in relevant sections of this document.]*

_____	**Purpose**	_____
Participant's Initials		*Investigator's Initials*

[Explain in plain language, at a sixth-grade reading level, that this is a research study and the purpose of the research study. If participants are not native English speakers, all consent materials must be communicated in a language participants understand.]

_____	**Procedures**	_____
Participant's Initials		*Investigator's Initials*

[Explain in plain language at a sixth-grade reading level:

1. *Describe the subject's participation in the study.*
2. *Where the research-related activities will take place.*
3. *The approximate number of subjects involved in the study.*
4. *Describe any procedures that are experimental.*
5. *If there will be audio or video recordings.*
6. *A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.*
7. *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
8. *If appropriate, whether deception will be part of the experimental protocol.*
9. *If appropriate, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*

Length of Study

Participant's Initials *Investigator's Initials*

[Provide an estimate of the length of time the participant will contribute or be expected to participate.]

Risks or Discomforts

Participant's Initials *Investigator's Initials*

[Describe any reasonably foreseeable risks, inconveniences, or discomforts the participant may experience. Indicate that some risks may be unforeseeable. Risks include physical risks and psychosocial risks. Explain the severity and likelihood of each risk. Indicate if there are any risks to fetuses or embryos, if the subject is pregnant or may become pregnant.]

[Indicate the researcher may terminate participation without the subject's consent and what circumstances would warrant termination of participation.]

[If appropriate, describe any risks to the subject for withdrawing from the project and the procedures for orderly termination of participation by the subject.]

[If the project entails only minimal risks, include the statement:]

This study involves only minimal risk. 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.

_____	**Benefits**	_____
Participant's Initials		*Investigator's Initials*

[Detail potential benefits to the individual subject as well as potential benefits to others.]

_____	**Alternative Methods**	_____
Participant's Initials		*Investigator's Initials*

[If the research pertains to treatment for any condition, describe any appropriate alternative procedures or courses of treatment (if any) that may be advantageous to the participant. This section may be removed in cases where it does not apply.]

_____	**Confidentiality of Records**	_____
Participant's Initials		*Investigator's Initials*

You understand that the research study results may be published but that your name or identity will not be revealed and that your records will remain confidential.

[If you plan to quote individual participants or identify them by name, revise this point appropriately.]

[*Describe the specific procedure for maintaining the subject's confidentiality. Indicate specifically how the investigator will keep the names of subjects confidential, the use of subject identifiers (codes), and how this information will be secured, for example, by a password-protected computer. If tape recordings or videotapes are made, if they will be used for educational purposes, and when they will be erased.*].

The data will be available only to those persons who have a job-related need to know, such as researchers, members of the Institutional Review Board (who protect human subjects of research), or regulatory personnel who oversee research.

Compensation

Participant's Initials *Investigator's Initials*

[Describe any compensation or incentives for participating in the project. Include the amount of compensation if the subject withdraws from the study. Indicate if there are any costs to the subject for participating in the study. Indicate whether the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit]

*If there is no compensation, this section should state, "*You will not receive any compensation or incentives for participating in this voluntary study.*"*

Treatment for Research-Related Injury

Participant's Initials *Investigator's Initials*

[[For studies that include more than minimal risk, including psychosocial, financial, or physical risk, and for any activity that includes physical activity, the following language must be present:]

Kansas Health Science University will not provide medical treatment or other forms of reimbursement to persons injured as a result of or in connection with participation in research activities conducted by Kansas Health Science University or its faculty, staff, or students. If you believe that you have been injured as a result of participating in the research covered by this consent form, you can contact _____. If you need immediate medical care, you should contact your physician or seek treatment at an emergency medical facility.

Voluntary Nature of the Study

Participant's Initials *Investigator's Initials*

Your participation in this study is purely voluntary. Your decision on whether to participate will not affect your relationships with Kansas Health Science University *[and/or insert name of any other cooperating institution],* nor will there be any penalty or loss of benefits to which you are otherwise entitled. If you choose to participate in this study, **you are free to withdraw at any time** without affecting those relationships and without penalty or loss of benefits to which you may otherwise be entitled.

Collection of Identifiable Private Information or Biospecimens

Participant's Initials *Investigator's Initials*

[If information may be used in future research:]

This study will collect identifiable private information or biospecimens. Identifiers might be removed from the identifiable private information or identifiable biospecimens. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

[If information will not be used in future research:]

This study will collect identifiable private information or biospecimens. Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Research Sponsors

Participant's Initials *Investigator's Initials*

[For studies supported by an outside party, the researcher must disclose the funding entity and include information about the financial arrangement and how it is being managed. If there are no sponsors, this section may be eliminated.]

Whom to Contact

Participant's Initials *Investigator's Initials*

You may ask any questions you have now. If you have questions later, **you are encouraged** to contact *[include name, telephone number, and email]*.

[For studies undertaken by students, include:]

You may also contact the researcher's supervisor at *[include name, telephone number, and email:]*_____.

In the event of research-related harm, you can contact *[name, telephone number, and email]*.

If you have questions about the study or your rights as a participant, but do not feel comfortable talking with the researcher(s), you may contact the chairperson of the Institutional Review Board (IRB) at Kansas Health Science University. You may contact David Shubert at Kansas Health Science University, 217 E. Douglas, Wichita, KS 67202; telephone 316-315-5467.

You will be given a copy of this information for your records.

Statement of Consent

I have read the above statement. I have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I have been given sufficient time to consider whether or not to participate in this study. I believe that I understand the purpose of the study as well as the potential benefits and risks that are involved. I hereby give my informed and free consent to be a participant in this study.

Participant Name (please print) _____

_____ _____

Signature of Participant Date

I certify that I have explained to the above individual the nature and purpose, potential benefits, and possible risks associated with participation in this research study, answered any questions raised, and witnessed the above signature. I have provided the subject with a copy of this signed consent document.

_____ _____

Signature of Investigator Date

Please submit all material in original, plus three copies to the KHSU IRB.

Informed Consent Evaluation Checklist			
Informed Consent Criterion	Meets Requirements in 45CFR46 116(b)(c)		Comments
116(a)(3) Language is clear and understandable to prospective subjects.	YES	NO	
116(a)(2) Informed consent process allows sufficient time to discuss and consider whether or not to participate and minimizes the possibility of coercion or undue influence.	YES	NO	
116(b)(1) Clear statement purpose of research, that project is research, expected duration, description of procedures, and identification of any experimental procedures.	YES	NO	
116(b)(2) Description of reasonably foreseeable risks or discomfort to the subject.	YES	NO	
116(b)(3) Description of reasonably expected benefits to the subject or to others.	YES	NO	
116(b)(4) Disclosure of alternative procedures or treatments that might be advantageous to the subject.	YES	NO	
116(b)(5) Description of how the confidentiality of the subject will be maintained.	YES	NO	
116(b)(6) Explanation of any compensation, including medical treatments.	YES	NO	
116(b)(7) Contact information for answers to questions about the project and whom to contact in the event of a research-related injury.	YES	NO	
116(b)(8) Statements that participation is voluntary, there is no penalty for refusing to participate, and subjects have the right to withdraw from the project at any time without penalty.	YES	NO	

116(b)(9) Statement that identifiers might be removed and the information/biospecimens might be used for future research; Or Statement that information/biospecimens will not be used for future research.	YES	NO	
116(c)(1) Statement that the treatment or procedure may include unforeseeable risks to the subject (or fetus or embryo).	YES	NO	
116(c)(2) Circumstances in which the subject's participation may be terminated by the investigator.	YES	NO	
116(c)(3) Disclosure of any costs to the subject.	YES	NO	
116(c)(4) Consequences (not penalties) for the subject's decision to withdraw from the research project and process or orderly termination of participation.	YES	NO	
116(c)(5) Statement that new findings may relate to the subject's willingness to participate will be provided to the subject.	YES	NO	
116(c)(6) Approximate number of subjects participating in the project.	YES	NO	
116(c)(7) If biospecimens may be used for commercial profit.	YES	NO	
116(c)(8) Whether clinically relevant research results will be disclosed to subjects.	YES	NO	
116(c)(9) Whether the research includes whole genome sequencing.	YES	NO	

B. Broad Consent Template

Broad Consent for the Storage, Maintenance, and Secondary Research Use of Identifiable Private Information or Identifiable Biospecimens

*[**General Note**: This model consent form may be used as a general template for researchers in drafting participant broad consent forms for storage, maintenance, and secondary research of identifiable private information/biospecimens (collected for either research studies other than the proposed research or nonresearch purposes). Researchers may adapt this template to fit the needs of the specific research studies they are conducting, but they are responsible for ensuring the consent forms contain all necessary information and comply with relevant laws and regulations, including the Office for Human Research Protections' informed consent requirements (45 CFR 46.116(d)). Required statements are included in black type]. "Investigator" may refer to the PI or another designated representative of the research project. "Participant" may refer to either the participant or a Legally Authorized Representative.*

Title of Study: *[insert study title]*

Principal Investigator*: [name of PI]*

Investigators: *[List all researchers involved in this study with their academic titles/degrees.]*

Contact Information: *[name, phone, email for whom to contact with questions. You may list separate contacts for whom to contact with questions about the project or this consent form and whom to contact in the event of a research-related injury. You must also provide this contact information in relevant sections of this document.]*

_____		_____
Participant's Initials	**Purpose**	*Investigator's Initials*

[Explain in plain language, at a sixth-grade reading level, that this is a research study. Include a general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted. If participants are not native English speakers, all consent materials must be communicated in a language participants understand.] If appropriate, whether potential research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.]

Participant's Initials	**Types of Samples**	*Investigator's Initials*

[Describe the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens.]

Participant's Initials	**Risks or Discomforts**	*Investigator's Initials*

[Describe any reasonably foreseeable risks, inconveniences, or discomforts the participant may experience. Indicate that some risks may be unforeseeable. Risks include physical risks and psychosocial risks. Explain the severity and likelihood of each risk. Indicate if there are any risks to fetuses or embryos, if the subject is pregnant or may become pregnant.]

[Indicate the researcher may terminate participation without the subject's consent and what circumstances would warrant termination of participation.]

[If appropriate, describe any risks to the subject for withdrawing from the project and the procedures for orderly termination of participation by the subject.]

[If the project entails only minimal risks, include the statement:]

This study involves only minimal risk. 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.

Participant's Initials	**Timeline**	*Investigator's Initials*

*[*Describe the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite) and the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite).]

Participant's Initials	**Benefits**	*Investigator's Initials*

[Detail potential benefits to the individual subject as well as potential benefits to others.]

Participant's Initials	**Details of Research Studies**	*Investigator's Initials*

[Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies.]

Participant's Initials	**Feedback to Subjects**	*Investigator's Initials*

[Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject. Feedback may be impossible if the data has been de-identified.]

Participant's Initials	**Confidentiality of Records**	*Investigator's Initials*

You understand that the research study results may be published but that your name or identity will not be revealed and that your records will remain confidential.

[If you plan to quote individual participants or identify them by name, revise this point appropriately.]

[*Describe the specific procedure for maintaining the subject's confidentiality. Indicate specifically how the investigator will keep the names of subjects confidential, the use of subject identifiers (codes), and how this information will be secured, for example, by a password-protected*

computer. If tape recordings or videotapes are made, if they will be used for educational purposes, and when they will be erased.].

The data will be available only to those persons who have a job-related need to know, such as researchers, members of the Institutional Review Board (who protect human subjects of research), or regulatory personnel who oversee research.

Participant's Initials	**Commercial Use**	*Investigator's Initials*

[Indicate whether the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit]

*If there is no compensation, this section should state, "*You will not receive any compensation or incentives for participating in this voluntary study.*"*

Participant's Initials	**Treatment for Research-Related Injury**	*Investigator's Initials*

[[For studies that include more than minimal risk, including psychosocial, financial, or physical risk, and for any activity that includes physical activity, the following language must be present:]

Kansas Health Science University will not provide medical treatment or other forms of reimbursement to persons injured as a result of or in connection with participation in research activities conducted by Kansas Health Science University or its faculty, staff, or students. If you believe that you have been injured as a result of participating in the research covered by this consent form, you can contact *(name, email, phone number)*. If you need immediate medical care, you should contact your physician or seek treatment at an emergency medical facility.

Participant's Initials	**Voluntary Nature of the Study**	*Investigator's Initials*

Your participation in this study is purely voluntary. Your decision on whether to participate will not affect your relationships with Kansas Health Science University *[and/or insert name of any other cooperating institution],* nor will there be any penalty or loss of benefits to which you are otherwise entitled. If you choose to participate in this study, **you are free to withdraw at any**

time without affecting those relationships and without penalty or loss of benefits to which you may otherwise be entitled.

Participant's Initials	**Collection of Identifiable Private Information or Biospecimens**	*Investigator's Initials*

This study will collect identifiable private information or biospecimens. Identifiers might be removed from the identifiable private information or identifiable biospecimens. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Participant's Initials	**Whom to Contact**	*Investigator's Initials*

You may ask any questions about your rights and about the storage and use of your identifiable private information or identifiable biospecimens. If you have questions later, **you are encouraged** to contact *[name, telephone number, and email]*.

[For studies conducted by students, include:]

You may also contact the researcher's supervisor at *[name, telephone number, and email].*

In the event of research-related harm, you can contact *[name, telephone number, and email]*.

If you have questions about the study or your rights as a participant, but do not feel comfortable talking with the researcher(s), you may contact the chairperson of the Institutional Review Board (IRB) at Kansas Health Science University. You may contact David Shubert at Kansas Health Science University, 221 S. Topeka, Wichita, KS 67202; telephone 316-315-5476.

You will be given a copy of this information for your records.

Statement of Consent

I have read the above statement. I have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I have been given sufficient time to consider whether or not to participate in this study. I hereby give my informed and free consent to be a participant in this study.

Participant Name (please print) _____

_____ _____

Signature of Subject Date

I certify that I have explained to the above individual the nature and purpose and the possible risks associated with participation in this research study, answered any questions raised, and witnessed the above signature. I have provided the subject with a copy of this signed consent document.

_____ _____

Signature of Investigator Date

Please submit all material in original, plus three copies to the KHSU IRB.

Broad Consent Evaluation Checklist			
Broad Consent Criterion	Meets Requirements in 45CFR46 116(a)(b)(c)(d)		Comments
116(a)(3) Language is clear and understandable to prospective subjects.	YES	NO	
116(a)(2) Informed consent process allows sufficient time to discuss and consider whether or not to participate and minimizes the possibility of coercion or undue influence.	YES	NO	
116(a)(4) Provides information about the study that a reasonable person would want to have.	YES	NO	
116(d)3. A description of the identifiable private information/biospecimens that might be used in research, whether sharing might occur, and the types of institutions or researchers that might be conducted.	YES	NO	
116(c)9. Whether the research includes whole genome sequencing.	YES	NO	
116(d)2. General description of the types of research that may be conducted.	YES	NO	
116(b)(2) Description of reasonably foreseeable risks or discomforts to the subject.	YES	NO	
116(d)4. A description of the period of time that the identifiable private information/biospecimens may be stored and maintained and a description of the period of time that the identifiable private information/biospecimens may be used (which period of time could be indefinite).	YES	NO	
116(b)(3) Description of reasonably expected benefits to the subject or to others.	YES	NO	

116(d)5. Whether subjects will be provided details about specific research studies, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies.	YES	NO	
116(d)6. Whether clinically relevant research results, including individual research results, will be disclosed to the subject.	YES	NO	
116(b)(5) Description of how the confidentiality of the subject will be maintained.	YES	NO	
116(c)(7) If biospecimens may be used for commercial profit.	YES	NO	
116(d)7. An explanation of whom to contact for answers to questions and whom to contact in the event of research-related harm.	YES	NO	
116(b)(8) Statements that participation is voluntary and subjects have the right to withdraw.	YES	NO	

C. Child's Assent Form

Child's Assent to Participate in a Research Project

Title of Study: *[insert study title]*

Principal Investigator*: [name of PI]*

Investigators: *[List all researchers involved in this study with their academic titles/degrees.]*

Contact Information: *[name, phone, email for whom to contact with questions. You may list separate contacts for whom to contact with questions about the project or this consent form and whom to contact in the event of a research-related injury. You must also provide this contact information in relevant sections of this document.]*

WHAT IS RESEARCH?

We are asking you to be part of a research study. Research is a way to test new ideas. Research helps us learn new things. Being in research is your choice. You can say Yes or No. Whatever you decide is okay. No one will be mad at you if you say No.

WHY ARE WE DOING THIS RESEARCH?
[Provide an age-appropriate description of the research project]

WHAT WILL HAPPEN IN THE RESEARCH?
[Provide an age-appropriate description of what the subject can expect to experience]

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?
[Provide an age-appropriate description of potential benefits]

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?
[Provide an age-appropriate description of potential risks and how the researchers will mitigate/minimize potential risks.]

WHAT ELSE SHOULD YOU KNOW ABOUT THE RESEARCH?

- Being in the research is your choice. You can say Yes or No. It is okay to say No. No one will be mad at you if you decide to say No.
- If you say Yes now and change your mind later, that is also okay. You can stop being in the research at any time. If you want to stop being in the research, all you have to do is tell us.
- Take all the time you need to make your choice. Ask us any questions you have.
- It is also okay to ask more questions after you decide to be in the research. You can ask *[Principal Investigator]* questions at any time.
- This study has been okayed by the Kansas Health Science University Institutional Review Board (a group that is there to make sure you are safe). If you have any questions or worries while you are in this research, you may talk to your parents, and they can talk to

[Principal Investigator]. They can also talk to David Shubert, who is the Chair of the Institutional Review Board, at 316-315-5476 or e-mail at dshubert@kansashsc.org

Your parents can keep a copy of this paper.

CHILD'S ASSENT

After you have read this form and talked about this research with your parents and you decide that you want to be in this research, please sign or write your name below.

Research Subject	Date

PARENTAL PERMISSION

Parent/Guardian 1	Date
Parent/Guardian 2	Date

I have explained this assent form with *[Child's Name]* and answered all of their questions. I witnessed the above signatures. I have provided the subject with a copy of this signed assent document.

Investigator	Date

Please submit all material in original, plus three copies to the KHSU IRB.

D. Parental Permission Form Template

Parental Permission to Participate in a Research Study

*[**General Note**: This model consent form may be used as a general template for researchers in drafting participant consent forms for specific research studies. Researchers may adapt this template to fit the needs of the specific research studies they are conducting, but they are responsible for ensuring the consent forms contain all necessary information and comply with relevant laws and regulations, including the Office for Human Research Protections' informed consent requirements (45 CFR 46.116). Required statements are included in black type.]*

Title of Study: *[insert study title]*

Principal Investigator*: [name of PI]*

Investigators: *[List all researchers involved in this study with their academic titles/degrees.]*

Contact Information: *[name, phone, email for whom to contact with questions. You may list separate contacts for whom to contact with questions about the project or this consent form and whom to contact in the event of a research-related injury. You must also provide this contact information in relevant sections of this document.]*

_____	**Purpose**	_____
Parent/Guardian's Initials		*Investigator's Initials*

[Explain in plain language, at a sixth-grade reading level, that this is a research study and the purpose of the research study. If participants are not native English speakers, all consent materials must be communicated in a language participants understand.]

_____	**Procedures**	_____
Parent/Guardian's Initials		*Investigator's Initials*

[Explain in plain language at a sixth-grade reading level:

1. *Describe the subject's participation in the study.*
2. *Where the research-related activities will take place.*
3. *The approximate number of subjects involved in the study.*
4. *Describe any procedures that are experimental.*

5. *If there will be audio or video recordings.*
6. *A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.*
7. *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
8. *If appropriate, whether deception will be part of the experimental protocol.*
9. *If appropriate, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*

Length of Study

Parent/Guardian's Initials *Investigator's Initials*

[Provide an estimate of the length of time the participant will contribute or be expected to participate.]

Risks or Discomforts

Parent/Guardian's Initials *Investigator's Initials*

[Describe any reasonably foreseeable risks, inconveniences, or discomforts the participant may experience. Indicate that some risks may be unforeseeable. Risks include physical risks and psychosocial risks. Explain the severity and likelihood of each risk. Indicate if there are any risks to fetuses or embryos, if the subject is pregnant or may become pregnant.]

[Indicate the researcher may terminate participation without the subject's consent and what circumstances would warrant termination of participation.]

[If appropriate, describe any risks to the subject for withdrawing from the project and the procedures for orderly termination of participation by the subject.]

[If the project entails only minimal risks, include the statement:]

This study involves only minimal risk. 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.

_____	**Benefits**	_____
Parent/Guardian's Initials		*Investigator's Initials*

[Detail potential benefits to the individual subject as well as potential benefits to others.]

_____	**Alternative Methods**	_____
Parent/Guardian's Initials		*Investigator's Initials*

[If the research pertains to treatment for any condition, describe any appropriate alternative procedures or courses of treatment (if any) that may be advantageous to the participant. This section may be removed in cases where it does not apply.]

_____	**Confidentiality of Records**	_____
Parent/Guardian's Initials		*Investigator's Initials*

You understand that the research study results may be published but that your name or identity will not be revealed and that your records will remain confidential.

[If you plan to quote individual participants or identify them by name, revise this point appropriately.]

[*Describe the specific procedure for maintaining the subject's confidentiality. Indicate specifically how the investigator will keep the names of subjects confidential, the use of subject identifiers (codes), and how this information will be secured, for example, by a password-protected computer. If tape recordings or videotapes are made, if they will be used for educational purposes, and when they will be erased.*].

The data will be available only to those persons who have a job-related need to know, such as researchers, members of the Institutional Review Board (who protect human subjects of research), or regulatory personnel who oversee research.

Compensation

Parent/Guardian's Initials *Investigator's Initials*

[Describe any compensation or incentives for participating in the project. Include the amount of compensation if the subject withdraws from the study. Indicate if there are any costs to the subject for participating in the study. Indicate whether the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit]

*If there is no compensation, this section should state, "*You will not receive any compensation or incentives for participating in this voluntary study.*"*

Treatment for Research-Related Injury

Parent/Guardian's Initials *Investigator's Initials*

[[For studies that include more than minimal risk, including psychosocial, financial, or physical risk, and for any activity that includes physical activity, the following language must be present:]

Kansas Health Science University will not provide medical treatment or other forms of reimbursement to persons injured as a result of or in connection with participation in research activities conducted by Kansas Health Science University or its faculty, staff, or students. If you believe that you have been injured as a result of participating in the research covered by this consent form, you can contact _____.

Voluntary Nature of the Study

Parent/Guardian's Initials *Investigator's Initials*

Your participation in this study is purely voluntary. Your decision on whether to participate will not affect your relationships with Kansas Health Science University *[and/or insert name of any other cooperating institution],* nor will there be any penalty or loss of benefits to which you are otherwise entitled. If you choose to participate in this study, **you are free to withdraw at any time** without affecting those relationships and without penalty or loss of benefits to which you may otherwise be entitled.

Collection of Identifiable Private Information or Biospecimens

Parent/Guardian's Initials *Investigator's Initials*

[If information may be used in future research:]

This study will collect identifiable private information or biospecimens. Identifiers might be removed from the identifiable private information or identifiable biospecimens. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

[If information will not be used in future research:]

This study will collect identifiable private information or biospecimens. Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Research Sponsors

Parent/Guardian's Initials *Investigator's Initials*

[For studies supported by an outside party, the researcher must disclose the funding entity and include information about the financial arrangement and how it is being managed. If there are no sponsors, this section may be eliminated.]

Whom to Contact

Parent/Guardian's Initials *Investigator's Initials*

You may ask any questions you have now. If you have questions later, **you are encouraged** to contact *[include name, telephone number, and email]*.

[For studies undertaken by students, include:]

You may also contact the researcher's supervisor at *[include name, telephone number, and email:]*_____.

In the event of research-related harm, you can contact *[name, telephone number, and email]*.

If you have questions about the study or your rights as a participant, but do not feel comfortable talking with the researcher(s), you may contact the chairperson of the Institutional Review Board (IRB) at Kansas Health Science University. You may contact David Shubert at Kansas Health Science University, 221 S. Topeka, Wichita, KS 67202; telephone 316-315-5476.

You will be given a copy of this information for your records.

Statement of Permission

I have read the above statement. I have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I have been given sufficient time to consider whether or not to give permission for my child/ward to participate in this study. I believe that I understand the purpose of the study as well as the potential benefits and risks that are involved. I hereby give my permission for my child/ward to participate in this study.

Parent/Guardian 1 (sign)	Parent/Guardian 2 (sign)	Date

I certify that I have explained to the above individual the nature and purpose, potential benefits, and possible risks associated with participation in this research study, answered any questions raised, and witnessed the above signature. I have provided the subject with a copy of this signed consent document.

Signature of Investigator	Date

Please submit all material in original, plus three copies to the KHSU IRB.

Parental Permission Evaluation Checklist			
Informed Consent Criterion	Meets Requirements in 45CFR46 116(b)(c)		Comments
116(a)3. Language is clear and understandable to prospective subjects.	YES	NO	
116(a). Informed consent process allows the subject or LAR sufficient time to discuss and consider whether or not to participate in the project.	YES	NO	
116(b)1. Clear statement purpose of research, that project is research, expected duration, description of procedures, and identification of any experimental procedures.	YES	NO	
116(b)2. Description of reasonably foreseeable risks or discomfort to the subject.	YES	NO	
116(b)3. Description of reasonably expected benefits to the subject or to others.	YES	NO	
116(b)4. Disclosure of alternative procedures or treatments that might be advantageous to the subject.	YES	NO	
116(b)5. Description of how the confidentiality of the subject will be maintained.	YES	NO	
116(b)6. Explanation of any compensation, including medical treatments.	YES	NO	
116(b)7. Contact information for answers to questions about the project and whom to contact in the event of a research-related injury.	YES	NO	
116(b)8. Statements that participation is voluntary, there is no penalty for refusing to participate, and subjects have the right to withdraw from the project at any time without penalty.	YES	NO	
116(b)9. Statement that identifiers might be removed and the	YES	NO	

information/biospecimens might be used for future research; Or Statement that information/biospecimens will not be used for future research.			
116(c)1. Statement that the treatment or procedure may include unforeseeable risks to the subject (or fetus or embryo).	YES	NO	
116(c)2. Circumstances in which the subject's participation may be terminated by the investigator.	YES	NO	
116(c)3. Disclosure of any costs to the subject.	YES	NO	
116(c)4. Consequences (not penalties) for the subject's decision to withdraw from the research project and process or orderly termination of participation.	YES	NO	
116(c)5. Statement that new findings may relate to the subject's willingness to participate will be provided to the subject.	YES	NO	
116(c)6. Approximate number of subjects participating in the project.	YES	NO	
116(c)7. If biospecimens may be used for commercial profit.	YES	NO	
116(c)8. Whether clinically relevant research results will be disclosed to subjects.	YES	NO	
116(c)9. Whether the research includes whole genome sequencing.	YES	NO	

E. Conflict of Interest Template (Researcher)

Annual Researcher Conflict of Interest Disclosure Form

Name		**ACTIVE PROJECT Numbers**	
Work Phone		**Email**	

This form is to be completed annually by all active investigators and research staff. This form will be reviewed and retained in accordance with the KHSU-KansasCOM Institutional Review Board Policy.

Declaration of No Interests in External Entities

☐	No one in my household has any ownership, equity interest, financial support, property (including intellectual property), or relationships with an entity outside of Kansas Health Science University which may be perceived to create a conflict of interest for the human subjects research in which I am engaged in under the Kansas Health Science University Federal Wide Assurance ("FWA") on file with the U.S. Department of Health and Human Services ("HHS") Office for Human Research Protections ("OHRP"). (If this box is selected, skip to "Certification.")

General Disclosure of Interests in an External Entity

Check all of the applicable boxes that relate to your **present and past** relationships (for the previous 12 months).

Private Companies

☐	Someone in my household holds (or has held in the past 12 months) an equity interest, regardless of the value of the equity interest, of a non-publicly traded entity outside of the Kansas Health Science University, which may be perceived as creating a conflict of interest for the human subjects research in which I am engaged in under the Kansas Health Science University FWA.

☐	Someone in my household received (or has received in the past 12 months) financial support of $5,000 or more (aggregate for a 12-month period) from a non-publicly traded entity outside of the Kansas Health Science University which may be perceived to create a conflict of interest for the human subjects research in which I am engaged in under the Kansas Health Science University FWA. ***Note: This includes speaker or consulting fees, honoraria, paid authorship, etc., paid directly to you/your household; this does not include travel payment and/or reimbursement.***
☐	Someone in my household holds (or has held in the past 12 months) intellectual property rights or benefits with a non-publicly traded entity outside of the Kansas Health Science University, which may be perceived to create a conflict of interest for the human subjects research in which I am engaged in under the Kansas Health Science University FWA.
Publicly-Traded Companies	
☐	Someone in my household has (or has had in the past 12 months) a significant financial interest in a publicly traded company; this is **defined as a combined total of $5,000 or more in equity interest** (i.e., stock) **and financial support** (aggregate for a 12-month period) from a publicly traded entity outside of the Kansas Health Science University which may be perceived to create a conflict of interest for the human subjects research in which I am engaged in under the Kansas Health Science University FWA. ***Note: This does include speaker fees, honoraria, paid authorship, etc., paid directly to you/your household; this does not include travel payment and/or reimbursement.***
☐	Someone in my household holds (or has held in the past 12 months) intellectual property rights or benefits with a publicly traded entity outside of the Kansas Health Science University, which may be perceived to create a conflict of interest for the human subjects research in which I am engaged in under the Kansas Health Science University FWA.
Other	
☐	Someone in my household received (or has received in the past 12 months) sponsored or reimbursed travel expenses, regardless of the value of the travel, from an entity outside of the Kansas Health Science University, which may be perceived to create a conflict of interest for the human subjects research in which I am engaged in under the Kansas Health Science University FWA. ***Note: This includes pre-payment of travel by the external agency (based on fair market value estimates) and reimbursement of out-of-pocket travel***

	expenses paid directly to you/your household for speaking engagements, training, etc., including travel to Research Investigator Meetings.
☐	Someone in my household receives (or has received in the past 12 months) financial support related to human subjects research, regardless of the amount of compensation pledged or received from an entity outside of the Kansas Health Science University which may be perceived to create a conflict of interest for the human subjects research in which I am engaged in under the Kansas Health Science University FWA. ***Note: This includes incentive payments, bonus payments, or finders' fees; this does not include reimbursement of your salary expenses or professional medical services for your participation in the conduct of the research.***
☐	Someone in my household holds (or has held in the past 12 months) a management role (paid or unpaid) that allows for decision-making authority in an entity outside of the Kansas Health Science University, which may be perceived to create a conflict of interest for the human subjects research in which I am engaged in under the Kansas Health Science University FWA. ***Note: This does include administrative, scientific, or technical appointments.***

Declaration of Disclosure of Interests in an External Entity
For all of the boxes selected above ("General Disclosure of Interests in an External Entity"), detail the nature of the interest disclosed. Requested details include: the type of external entity (public/government, for-profit, non-profit); the business of the external entity; aggregate amount of compensation or fair market value of ownership/interest; details of travel (i.e., destination, method of travel; number of nights' lodging); a description of the potential for conflict and any mitigating/limiting factors of the relationship. Kansas Health Science University reserves the right to request additional details.
Potential Impacts
Please explain the impact, if any, your financial interests may have on your conduct of Kansas Health Science University research.

Plans to Mitigate
Please describe your plan for managing the potential conflict of your financial and research interests in order to help ensure that the protection and rights of research subjects are maintained.
Certification
I certify that the responses to the questions above are accurate and complete and that my responses constitute a full disclosure of any conflicting interests and activities that have the potential to affect the rights of human subjects involved in research, if any. I certify that I will disclose any conflicts of interest that arise during the course of the study as soon as reasonably possible, in addition to annually reporting such potential or actual conflicts of interest.

Signature		Date	

17. USEFUL CONTACTS

- Dr. Duane Brandau, Director of Research and Scholarly Activity
- Dr. David Shubert, IRB Chair
- Cayuse Human Ethics Platform. https://kansashsc.app.cayuse.com/
- CITI Training Modules. https://www.citiprogram.org/index.cfm?pageID=14&message=64#view

KANSAS HEALTH SCIENCE UNIVERSITY

KANSAS COLLEGE *of* OSTEOPATHIC MEDICINE