

	Institutional Review Board	
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Responsibility: OIRB		Page 1 of 12

Continuation Review
Policy and Procedure

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I. Policy

A. The Institutional Review Board (IRB) conducts substantive and meaningful continuation review at intervals appropriate to the degree of risk, but at least annually, for research meeting the following criteria. The research protocol must satisfy the criteria set forth in 45 CFR 46.111, 21 CFR 56.111, and 38 CFR 16.111 for the IRB to approve the protocol for continuation.

1. Research that involves greater than minimal risk to subjects; OR
2. Research that is FDA regulated:
 - a) Involves a drug or biologic
 - b) Clinical investigation of a medical device; OR
3. Research that involves no greater than minimal risk to subjects, was initially approved by the IRB prior to January 21, 2019, and have not transitioned to 2018 Final Common Rule; OR
4. Research meeting 2018 Final Common Rule Expedited Review criteria, but determined and documented by IRB to require continuing review.

B. The IRB may only use expedited review procedures for [continuation review](#) (CR) under the following circumstances:

1. All research approved prior to January 21, 2019 that have not transitioned to the 2018 Final Common Rule, OR, all FDA-regulated studies regardless of approval date:
 - a) The research was initially eligible and continues to be eligible for expedited review procedures; OR
 - b) The research involves the study of drugs and/or medical devices AND either does not require an Investigational New Drug (IND) (21 CFR Part 312) and/or an Investigational Device Exemption (IDE) (21 CFR Part 812) application and/or the device is approved for marketing and being used in accordance with the approved labeling. The IRB must also have previously determined and documented at a convened meeting that the research is no greater than minimal risk and no additional risks have been identified; OR
 - c) For research initially reviewed by the convened IRB and was determined to be greater than minimal risk:

- (1) The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; OR
 - (2) Where no subjects have been enrolled at the HSC and no additional risks have been identified either at the HSC or at any site if the research involves a multi-site study; OR
 - (3) The only remaining research activities are limited to data analysis.
 2. All Non-FDA-regulated research approved on or after January 21, 2019
 - a) The study was initially eligible and continues to be eligible for expedited review procedures, whereby, continuing review was required and explicitly justified to enhance protection of research subjects; OR
 - b) Research that was originally approved by a convened IRB and has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study will be reviewed by expedited procedures and determined if additional continuing reviews are required:
 - (1) Data analysis, including analysis of identifiable private information or identifiable biospecimens, OR
 - (2) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care
 - C. In accordance with federal requirements and where continuing review required, the IRB approval period can extend no longer than one year after the start of the approval period in which the study was approved or conditionally approved. The PI may not continue research after expiration of IRB approval; continuation is a violation of federal requirements specified in 45 CFR 46.103(a), 21 CFR 56.103(a), and 38 CFR 16.103(a). If the IRB approval has expired, the PI must cease all research activities and may not enroll new subjects in the study after the expiration of the IRB approval. Continuing participation of already enrolled subjects in a research project during the period when IRB approval has lapsed may be appropriate, for example, when the IRB determines the research interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects.
 - D. During continuation review, the IRB determines whether the progress report contains information that may indicate that a study has been modified or changed without prior IRB approval.
 - E. At the time of continuing review the IRB will determine whether there is any new information provided by the investigator, or otherwise available to the IRB, that would alter the IRB's previous conclusion (see [IRB Approval of Research Policy and Procedure](#)).
- II. Procedures
- A. CR Requests, Submissions, and Screening
 1. Using the letters generated by ORCA, reminders are sent to the PI (and a coordinator, if designated) before the IRB approval period expires (e.g., approximately eight weeks and four weeks prior to expiration). The PI is responsible for responding to those requests in a timely manner.
 2. The PI is responsible for completing the application for CR according to the instructions on the form.
 3. For research requiring continuing review, as described in section I.A. above, the PI must submit continuation review reports (approximately one month prior to expiration).

4. See the [Study Inactivation Policy and Procedure](#) for details on circumstances in which a PI may close a study.
5. Upon receipt of the CR materials, the OIRB staff screen the application to determine whether the study is eligible for expedited review and to determine whether the submission is complete.
6. OIRB staff also screen the application to ensure compliance with selected federal requirements, such as need for prisoner representative review.
7. If the CR submission includes a new unanticipated problem report, the OIRB staff may separate the unanticipated problem report from the CR materials and process it separately. The UPIRSO is reviewed following standard procedures. (See the [Unanticipated Problems Involving Risk to Subjects or Others \(UPIRSO\) And Unanticipated Adverse Device Effects \(UADE\) Policy and Procedure](#))
8. If the CR submission includes a new modification request (amendment) the OIRB staff will process the amendment under the same cover. If the modification request cannot be processed under the same cover, the PI will be asked to submit a separate amendment which will be evaluated following standard procedures. (See the [Modification and Amendments Policy and Procedure](#))
9. If the CR submission includes information to indicate changes were made without IRB approval the OIRB staff flag the study for further analysis and consult the IRB Director, Associate Director, Chair, or Expedited Reviewer for guidance. The OIRB staff may contact the investigator to clarify the statement, request submission of a report of non-compliance or other appropriate actions. If the information indicates possible noncompliance, the OIRB staff follows guidance provided in the [Noncompliance Policy and Procedure](#).
10. When the OIRB receives the CR materials, the OIRB staff conducts a preliminary screening of the materials submitted to ensure the materials are complete and consistent with IRB requirements. The CR materials are compared with the IRB's protocol records to identify inconsistent, inaccurate or omitted information. OIRB staff makes corrections when appropriate and contacts the PI for any remaining issues and asks the PI to review the changes made by OIRB staff. Corrected reports are requested prior to final review, if time permits.
11. During screening, the OIRB staff updates the OIRB database as needed based on information provided by the PI in the CR materials. The OIRB staff compares answers in the CR materials with the data in the existing IRB file (i.e., physical file, electronic file or database).
12. The OIRB staff screen for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and/or Family Educational Rights to Privacy Act (FERPA) concerns.
13. The OIRB schedule the study for a convened meeting date (if applicable) or route to the Expedited Reviewer.
14. The OIRB staff contact ad hoc and cultural consultants regarding issues for which the IRB does not have the appropriate expertise, using the same procedures as outlined in the [Initial Review of Research Policy and Procedure](#).
15. The OIRB may request additional information or materials from the PI if the application is not complete. If the PI does not respond, OIRB staff makes several attempts to contact the PI and/or research staff for additional information/materials, provided there is sufficient time before the end of the approval period.
16. If the OIRB does not receive a response from the PI, the OIRB sends the CR to the IRB (see [Study Inactivation Policy and Procedure](#)). If the approval period limits the amount of time available to resolve outstanding issues, the OIRB staff may schedule the protocol for IRB review "as is" to avoid a lapse of

approval caused by further administrative procedures. The OIRB staff forwards any applicable notes detailing the missing or incomplete materials to the IRB.

B. Continuation Review Procedures by a Convened IRB

1. The HSC has designated all IRBs operated by the HSC to review non-exempt human research conducted under its Federalwide Assurance (FWA). Continuing review of research will be performed by any of the designated IRBs. The comprehensive administrative/regulatory pre-review allows the OIRB staff to make reviewer assignments based on study's scientific or clinical focus area, significant ethical or regulatory issues, or issues related to local context of research (e.g., cultural issues). The OIRB staff assigns a primary reviewer to each CR based on the IRB member's educational background and expertise. For research requiring expertise in multiple areas of science or ethics, additional reviewers may be assigned as determined by the OIRB staff, Director or Chair. Reviewers may request the OIRB provide additional expertise as well. Generally, the OIRB staff make the reviewer assignments, if needed, the Regulatory Specialist, IRB Director or Chair may assist with this process. Information on each IRB member's earned degrees, scientific status, representative capacity (e.g., knowledge related to children, pregnant women, prisoners, economically disadvantaged, educationally disadvantaged, cognitively impaired adults or students), and indicators of experience (e.g., scientific and clinical experience, certifications, licensure, etc.) are maintained in the OIRB database.
2. In selecting the reviewers, he/she must have appropriate scientific or scholarly expertise. If necessary, ad hoc or cultural consultants with appropriate expertise will be asked to participate in the pre-review and/or IRB review process. Ad hoc or cultural consultants are generally recruited from the membership of other UTHSCSA IRBs, UTHSCSA schools or affiliated institutions. This determination may be made by the IRB Chair/Alternate Chair or the IRB Director/Associate Director. If, during the meeting, the Primary reviewer is absent IRB Chair/Alternate Chair/Regulatory Specialist may serve as the primary reviewer with input of the members present.
3. Approximately 5 days prior to the meeting, the IRB members scheduled to attend the meeting receive access to the following items, but not limited to:
 - a) The completed Progress Report Form including a protocol summary containing the relevant information necessary to determine whether the proposed research continues to fulfill the criteria for approval and status report of the progress of the research;
 - b) Attachments (e.g., updates/changes, explanations, any relevant multi-center trial reports);
 - c) A copy of the current consent/assent form for which the investigator is seeking IRB re-approval;
 - d) Reviewer checklist;
4. All IRB members are responsible for reviewing all information in the review packet in advance of the meeting (including those protocols for which the IRB member is not the primary reviewer) in enough depth to be familiar with the protocol, to be prepared to discuss the protocol at the meeting, and to be prepared to determine whether the research meets the regulatory criteria for approval.
5. When documentation of informed consent is required, the IRB reviews the informed consent document(s) submitted for re-approval to ensure accuracy and completeness and any newly proposed consent document.
 - a) The IRB can observe or request observation of a research participant(s) being consented. The Office of Regulatory Affairs & Compliance will observe and report findings back to the IRB. Protocols selected for observation may include those that involve:
 - (1) High risks to participants
 - (2) Particularly complicated procedures or interventions

- (3) Potentially vulnerable populations (e.g., ICU patients, children)
 - (4) Study staff with minimal experience in administering consent to potential study participants, or
 - (5) Other situations where the IRB has concerns that consent process might not be proceeding well.
 - (6) The consent observation procedure is found in the IRB "[Guidance on Observation of the Consenting Process](#)".
6. The OIRB staff ensure that the complete IRB protocol record is available to all IRB members prior to and, if requested, during the convened meeting. All IRB members have the opportunity to discuss each research protocol during the convened meeting.
 7. The convened IRB assesses the CR materials using the federal criteria for approval (i.e., 45 CFR 46.111, 21 CFR 56.111, 38 CFR 16.111) (See [IRB Approval of Research Policy and Procedure](#)).
 8. When the IRB reviews research that involves categories of subjects vulnerable to coercion or undue influence, the OIRB staff ensures that adequate representation or consultation is present for discussions of research involving vulnerable human subjects (See [IRB Approval of Research Policy and Procedure](#)).
 9. The IRB/OIRB staff conducts the convened meeting in accordance with the [Conduct of IRB Meetings Policy and Procedure](#). Members who have a conflict of interest follow procedures outlined in both the Conduct of IRB Meetings and [IRB Member and Consultant Conflict of Interest Policy and Procedure](#).
 10. The OIRB staff serves as intermediaries between the PI and the IRB primary reviewer. However, the primary reviewer may contact the PI directly for clarification. The reviewer documents the issues discussed with the PI in the CR materials.
 11. Primary Reviewer at the convened meeting – continuing review of research at a convened meeting of the IRB relies on a primary reviewer system. A reviewer from the membership is assigned to each business item. The primary reviewer system does not prohibit any member of the Board from obtaining, reviewing and providing input on any business item scheduled for a convened meeting.
 12. Primary Reviewer review: approximately 5-10 days prior to the convened meeting, the OIRB staff make the following information available to the primary reviewer for review:
 - a) A completed Progress Report Form (progress report) for each study, which includes, when applicable, the number of subjects enrolled and withdrawn from the study; summary of unanticipated problems involving risks to the subject or others; recent literature; complaints about the research; and any new, significant findings (new findings and implications for subject participation);
 - b) A protocol summary and status report on the progress of the research;
 - c) A copy of the currently approved sponsor protocol for externally sponsored research (including any prior IRB approved modifications) and/or research description (summary which addresses all elements of criteria for approval);
 - d) and if applicable:
 - (1) A cover memo if it contains pertinent information to review of protocol;
 - (2) Attachments (e.g., updates/changes, explanations)

- (3) Summary data safety and monitoring reports;
 - (4) A copy of the current consent document and if different a copy of the consent form for which the investigator is seeking IRB approval;
 - (5) A revised grant application;
 - (6) Primary Reviewer Checklist for Continuation Review;
 - (7) The OIRB staff recommendations;
 - (8) A request for modifications to the research (amendment request) and applicable attachments.
 - (9) See the CR form for a complete list of information and attachments the PI must submit.
13. The reviewer is responsible for:
- a) Reviewing the progress report and comparing with their review of the complete IRB record including any previous reports and protocol modifications previously approved by the IRB;
 - b) Informing the full IRB of any discrepancies in the materials provided for CR;
 - c) Reviewing new disclosures of protocol related conflict of interest disclosure, alerting the IRB if a disclosure is made. If a disclosure is made, the review will summarize the conflict and proposed management plan to the IRB (if a management plan is not provided from the COIC, the reviewer will provide recommendations to manage the conflict to the IRB);
 - d) Conducting an in-depth review (See [IRB Approval of Research Policy and Procedure](#) for details)
 - e) Identifying information in the progress report that may indicate that changes or modifications to the study have been made without the IRB's approval and should have an external reviewer verify whether any material changes have occurred. If the information indicates possible noncompliance, the IRB follows guidance provided in the [Noncompliance Policy and Procedure](#).
14. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review. The minutes of the meeting document the information provided by the consultant. (See [IRB Minutes Policy and Procedure](#).)
15. Primary reviewers provide recommendations to the IRB at the convened meeting on issues which they determine do not meet the federal criteria for approval, are controverted, need additional information, or concern compliance with the HSC human research training requirements.
16. If the primary reviewer is unable to attend the meeting, the reviewer's written comments or recommendations are presented by the Chair or Regulatory Specialist to the IRB at the convened meeting.
17. The IRB considers each CR scheduled for full review separately for approval. At the meeting, the IRB reviews the CR report and any controverted issues and their resolution prior to voting. During discussion, the IRB members only raise those controverted issues that the IRB determines do not meet the federal criteria for approval as specified in 45 CFR 46.111, 21 CFR 56.111, and 38 CFR 16.111. IRB approval of the CR materials documents that the IRB agrees with the PI assessment of any specific findings included in the CR report that were not previously addressed by the IRB.
18. The IRB ensures the PI provides any significant new findings that might relate to the subject's willingness to continue participation in accordance with regulations.

19. The convened IRB makes the final determination on the outcome of the review. The meeting deliberations are documented in the meeting minutes.

C. Expedited Continuation Review

1. The IRBD, IRBAD, Chair, Expedited Reviewer or designee serves as the expedited reviewer for expedited CR protocols. If the individual performing expedited review has a conflict of interest (e.g., is study personnel on a protocol for continuation review), is unavailable, or does not have the appropriate expertise to review the CR, the OIRB staff assign responsibility for the CR to the Chair, Alternate Chair, or a voting member of the IRB.
2. The OIRB staff provides the expedited reviewer access to the same information provided to a convened IRB including the following, but not limited to:
 - a) A completed Progress Report Form for each study, which includes, when applicable, the number of subjects enrolled and withdrawn from the study; summary of unanticipated problems involving risks to the subject or others; recent literature; complaints about the research; and any new, significant findings (new findings and implications for subject participation described);
 - b) A protocol summary and status report on the progress of the research;
 - c) A copy of the currently approved sponsor protocol for externally sponsored research (including any prior IRB approved modifications) and/or research description (summary which addresses all elements of criteria for approval);
 - d) and if applicable:
 - (1) A cover memo if it contains pertinent information to review of protocol;
 - (2) Attachments (e.g., updates/changes, explanations)
 - (3) Summary data safety and monitoring reports;
 - (4) A copy of the consent form for which the investigator is seeking IRB approval;
 - (5) A revised grant application;
 - (6) Primary Reviewer Checklist for Continuation Review;
 - (7) The OIRB staff recommendations;
 - (8) A request for modifications to the research (amendment request) and applicable attachments.
3. The designated expedited reviewer(s) is responsible for reviewing all information in the expedited review packet in enough depth to be familiar with the protocol, to determine whether the research is eligible for expedited review, and to determine whether the research meets the regulatory criteria for approval.
4. The designated expedited reviewer(s) is responsible for making the final determination that the protocol meets the criteria for expedited review as outlined above. If the expedited reviewer determines full review is necessary, (s)he documents this requirement in the Expedited Approval/Administrative Review Documentation form. Upon receipt of the reviewer's recommendation, the OIRB staff implements full continuation review procedures.

5. The designated expedited reviewer(s) applies the same criteria for approval as outlined above for full review (i.e., applies 45 CFR 45.111, 21 CFR 56.111, and 38 CFR 16.111), and considers whether research approved prior to January 21, 2019, may be transitioned to the 2018 Final Common Rule on a case by case basis. The expedited reviewer completes the "Expedited Approval/Administrative Review Documentation form." as documentation of his/her determination, including when a study is transitioned to the revised Common Rule. The expedited reviewer raises controverted issues he/she determines do not meet federal criteria and/ or may request additional information.
 6. When documentation of informed consent is required, the expedited reviewer reviews the informed consent document(s) submitted for re-approval to ensure accuracy and completeness.
 7. The OIRB staff serves as intermediaries between the PI and the IRB expedited reviewer. However, the expedited reviewer may contact the PI directly for clarification. The reviewer documents in the CR materials the issues discussed with the PI.
 8. The expedited reviewer documents in the CR materials any determination pertaining to specific findings, as mandated by federal regulations that were not previously addressed by the IRB. (Expedited reviewer approval of the CR materials documents that the reviewer agrees with the PI's assessment of the specific findings).
 9. The expedited reviewer ensures the PI provides any significant new findings that might relate to the subject's willingness to continue participation in accordance with regulations. The reviewer uses the IRB Continuation Review: Primary Reviewer Checklist as a prompt.
 10. If the approval might lapse before completion of the CR, the expedited reviewer can make a determination to allow subjects currently participating to continue in accord with procedures described in the section below on lapses of approval.
 11. OIRB staff list expedited CRs on the Expedited Report to advise the IRB of the expedited CRs.
- D. VA Research: Additional Issues for Expedited and Full CR
- a) If the IRB has not previously made a determination, the VA Associate Chief of Staff (ACOS), using the VA Research section of the Reviewer Checklist as a guide, prompt the convened IRB or the expedited reviewer through the OIRB staff to make determinations as required by VA regulations.
- E. Review Outcome(s)
1. Convened Review
 - a) Generally, the primary reviewer makes a motion; another member seconds the motion, and then the convened IRB votes for or against or abstains from the motion. The motion may be one of the following four actions:
 - (1) **Approved** - IRB approval indicates that the IRB has concluded that the research (including the research plan and consent forms) meets the federal criteria for approval. IRB approval verifies that the IRB agrees with the information/materials submitted for continuation of the protocol and/or specific findings described in the CR report by the PI. The OIRB staff sends the investigator an approval letter, accompanied by an informed consent document (if applicable) with the affixed "IRB Approval" validation stamp, which includes valid date of IRB approval.
 - (2) **Conditional Approval** – IRB conditional approval indicates that the IRB has approved the protocol for continuation. The investigator must submit minor revisions or clarifications to the progress report, consent, or any other applicable documents identified during the review. The

submission of revisions required by the IRB must be provided within the time period specified by the IRB. Depending upon the nature of the required conditions, the IRB could designate the IRB chair, a specific IRB member with appropriate expertise, an IRB administrator, or a qualified OIRB staff person to review the changes and determine whether the conditions of approval have been satisfied. The OIRB staff sends the investigator a letter describing the revisions requested by the IRB.

- (a) The PI responds to each of the IRB's conditions and sends the response to the OIRB, who gives the response to the designated reviewer. The Chair or designee may forward the responses to the entire IRB for additional review (return to the convened Board), request additional information from the investigator, or approve the response.
 - (b) The OIRB staff track the status of response to conditions. If a response is not received within a reasonable time period (with the exception of extenuating circumstances), the OIRB forwards the protocol to the convened IRB. The convened IRB determines whether additional action (including suspension or termination) is appropriate .
- (3) **Tabled/Deferred** - A vote of tabled or deferred indicates that the IRB withholds continuing approval pending submission of major revisions/additional information. The IRB considers whether the deferral of the study may result in a [lapse in approval](#) and follows the guidelines provided in that section of this policy. The OIRB staff sends the investigator a letter listing the reasons for tabling and includes a description of the revisions or clarifications requested. For some studies, the IRB may appoint one or more members of the IRB to discuss the reasons with the investigator.
- (a) The OIRB staff track the status of response to tabling in the IRB minutes and agenda. The convened IRB determines whether additional action (including suspension or termination) is appropriate if a response is not received within a reasonable time period.
- (4) **Disapproved** – A vote to disapprove research indicates that the IRB will not allow the research to continue. Disapproval of a protocol usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the proposed research does not meet the federal criteria for IRB approval. Disapproval generally indicates that even major revisions to the application will not correct the issues preventing approval. The OIRB staff sends the investigator a letter describing the reasons for disapproving the protocol.
- b) Duration of approval
- (1) the IRB determines the length of approval, as appropriate to the degree of risk but not longer than one year from the meeting date that the study was approved or conditionally approved (unless anniversary date is used, see below).
 - (2) The IRB may set a shorter approval period for:
 - (a) high risk protocols or protocols with UPIRSOs;
 - (b) protocols with high risk/low potential benefit ratios;
 - (c) studies involving the first use of an experimental drug or device in humans where safety data is limited;
 - (d) studies involving research procedures not normally reviewed by the IRB;

- (e) research with a history of noncompliance issues; or
 - (f) any other study the Board determines a shorter approval period and the resultant continuing review are appropriate.
2. For expedited CR, the expedited reviewer may make the following determinations:
- a) approved;
 - b) conditional approval; or
 - c) review by the convened Board required.
 - d) The expedited reviewer exercises all the authority of the IRB except the reviewer may not disapprove the CR. Only the convened IRB may disapprove the CR.
 - e) The expedited reviewer determines the duration of approval in the same manner as the convened review (as described above); whether continuing review is required at the next interval according to the appropriate regulations; or that continuing review is no longer required for research initially approved prior to January 21, 2019, that has been transitioned to the 2018 Final Common Rule.
3. Use of anniversary dates when CR is determined to occur annually – CR approved or conditionally approved for one year by either the convened board or expedited review may retain the current expiration date (day and month) as the date by which the next continuing review must occur (expiration date), if the approval/conditional approval occurs within 30 days before the IRB approval period expires. For full CR, the OIRB staff includes the approval period in the meeting minutes.
- a) When full CR is conditionally approved, the OIRB staff issue final approval after the IRB Chair or designee reviews and approves the PI's response.
 - b) When full CR is tabled/deferred due to substantive issues identified during the review at one convened meeting and subsequently reviewed and approved by another convened meeting, the approval period starts with the date of the subsequent convened IRB meeting.
 - c) Upon request, OIRB staff also sends the PI and funding agency Certification of Approval form.
4. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit his/her concerns to the IRB in writing with a justification for altering the IRB decision. The IRB reviews the request using the standard IRB review procedures.

F. Lapse of Approval

1. Non-VA Studies

- a) The length of approval determined by the IRB results in an approval period (start date and an expiration date). The expiration date is the first day that IRB approval has expired (lapse of approval). On the expiration date, if the IRB has not reviewed and re-approved the research the research must stop, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval.
- b) It is the Principal Investigator's responsibility to conduct research under a current IRB approval. The PI is responsible for planning ahead to meet the required continuing review dates and prevent a lapse in approval. The PI is also responsible for stopping research that has lapsed unless it is in the best interest of the subjects. If research is conducted on or after the expiration date without IRB approval, the PI must submit a report of noncompliance (see [Noncompliance Policy and Procedure](#)).
- c) If a PI fails to return the CR or the IRB has not completed review by the end of the current approval period, the OIRB staff promptly notifies the PI that the approval will lapse or has lapsed. The OIRB

staff will inform the PI that research must cease and no new subject enrollment may occur after the date of lapse. The OIRB staff also inform the PI that he/she should, if appropriate, notify subjects that the study approval has lapsed and that, if applicable, it is his/her responsibility to notify the funding agency of the expiration of the IRB approval.

- d) The PI may ask the IRB for permission to allow subjects currently participating to continue due to overriding safety concerns, ethical issues, or because it is in the best interest of the individual subjects. The IRB reviews the possible implications of stopping research and whether other actions should be taken to avoid a lapse in approval due to overriding safety concerns, ethical issues, or because it is in the best interest of the individual subjects. In either case, the IRB makes the final determination of whether research activities (e.g., continued administration of a study drug) may continue after the current expiration date. The OIRB or IRB notifies the PI in writing of that determination. (For VA studies, see [Lapse of Approval in VA Studies](#) below.)
- e) In the case of a study was tabled and the PI is actively pursuing renewal, but he/she could not respond to the IRB request for changes before the end of the approval period, which resulted in a lapse of approval, OIRB staff send the resubmitted materials to the same IRB that requested the changes. The IRB may subsequently approve the study for continuation.
- f) If a protocol approval has expired due to failure of the PI to submit a continuation review report or to respond to the IRB's request for revisions and the PI subsequently submits the CR materials/revisions after the study has expired, the OIRB requests from the PI a written summary of events that occurred in the interim. If the PI submitted the materials/revisions less than three months after the expiration date, OIRB staff forward the PI's summary and the CR materials/revisions to the IRB. The IRB reviews the materials/revisions following procedures outlined in this policy and may re-approve the study if no research activity has occurred after the expiration date. The new approval period will take into account the previous expiration date and not approve the study for a full year, rather the original expiration date will be used to avoid the potential for positive reinforcement for allowing a study to lapse.
- g) If a protocol approval has expired due to failure of the PI to submit a CR report or respond to the IRB's request for revisions the study records may be inactivated (see [Study Inactivation Policy and Procedure](#)).
- h) A lapse of IRB approval does not constitute a suspension of approval under Food and Drug Administration, Department of Health and Human Services, or VA regulations.

2. VA Studies

- a) If approval of a STVHCS study lapses during the CR process, already enrolled subjects may only continue research activities when the IRB, IRB Chair or Director, in consultation with the STVHCS Chief of Staff (with copies of all correspondence sent to the STVHCS ACOS for Research and Development), finds that it is in the best interest of individual subjects to continue participation.
- b) For STVHCS research for which approval has lapsed, the IRB notifies the PI to immediately submit to the IRB Chair a list of subjects for whom stopping research activities would cause harm.
- c) If applicable, IRB policy requires the PI to notify the funding agency of the lapse of IRB approval.
- d) During the time period in which consultation is occurring within the VA, the IRB may determine that subjects may continue at HSC.

III. References

- A. Definitions (see [Glossary](#))
- B. Regulatory (see [Policy on Policies Policy and Procedure](#))