**IRB-HSR/Study Tracking #:**  **Expedited Review**  **Full Board Review  IRB Update**

**Meeting Date:** **Initials of Admin Staff who completing form:**

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| **OK?** | **Review Criteria:** | | | | **Comments** | |
| **MAIN PAGE REVIEW** | | | | | | |
|  | **STATUS**: Compare the Current Status checked on Status Report to the Current Status at top of this page. | | | | | |
| No change | | | |  | |
| Status Change This change will be considered a Receipt.  Update database as necessary. Add approval comment and update Regulatory page as necessary with expedited criteria #8 choices.  **FB: Update database after the meeting.** | | | | **Approval form comments:** Study status changed from \_to  per Status Report OR  per Protocol Status Change Form on file with this continuation. | |
| A. Open to Enrollment | | | | D (1) Closed to enrollment; subjects being treated. | |
| B. Temporarily Closed to Enrollment | | | | D (2) Closed to enrollment, follow-up only | |
| C. Closed to enrollment, no subjects enrolled | | | | D (3) Closed to enrollment, data analysis | |
| Database Open | | | | Database Closed | |
| Study on Hold | | | |  | |
| RE-OPEN with this continuation:  Separate reopening event is required:  Event type = Approval Protocol reopening  Review Type = same as Continuation Review  Agenda = None | | | | **FB Continuation Receipt comment:** This study was previously closed/expired on (insert). The PI is requesting that, with the approval of this continuation the study be reopened with a status of (insert).  **Continuation Approval form comments:** This study was previously closed/expired on (insert). With the approval of this continuation, the protocol is now re-opened with the status of (insert).  **Reopening Approval form comments:** Study reopened with the Continuation approved on (insert date) | |
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|  | **ENROLLMENT**   1. Review how many subjects have enrolled, and update Subjects Studied field/Enrollment table in database as necessary. 2. If over-enrollment has occurred study team must do a modification to increase enrollment if study is open to enrollment. Deviation form must be completed and submitted by the study team.. 3. Review Enrollment Numbers (IRB-HSR is Single IRB of Record for multi-site Study) compared to IRB Online if box for **IRB-HSR: IRB of Record for all Site is checked then status report NA is blank. If not checked then Status report NA is checked** | | | | **Approval Form Comment if there was over enrollment:**  Correction: Correct the NA Box if needed on status report based on IRB-HSR: IRB of Record for all Sites in IRB Online. | |
|  | Verify any Comment on Main page of the database is resolved or confirm this is NA. Add receipt comments to the approval comment. | | | | | |
|  | Verify if PAM occurred during review period, reports, letters, or response to audits have been submitted. Include all as part of Full Board agenda file (if not already in IRB Pro). Receipt comment for all new documents submitted with continuation. | | | | | |
| **REGULATORY PAGE CHECK:** | | | | | | |
| NA | **DSMB/C REVIEW:** Verify DSMB reports are on file. Do not place on the agenda for review until issues with the DSMB are resolved.  For Cancer Center DSMC: The CCDSMC meets every month but only produces a report if there are issues. If a PAM review has occurred, there should be a DSMC letter for each PAM review. The CCDSMC does not review studies with no enrollment OR those in Follow Up/Data Analysis | | | | | |
| NA | **CERTIFICATE OF CONFIDENTIATLIY:**  **Non-federally funded:** Verify CoC approval letter is on file and is not expired  If received with continuation, include in receipt comment and update Reg page, CoC expiration field   * If expired- request CoC approval, extension application, or documentation from agency that it is in process. * If not received, the IRB approval will be allowed to expire. Continuation may be approved with conditions if there is no enrollment.   **Federally funded:** Verify “Cert. of Confidentiality without Expiration Date” is checked on Reg page. This applies to affiliated grants initially approved after 10/1/17; if there are no grants and funding is through contract, apply 10/1/17 date to initial study approval. | | | | | |
| NA | **PROTOCOLS APPROVED TO ENROLL PRISONERS:**  Research Involving Prisoners Checklist must be completed.  ***Full Board review:*** include checklist in agenda documents. Prisoner Representative must attend meeting when protocol enrolling prisoners is being reviewed. Scientific reviewer may complete the checklist UNLESS research is being conducted inside the Bureau of Prisons.  ***Expedited review:*** Prisoner Representative must concur with written communication (e.g., email) that the potential risks inherent to the studyare not greater than those ordinarily encountered in daily life or during the performance of routine physical and  psychological examinations for the prisoner population. Completion of the Prisoner Checklist is NOT required.  **Prisoner Checklist is NOT required if** the study does not involve an interaction/ intervention (e.g., chart review under waiver of consent) or the study has had no enrollment (approved under Category #8b) *See AG. 3-34 for additional info.* | | | **FB Continuation Receipt comment:**  Prisoner representative MUST be present for the review of the continuation.  **Approval Form Comment:**  **all studies:** A majority of the IRB (exclusive of the prisoner representative) has no association with the prison(s) involved and a qualified prisoner representative was involved in the review  ***if full board review add:*** *and voted on the continuation.*  **all studies:** The Prisoner Representative concurred with the permission for prisoners to enroll as subjects in the research. | | |
| NA | **PROTOCOLS APPROVED TO ENROLL MINORS** | | | | | |
| Enrollment requiring 2 parent signatures:verify if wards of the state were enrolled.  If wards were enrolled without permission, request protocol deviation | | | | | |
| If minors reach age of majority (18 yrs in VA) confirm Age of Majority Cover Letter + Consent Addendum or Waiver is present.  If not present, process Age of Majority modification with continuation following [Age of Majority instructions](file:///\\pi11.admin.virginia.edu\vprweb-users\IRB\IRB-HSR\Documents\Continuations\Age%20of%20Majority\Age%20of%20Majority%20Modification%20Instructions.docx) | | | | | |
|  | **-** | | | - | | |
|  | Verify training is current for all study personnel for all studies requiring Full Board continuation review.  Remove those with expired training and Upload Certificate | | | **Approval Form Comment:** The IRB determined the modification met the criteria for approval per the federal regulations and was approved per 45CFR46.110(b)(2) and (if study involves investigational drug/device/biologic) 21CFR56.110(b)(2).  Modification expedited: Minimal risk/Minor change:(Omit for FB)  (Insert names) were administratively removed from this protocol due to expired Human Subject Protection Training. | | |
|  | If regulated by 2018 Common Rule:  Study regulated by FDA, Justice or other sponsor that is not a common rule agency that require expedited continuation review. | | | NA- Full Board Review  **Approval Form Comment:** An expedited continuation review was conducted per requirements of the sponsor or regulatory agencies. | | |
| **ADDITIONAL VERIFICATIONS** | | | | | | |
|  | **QUESTIONS:** Review all responses. All questions should be addressed, and the responses should be consistent with information in the database. | | | | | |
|  | **Verify Completed by Section** is complete | | | | | |
|  | **RECEIPTS**: List in the approval comments documents received.  DSMB Doc include recommendations in comment | | | | | **Approval Form Comment:**  On file with this submission are the following documents: (List) |
| **EXPEDITED STUDIES ONLY** | | | | | | |
| 1. Verify Expedited Categories are listed on Regulatory Page and on the Meeting Page. 2. Use the Regulatory Insert feature to insert expedited categories, copy and paste into comments on Meeting page. 3. Insert PLEASE REMEMBER text section of the regulatory insert information into the approval comment | | | | | | |
|  | Category # 8a | Follow up only- | | | |
|  | Category # 8c | Data Analysis Only | | | |
|  | Category # 8b | No Enrollment | | | |
|  | Category # 9 | Humanitarian Device Exemption  other: | | | |
| **PLACE ON THE AGENDA** | | | | | | |
|  | 1. On the Meeting Continuation view change responses to Y/N. 2. Change event to EXPEDITED or FULL BOARD and enter the event date. | | | | | |
|  | Update EVENT for Full Board studies: change AGENDA TYPE to ADDENDUM, designate IRB 3. Add your Name | | | | | |
| **All other modifications to the protocol or consents must be submitted separately by the study team via IRB PRO.** | | | | | | |
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| NA- FOR ALL FOR NOW | **Transition to 2018 Common Rule**  If study is regulated under Pre 2018 Rule, not regulated by Dept of Justice (or other non- common rule agency), is closed to enrollment and there has been no interaction with subjects in last 60 days and one of the following is true take the steps noted below:  Expedited Review, not regulated by the FDA with status changed to FU or DA AND NO outside sponsor  Expedited Review, regulated by the FDA with status changed to DA AND NO outside sponsor  Full Board Review with status changed to DA AND NO outside sponsor  STEPS TO TAKE:   * Main page- change REGULATED BY to 2018 Rule * Enter Receipt Event. Enter the following in the Comment Field. *Study will now be regulated by the 2018 Common Rule.* * Close grant funding this study if it is not funding other studies regulated by the pre 2018 Common Rule. Add the following to Grant Closure Event Comment Field and in an email notification to study team:   *This grant has been closed as it no longer funds any protocol regulated by the pre-2018 version of the Common Rule.* |

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| **IRB UPDATE** | | | |
|  | **STATUS**: Compare the Current Status checked on Status Report to the Current Status at top of this page. | | |
| No change |  | |
| Status Change This change will be considered a Receipt.  Update database as necessary. Add approval comment and update regulatory page. | **Approval form comments:** Study status changed from \_to  per IRB Update | |
| A. Open to Enrollment | D (1) Closed to enrollment; subjects being treated. | |
| B. Temporarily Closed to Enrollment | D (2) Closed to enrollment, follow-up only | |
| C. Closed to enrollment, no subjects enrolled | D (3) Closed to enrollment, data analysis | |
| Database Open | Database Closed | |
| Study on Hold |  | |
|  | **ENROLLMENT**   1. Review how many subjects have enrolled, and update Subjects Studied field/Enrollment table in database as necessary. 2. If over-enrollment has occurred add Comment and if open to enrollment, request a modification to enrollment numbers. Study will need to submit a deviation for over enrollment. 3. Review Enrollment Numbers (IRB-HSR is Single IRB of Record for multi-site Study) compared to IRB Online if box for **IRB-HSR: IRB of Record for all Site is checked then status report NA is blank. If not checked then Status report NA is checked** | **Approval Form Comment if there was over enrollment:**  With this submission the minor violation of over-enrollment was noted. Study was approved to enroll x and Y were enrolled.  Correction: Correct the NA Box if needed on status report based on IRB-HSR: IRB of Record for all Sites in IRB Online. | |
| NA | **PROTOCOLS APPROVED TO ENROLL MINORS**  If minors reach age of majority (18 yrs in VA) confirm Age of Majority Cover Letter + Consent Addendum or Waiver is present.  If not present, instruct study team to submit Age of Majority modification. Continue to process IRB Update. | | |
|  | **RECEIPTS**: List in the approval comments documents received. | | **Approval Form Comment:**  On file with this submission are the following documents: (List) |
| **CREATE RECEIPT EVENT**  Update Meeting Continuation page: Change responses to Y/N, review type is IRB UPDATE and enter the date reviewed.  Confirm Receipt Event is Review Type: None, Agenda Type: None | | | |
| **NOTIFY STUDY TEAM**  Send a completion email through IRB Pro to notify study team of receipt.  Subject line should include “IRB Update”.  Add the following sentence to the email: As of this date, you may continue your study for another year. A printable version of the study details can be obtained from your view in IRB Online on main page and can be printed or saved as PDF.  **If the update is for a study that UVA is IRB of Record with Relying Sites, add following sentence:** Note, the IRB does not execute Continuation Assurance/Approval Forms for studies that meet specific requirements under the 2018 Common Rule. IRB-HSR [#] met that requirement. As a result, this IRB Update process also includes [Relying site(s)] set forth by the Reliance Agreement with UVA as the IRB of Record. | | | |