Kentucky State University (KSU)
Human Research Protection Program (HRPP)
Policies and Procedures

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professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Research does not include the following activities:

1) Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to

Procedures for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

Procedures for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB in accordance with federal regulations. Research that has been reviewed and approved by the IRB is subject to continuing IRB review and must be reevaluated at least annually or more frequently if needed.

III. COMPOSITION AND MANAGEMENT OF THE IRB

3.1 Appointment of Members

The IRB will be comprised of a minimum of five regular voting members qualified through experience and expertise to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. Members will include faculty and staff of the University, as well as members from outside the University. The Provost or President will appoint members to the IRB and will appoint the Chair of the IRB in consultation with OSP staff. OSP staff will not serve as regular voting members of the IRB, but can serve as alternate members under circumstances where an alternate is needed. The Chair should not be an OSP staff member. Members are appointed for one or two-year renewable terms and for a maximum appointment of six consecutive years.

3.2 Affiliations of Members

The IRB must include at least one member with each of the following primary affiliations: nonscientific, scientific, and nonaffiliated with KSU. Members with scientific affiliations are generally those individuals with training, background, and occupations in STEM fields, behavioral sciences, and health-related disciplines, and/or who conduct scientific research on a regular basis. Members with nonscientific affiliations are individuals with training, background, and occupations in the humanities, interpretive social sciences, and arts and/or who do not regularly conduct scientific and quantitative research. Nonaffiliated members may not be affiliated with KSU or be a part of the immediate family of a person who is affiliated with KSU. It is possible for a member to fill two roles; for example, a member could be otherwise unaffiliated with the institution and have a primary concern in a non-scientific area. This individual would satisfy two of the membership requirements of the regulations.

The IRB will not consist entirely of members of one profession or discipline. The IRB shall be diverse in its composition and consideration will also be given to the race, gender, and cultural background of each member. In addition, the IRB composition will be sensitive to such issues as community attitudes, promoting respect for its advice and counsel.

3.3 Qualifications of Members

date of the period that the member would like to be placed on inactive status. It should

being provided for IRB review. Researchers seeking a determination that their research is exempt are not required to complete CITI training; however, CITI training is strongly recommended for all researchers conducting exempt research.

V. PREPARING FOR RESEARCH REVIEW

Researchers should contact OSP staff prior to beginning any new research project involving human subjects, even if the researcher believes that their research is exempt. The IRB must review all non-exempt research protocols involving human subjects at a meeting of the full IRB, except in cases when the research qualifies for the expedited review

qualification will conduct a preliminary screening of the human research applications and supporting documents submitted by researchers. OSP staff may make suggestions to researchers for revisions on the application form before forwarding the application to the IRB. Furthermore, if any of the required documents are missing upon submission, the OSP staff will ask the researchers for the missing documents and will not submit the application for review until all the relevant documents have been provided.

The type of review that a study receives is commensurate with the level and type of risk to participants involved. These risks include the probability and severity of possible harm to the participants' physical, psychological, social, or economic welfare.

5.5 Protocol Review Timeline

Applications that meet exemption criteria will be processed quickly and normally reviewed within a week following receipt. Applications meeting one or more expedited review categories will be processed quickly and normally be reviewed within two weeks following receipt. Applications that require full review by the IRB must be received approximately 30 days in advance of a scheduled IRB meeting.

5.6 Distribution of Materials to the IRB

In cases where a full review is needed, all active voting IRB members will receive all documents submitted by the researchers one week prior to the meeting date. Documents will be distributed electronically by email and/or a file sharing platform.

Additional materials included in the meeting packets will include a copy of the previous meeting's minutes, a list of all determinations of exempt status and expedited actions taken since the previous meeting and a copy of the meeting agenda.

All IRB members will have access to and may review files containing all the applications reviewed in the past year or that are under review. These files will include applications for exemption and expedited review, as well as applications for full review.

VI. DETERMINATION OF EXEMPT STATUS

6.1 Exempt Categories

According to 45 CFR § 46.104, as of 2023, research activities are exempt from the human

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. For purposes of conducting the limited IRB review required by 45 CFR § 46.104(d)(7)), the IRB need not make the determinations on 1. through 7. of this section, and shall make the following determinations: (i) 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 (ot)2 [4)-6.1 (5)4 ((ot)2 [4)-6.1 (Td(§)t)12 (hi)6 (t)2 (s[7)t)12 (hi 0 Td[27

2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

3. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

4. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

5. Except for broad consent obtained in accordance with paragraph (d) of this section: (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

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

Basic Elements

45 CFR § 46.116 offers the following outline of the basic elements of informed consent:

> Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:
>
> 1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
>
> 2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others that may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, 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 the subject or the legally authorized representative, if this might be a possibility; or (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies

The IRB will assess whether the risks to subjects are reasonable in relation to the anticipated benefits, if any, to the subjects, and the importance of the knowledge reasonably expected to result from the research. The IRB will 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 federal regulations do not allow the IRB to evaluate the possible long-range effect of applying the knowledge gained through the research. The IRB is required to review any possible benefits a subject may derive from participation in research, or the benefits of new knowledge that may justify asking a person to undertake the risks of the study.

According to 45 CFR § 46, 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. For the prison population, minimal risk is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or the routine medical, dental, or psychological examination of healthy persons.

Selection of Subjects

The selection of subjects should be equitable and free of any coercion, both explicit and

require an appropriate monitoring procedure that could include monitoring of the consent process, observation of the research procedures, formulation of a data and safety monitoring plan, and review of research related records.

Reasons for requiring IRB review more frequently than annually may include but are not limited to: securing the confidentiality of sensitive information, monitoring the safety of subjects, and ensuring

regulatory criteria for approval.

The full review of research must be substantive and meaningful with a recorded vote for, against, abstentions, and recusals from each study. The minutes of IRB meetings should document with sufficient detail the deliberations, actions, and votes for each protocol undergoing review by the convened IRB, in addition to a written summary of the discussion of issues related to each application and their resolution.

Review by the full Board at a convened meeting is warranted in circumstances such as the following: the research protocol involves more than minimal risk of harm to subjects, which can include physical, emotional, social, psychological, or financial risks; a certificate of confidentiality is requested; the research involves recruitment of vulnerable populations; and/or a conflict of interest or potential conflict of interest exists.

OSP staff will be responsible for determining if the review of a protocol requires coordination with other University committees or consideration of additional federal regulations and requirements other than those contained in 45 CFR § 46. For example, the agency funding a project may have additional requirements that will have an impact on the review process. OSP staff will provide guidance to the IRB in cases where coordination is needed or where there are additional requirements.

8.2 Primary/Secondary Reviewers

The IRB Chair in consultation with the HRPP specialist assigns a primary and secondary reviewer for each protocol in advance of each full Board meeting. All members, including the IRB Chair, may serve as a primary or secondary reviewer. In selecting the primary reviewer, consideration is given to the individual's knowledge of the subject area embodied in the proposal. The primary and secondary reviewers conduct an in-depth review of all items required for IRB submission of a new application, including informed consent/assent documents and all supplemental materials.

The primary and secondary reviewers are encouraged to contact the IRB Chair and OSP staff in advance of the B

knowledge of the populations that are the focus of the study. All ad hoc or cultural consultants will have access to the same information in

concerns or questions to be discussed.

DISAPPROVED. In the case of disapproval, OSP staff generates a letter describing the reasons for disapproving the protocol and provides it to the researcher. A study may be disapproved if the IRB has enough information to make the necessary determinations of approval in line with the federal criteria but believes the research protocol does not meet the criteria and is unable to provide suggested changes.

8.6 Approval Periods

During the convened meeting, the IRB determines the approval period, as appropriate to

In accordance with 45 CFR § 46.110, HHS has established guidelines regarding the applicability of expedited review and categories of research that are eligible for expedited review. These guidelines are posted on the HHS website and are as follows:

Applicability

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not

further research involving human subjects until approval is renewed.

10.3 Considerations for Continuing Review

For continuing review, the IRB

which informed consent is being obtained. The IRB may consider any new information

on the IRB-approved protocol, this would represent a violation of the requirement that all

submission to the investigator, outlining the reasons for tabling the protocol, and includes a description of the revisions or clarifications requested.

DISAPPROVED. OSP staff generates a letter describing the reasons for disapproving the protocol and provides it to the researcher. A study is not approved if the IRB has enough information to make the necessary determinations of approval but believes the continuation of research does meet the criteria for approval.

10.6 Approval Periods

OSP staff will include in the letter approving the continuation of a project the beginning and end date of approval. During the convened meeting, the IRB determines the approval period as appropriate to the degree of risk but not less frequently than once per year for research retaining full Board review status. The date when a protocol is approved by the full Board, or by the primary reviewer following the completion of requested minor revisions to a protocol, determines the latest permissible date of approval and, therefore, the latest permissible date for the next continuing review.

10.7 Expedited Review

In general, if research did not qualify for

modification approval form to the OSP. As applicable, researchers should also provide a revised protocol summary, revised recruitment materials, revised consent form

Major changes are changes that may increase the risk to human subjects or raise new questions concerning risks to human subjects. Examples of major changes that may increase the risk to subjects are: increasing the length of time a subject is exposed to experimental aspects of the study; changing the originally targeted population to include a more at-risk population (e.g., adding children or pregnant women to the study); adding procedures where the risk of the additional procedure is

OHRP provides guidance regarding the reporting of unanticipated problems or adverse events, including the following clarifications.

Unanticipated Problems

Unanticipated problems include any incident, experience, or outcome that meets all of the following criteria:

1.

reviewed by a convened meeting, depending on the nature of the problem.

OHRP guidance indicates

identity of the person submitting an allegation to the extent possible.

13.1 Clarification of Terms

Noncompliance

Noncompliance consists of any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with either the research plan as approved by the IRB, federal regulations, or institutional policies.

Noncompliance may range from minor to serious, be unintentional or willful, and may occur once or several times. Noncompliance may result from the action of the participant, principal investigator, or staff and may involve a range of issues from relatively minor, administrative, or technical violations to more serious violations which pose risk to subjects and/or violations of their rights and welfare. Complaints or reports of noncompliance from someone other than the principal investigator are handled as allegations until such time that the report is validated or dismissed.

Serious Noncompliance

Serious noncompliance may include any behavior, action or omission in the conduct or oversight of human research that has been determined to: affect the rights and welfare of participants and others; increase risks to participants and others; reduce potential benefits or otherwise unfavorably alter the risk/benefit ratio; compromise the integrity or validity of the research; or result from the willful or knowing misconduct on the part of the principal investigators or study staff.

Serious noncompliance substantively comprises the effectiveness of the H9b0 (es)3.9 (s)14.1 (c

of a study such that important conclusions can no longer be reached, and it may suggest a likelihood that noncompliance will continue without intervention. Continuing noncompliance may also include failure to respond to a request from the IRB to resolve an episode of noncompliance or a pattern of minor noncompliance.

13.2 Reporting and Screening of Allegations

After receiving an allegation, OSP staff will share it immediately with the IRB Chair. The IRB Chair in consultation with OSP staff will conduct an initial assessment of the allegation. If the IRB Chair and OSP staff determine that an allegation or concern is substantiated but it has to do with minor or administrative issues, the IRB Chair or the OSP staff member serving as the HRPP specialist may manage the concern through communications with the principal investigator and/or the complainant.

After an initial assessment, the IRB Chair and HRPP specialist may determine that the noncompliance is not serious or continuing and no additional action is needed, or determine further inquiry and a convening of the full IRB are necessary. If the IRB Chair and HRPP specialist determines that the allegation may be substantiated and may involve serious or continuing noncompliance, the full IRB will convene and decide if further investigation is needed before corrective action is considered. If the allegation is sufficiently substantiated after the initial assessment and further investigation is not needed, the Board will allow the principal investigator to respond to the allegation either by meeting with the IRB or in writing before deciding on and directing corrective action, which may include suspension or termination of IRB approval.

13.3 Investigations of Allegations

If the IRB decides to pursue an investigation, the IRB Chair in conjunction with OSP staff will appoint an ad hoc subcommittee to conduct the investigation. The ad hoc subcommittee will consist of a minimum of three voting IRB members. OSP staff will also provide a letter to the individual against whom the allegation was raised (if the individual is not the principal investigator, staff will also notify the principal investigator of the project in question) notifying them of the investigation.

The ad hoc committee will gather information pertaining to the nature of the allegation, the approved IRB protocol, and the procedures followed in conducting the study. An IRB representative will interview the complainant or, in cases where the complainant requests anonymity, the individual who received the original allegation will interview the complainant. The ad hoc committee will also interview the principal investigator and, if applicable, anyone else against whom the allegation has been raised. Depending on the nature of the allegation/concern and the information collected during the interviews, the ad hoc committee may interview other individuals. In addition, the committee may examine research data, both published and unpublished; informed consent/assent forms; medical records; inclusion/exclusion criteria; and any other pertinent information. The ad hoc committee, in cases of a credible allegation of serious or continuing noncompliance, will have authority to request an interview with anyone related to the project or request

any information about the project that is the subject of the allegation.

When the ad hoc committee determines that its investigation is done, it will prepare, with the assistance of the HRPP specialist, a summary report for the full IRB. The report may consist of a summary of the allegation, interview summaries, and copies of pertinent information or correspondence. The report may or may not include recommendations for IRB action.

13.4 Procedures for Reviewing Potential Serious or Continuing Noncompliance

The IRB will review the materials presented by the ad hoc committee at a convened meeting at which a quorum is present. The materials provided will include the summary report of the alleged noncompliance and any other relevant materials. The convened IRB determines whether to request additional information or whether to interview additional witnesses. The IRB may give the principal investigator of the project under review the opportunity to meet with the convened IRB before it takes final action.

The convened IRB will make the determination whether the allegation is substantiated, and if so, whether the noncompliance is serious or continuing based on the materials compiled by the ad hoc committee and any additional information that it may request. The IRB may also find that the allegation is unjustified or that noncompliance is a minor issue. If the issue is minor, then it may be resolved through communication involving the IRB Chair, the HRPP specialist, the principal investigator, and the complainant.

Once the IRB has made a determination about the allegation, the convened IRB may vote to approve

considered resolved, and the OSP staff in consultation with the IRB Chair will provide a letter to the principal investigator indicating that the matter is resolved.

the IRB may defer responding to the allegation while a separate committee or disciplinary board completes an assessment and investigation of the allegation. A final report of the investigation will be provided to the IRB, and the IRB will determine if further action is needed to address issues of noncompliance. The IRB retains the authority to suspend approval of research while an investigation into research misconduct is ongoing when it believes suspension of approval is in the best interest of subjects.

XIV. SUSPENSION OR TERMINATION OF IRB APPROVAL

The convened IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB approval, that has been associated with serious or continuing noncompliance, or that has been associated with substantive harm to the rights and welfare of human subjects. Any suspension or termination of approval shall include a statement of the reason for the IRB action.

14.1 Suspension

The convened IRB may suspend approval of a protocol when it is believed to be in the best interest of participants to stop some or all protocol related activities temporarily. Studies may be suspended, put on hold durieriped,c5 Td[8 (bei)6 piu(ha)]d0 (ol)6 (d d)10 (u)9.9 (

with KSU on the study.

XV. RECORDS AND DOCUMENTATION

15.1 General Requirements

The OSP will be respBTTonsible for IRB records in accordance with 45 CFR § 46.115, which states that the University is required to prepare and maintain documentation of IRB activities including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress repBTTorts subm
2. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; changes in BTTor disapproving research; and a written summary of the discussion BTTof controverted issues and their resolution.
3. Records of continuing review activities, including the rationale for conducting continuing review of research that BTTotherwise would nBTTot require continuing review.
4. Copies of all corresBTTondence between the IRB and the investigators.
5. A list of IRB members in the same detail as described in 45 CFR § 46.108(a)(2).
6. Written procedures for the IRB in the same detail as described in]TJ0.002 Tj0.204Tc 0[(4)-

15.5 Copies of Revised Protocols

Following the approval of changes to a protocol either through the change in research activity approval process or continuing review, OHRP recommends that the investigator incorporate the revision into the written protocol and provide the OSP a copy of the revised protocol. This practice ensures that there is only one complete and up-to-date protocol. The revision dates should be noted on each revised page and the first page of the protocol itself. This procedure should also be used for revised and approved informed consent documents, which supersede previous one(s).

15.6 Retention of IRB Records

As stated in 45 CFR § 46.115(b), OSP will retain the IRB records described in section 15.1 for at least 3 years. Records relating to research reviewed by the IRB will be retained for at least 3 years after completion of the research. Records will be accessible to OSP staff, IRB members, and the designated Institutional Official. Investigators may request access to records relevant to their research projects. Furthermore, all records will be accessible for inspection and copying by authorized representatives of federal agencies at reasonable times and in a reasonable manner.

XVI. REVISING AND UPDATING HRPP POLICIES AND PROCEDURES

The following specifies the process of developing and initiating approval and implementation of changes to the current policies and procedures for KSU's HRPP and IRB.

When an HRPP policy or procedure requires modification, the IRB Chair in consultation with the HRPP specialist will draft a written proposal. Such proposal will include a statement of the need for the change, and a draft of the new policy or procedure. This proposal will be submitted to the IRB for consideration.

Minor procedural changes may not warrant this formal process and may be more appropriately termed IRB guidance or clarification. The IRB Chair will have discretion to determine what requires a formal policy or procedure change versus IRB guidance or clarification. Minor changes that the Chair determines fall into the IRB guidance or clarification category, and that do not contravene the policies and procedures herein, will be discussed and voted on at regularly scheduled IRB meetings.

Once the draft proposal of a revised policy or procedure has been reviewed by the HRPP specialist and/or the Director of Sponsored Programs (who may need to seek counsel from other staff/administrators to assure that the proposed policy and/or procedural change is consistent with KSU's policies and all relevant laws and regulations), it will be presented by email to the full Board for review and comments. The Board will be given one week ahead of a scheduled meeting to review the proposed change. IRB members should insert a comment into the document either indicating that they approve the

proposed change as written or suggest changes to the proposal.

After the review period, the Chair or the HRPP specialist will compile a final version of the policy or procedure. This version will be presented to the board at the IRB meeting. All