|  |  |  |  |
| --- | --- | --- | --- |
| ADMINISTRATIVE PRE-REVIEW AND ASSURANCE CHECKLIST-MODIFICATIONS/CONDITIONS | | | |
| **APPROVAL OVERVIEW** | | | | |
| **UVA Study Tracking # or IRB-HSR #** | **Initials of staff who processed this modification** | | | |
| **NEW VERSION DATES:** | | | | |
| IRB Application  Protocol:  Sub-study Protocol:  Consent(s): | | Investigator’s Brochure:  Data Security Plan:  Other, (specify):  Other, (specify): | | |
| **RESPONSE TO RECEIPT OF CONDITIONS** | | | | |
| Is this submission in response to a review of Receipt of Conditions? NO  YES  *If YES, and opening to enrollment, release ALL consents/ assents etc. to the study team.* | | | | |
| **UVA IRB-HSR to SERVE as sIRB/Reviewing IRB** | | | | |
| Is this modification for UVA IRB-HSR to serve as the sIRB of Record for a new site?  NO  YES If Yes, Complete [IRB-HSR as sIRB section](#_IRB-HSR_to_be) | | | | |
| **ADDITION OF RELYING SITE** | | | | |
| Is this modification to add a Relying Site?  NO  YES If Yes, Complete [Addition of Relying Site section](#_Addition_of_Relying)  *Note: Each relying site MUST be added with a separate sIRB Modification Approval Event Per AG-3-50.* | | | | |
| **REVISED INVESTIGATOR BROCHURE (IB)-NO CHANGE TO STUDY DOCUMENTS** | | | | |
| Is this modification to ONLY add a Revised IB that DOES NOT require revisions to study documents?  NO  YES  *Note: Confirm no revisions are required to the study documents including protocol, IRB application or consent(s) per study team/sponsor..* | | | | |
| ***If any item is checked BELOW, see Miscellaneous section PAGE 2 for wording to add to assurance comment field.*** | | | | |
| **MAIN PAGE:  no changes** | | | | |
| Change in protocol status? (If yes, enter new status):  [Title Change](#_Title_Change) in Study /sub study? | | | Revised Sponsor protocol #:  [Number of subjects change](#_Number_of_Subjects)d to:  # of subjects enrolled overall (UVA serving as sIRB):  Closing to Enrollment? # of subjects enrolled: | |
| **REGULATORY PAGE: no changes** | | | | |
| Specify any updates that need to be made on this page: See [FDA Regulated Studies](https://research.virginia.edu/sites/vpr/files/2019-08/fda_regulated_studies.docx) for additional info | | | | |
| **IND/IDE PAGE: : no changes** | | | | |
| Specify any new IND/IDE information: | | | | |
| **FUNDING PAGE: : no changes** | | | | |
| Sponsor/ Funding Change  [Grant/Contract changes](#_Grants_and_Contracts) Change or addition of grant #:  [Compensation change or addition](#_Compensation/Reimbursement): | | | | |
| **PEOPLE PAGE:** *see Personnel Page* **: no changes** | | | | |
| [Personnel Changes](#PersonnelChanges)  Add the following individual(s) to the following position(s):  Delete the following individual(s) from the following position(s): | | | | |
| **ADVERTS PAGE: : no changes Recruitment/Advertising/Pre-screening Plan** | | | | |
| Specify any updates that need to be made on this page: | | | | |
| **\*\*Is the PI a RN from the Professional Nursing Staff Organization? Nursing Research Department?**  Yes  No  If modification is reviewed by full board, an IRB member who is an RN employed by the health system must vote on the modification. | | | | |
| **If study meets any of the following add citations for federal regulations to receipt event/approval comment on assurance forms.**  **FDA Regulated  DoD Related Research Department of Justice Funded Research** | | | | |

|  |
| --- |
| **TABLES**  [Additional Reviews & Approval](#_Additional_Reviews_&)   Yes  No  [Certificates of Confidentiality](#_Certificates_of_Confidentiality)   Yes  No  Compensation/Reimbursement  Yes  No |
| [[Deception added](#_UVA_PI_now)](#_Compensation/Reimbursement)   Yes  No  [Drugs, Biologics, and Devices](#_Drugs,_Biologics,_and)   Yes  No |
| [Genetic Research/Specimen Banking](#_Genetic_Research/Specimen_Banking)   Yes  No |
| [Add or Enrolling Populations requiring Additional Protections](#VulnerablePop)   Yes  No  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [**Miscellaneous**](#Miscellaneous)  Yes  No  **IF YES, check only those that are applicable:**  [Blood/Specimen added](#_Blood/_Specimens_Added_1)  COVID-19 Treatment /Vaccine Study  International Site  [Laser added](#_Laser)  [Major Changes to protocol- new C of C – if applicable](#_Major_change-_new)  [Mod requested by PAM](#_Revisions_required_by)  [New procedures/visits added](#_New_procedures_and/or_1)  [Optional Procedures added](#_Optional_Procedures_Added)  [Pregnant Partner added](#_Pregnant_Partner)  [Randomization added](#_Randomization)  [Security Issues /InfoSec approval added](#_Security_Issues)  [Short Forms added](#_Short_Forms)  [Taping added](#_Taping_Added)  [Translation of the Consents to other Languages](#TranslationOfTheConsentsToOtherLanguages)  [Status Change](#_Status_change_1)  [Student Health Data (FERPA regulated)](#StudentHealthData)  [Study Site Outside State of Virginia added & study will enroll subjects <21 or those with impaired decision-making capacity](#StudySiteOutsideStateofVirginia)  [Sub-Study](#SubStudy) |
|  |
| [Protocol Approval Types and Categories](#ProtocolApprovalTypesandCategories)  Yes  No |
| [Scientific Changes](#ScientificChanges)  Yes  No |
| [Screening Log](#ScreeningLog)  Yes  No  [Sending Data/Specimens Outside of UVA/ to Center for Survey Research](#_Sending_Data_Outside)   Yes  No |
| [Waiver of Consent/Waiver of HIPPA](#_Waiver_of_Consent/Waiver)   Yes  No  [Waiver of Documentation of Consent, Alt of HIPAA Authorization](#_Waiver_of_Documentation)   Yes  N0 |

|  |
| --- |
|  |

|  |
| --- |
| **INSTRUCTIONS** |
| ***The Approval Overview on the first page of this form should be a snapshot of the items that need to be updated when the submission is received, and should be completed as soon as the pre-review is complete. Relevant information not listed in the Approval Overview is to be typed in the receipt protocol modification event in IRB online at the time of pre-review.***   * If there are any comments in the comment field on the MAIN PAGE that need to be addressed (e.g. pending PAM issues or other modification related issues) make sure they are incorporated with the modification. * Review **Main Page** “Type” (Expedited or Full Board), “Status”, “Approval Expiration”, and any other relevant information to get an overview of the study. * **Note the expiration date to see if the continuation is due within the next month or so. If it looks like there may be crossover between the modification and the continuation, consult with personnel performing continuation review.** * If study is **closed to enrollment**, make sure a consent was NOT submitted (should be a consent addendum if one is needed). * Make sure revisions were made to the **correct version** of the documents. If not, return modification to study team and request that they make revisions from to the current version(s). * If the study enrolls a vulnerable population, the IRB Member reviewer must complete the applicable vulnerable population checklist. |

|  |
| --- |
|  |
|  |

| IRB-HSR to be the sIRB | | **Tick applicable boxes below** | | **Approval Form Comments and Notes** (in purple) | |
| --- | --- | --- | --- | --- | --- |
| If the study was initially submitted as a single site study, the revised protocol/application should address the following sections:   1. Overall Enrollment # 2. Statistical analysis 3. Where are samples and data is to be submitted? 4. Add DSMP Appendix C to the Protocol   Update the Approved Enrollment # at All sites on main page  Verify if UVA study team will be using a Data Coordinating Center (DCC)?  [listed on Reliance Agreement request form]-if yes, add to COMMENTS field on the main page  Use approval event of *SIRB: Approval Protocol Modification: Addition of Relying Site”.* | **Pre-review Notes:** | | **Approval form comments:**  SOM CTO letter is on file.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  SOM CTO approval is needed when:   * UVA PI is becoming the **overall PI of a multi-site study**   If using Data Coordinating Center: LIST NAME | |

| Addition of Relying Site | **Tick applicable boxes below** | | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- | --- |
| Does the modification require a separate Reliance Agreement?  If yes, see AG 2-26,  If relying under SMART, additional RA not required.  NOTE: If not done as part of UVA IRB becoming the sIRB of record, Add DSMP Appendix C to the Protocol  Tick the following boxes on the Main Page:   * IRB-HSR: IRB of Record for all sites change * Verify who will serve as the HIPAA Privacy Board on the reliance page. If UVA IRB-HSR is HIPAA Privacy Board change   **Under RELIANCE TAB** (left hand menu on Events page), add applicable Relying site information [from request form]  Add approval date, N= [if enrolling]  Review site local context for specific language to be added to consent (e.g. Compensation in case of injury, HIPAA language, compensation amount [info found in Reliance Agreement request form)  Confirm SOM CTO review on file for UVA PI serving as overall PI of multisite study AND SOM CTO review required for addition of each Relying site | **Pre-review Notes:** | **Approval form comments:**  Addition of Relying Site: NAME; PI Name: NAME; N= (#)  SOM CTO REVIEW on file for addition of Relying Site *(NAME*)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Note-Add relying site responsibilities-information obtained from *Reliance Agreement Request form for UVA IRB-HSR to serve as sIRB*  *For each relying site, Use Pull Down list of Relying Sites to Choose the applicable site-ONE EVENT PER RELYING SITE*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **If applicable with Relying Site request:**  Waiver of HIPAA Authorization for review of Medical Records to identify/contact:The UVA IRB-HSR has granted Waiver of HIPAA Authorization via 45CFR 164.512(i)(2) to identify and/or contact subjects by direct contact by a person who is not their health care provider.  Direct contact may include phone, letter, direct email or approaching potential subjects. Phone, letter or emails will be approved by the UVA IRB-HSR prior to use.  The following HIPPA identifiers may be collected:  Name, medical record number, date of birth and contact information appropriate to the recruitment plan. The minimum necessary PHI to be collected includes only those items related to the inclusion/ exclusion criteria. | |

| Additional Reviews & Approval | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| Studies under the authority of the **PRC:**   * If the study is conducted under the authority of the PRC, check the regulatory page in the database to see if PRC approved is needed for the modification. “PRC Review of Mods Required” Note on Approval Overview page that PRC approval is needed. * If the study was originally reviewed by the full board and the study has a PRC # verify that the Cancer Center DSMP is selected as the DSMB on the Regulatory page of IRB Online. | **Pre-review Notes:** | **Approval form comments:**   1. PRC approval is on file. 2. *If additional changes are made following IRB review, and the version date of the IRB protocol on the approval issued by the PRC does not match the final version date, write the following*:Note: the version date of the IRB protocol approved by the PRC does not match the IRB approval form as additional changes resulted from the IRB’s administrative review. *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*   As a general rule, if the study is a UVA investigator-initiated cancer study, PRC approval is needed. Modifications of industry-sponsored cancer studies do not need PRC approval. Cooperative Group studies do not need PRC approval at all. Check the regulatory page (if the study was approved in 2008 or later) if you have any question about whether or not PRC approval is needed. If there is a question about PRC approval for older studies, the study team will need to let you know if PRC approval is needed. |
| **HIRE Committee** approval needed? If yes,   * Note on Approval Overview page that HIRE committee approval letter is needed when approval is processed. * Note on Approval Overview (Regulatory page) that “Y” needs to be reflected for “Radiation” * Review the radiation-related questions in Protocol Builder to make sure everything is covered. | **Pre-review Notes:** | **Approval form comments:**  HIRE Committee approval is on file.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  HIRE approval is needed if the modification adds radiation for research purposes and standard wording was not used. There are also other scenarios that require HIRE review and forms to be completed, so it is imperative that the Protocol Builder questions are reviewed when radiation for research purposes is being added.  Information about radiation for research purposes can be found at the following website link: [Radiation Exposure for Research Purposes](https://research.virginia.edu/irb-hsr/radiation-exposure-research-purposes) |
| **SOM CTO** approval needed? If yes,   * Note on Approval Overview page that SOM CTO letter is needed when approval is processed * Note on Approval Overview any items that need to be ticked in IRB online, depending on which scenario(s) to the right apply | **Pre-review Notes:** | **Approval form comments:**  SOM CTO letter is on file.  ***If applicable,*** The SOM CTO has determined that the study is ***choose one***   * exempt from an IND because (INSERT REASON e.g. the study will not increase risk to subjects) * exempt from an IND because the product being given is not considered to be a drug * not exempt from an IND   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  SOM CTO approval is needed when:   * UVA PI is becoming the **overall PI of a multi-site study** * **UVA PI held IND/IDE** was added with the modification * **IND/IDE is held by a PI** from another academic institution * There is a **question as to whether or not an IND is needed** * There is a question regarding SR vs NSR status of a device study   SOM CTO approval is NOT needed to determine exemption from an IDE |
| **UVA ESCRO Committee** approval needed? If yes,  Note on Approval Overview page that ESCRO committee approval is needed when approval is processed | **Pre-review Notes:** | **Approval form comments:**  Approval from the UVA ESCRO Committee is on file.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ESCRO Committee approval is needed if the study involves viable embryos. |
| **IBC** approval needed? If yes,   * Make sure the IBC number been provided. | **Pre-review Notes:** | **Approval form comments:**  IBC approval number is **(*insert IBC #*)**.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  IBC approval is required for processing or storage of a specimen that occurs at UVA outside of a clinical area.  If IBC approval is required, the study team will need to supply the IBC number. |

|  |  |  |
| --- | --- | --- |
| **Non-UVA IRB** approval needed? If yes,   * Note on Approval Overview page that an approval is needed from a non UVA IRB when approval is processed. * Make sure Non-UVA IRB is checked on Regulatory page when approval is processed– note on Approval Overview page * If applicable, make sure multi-site is checked on Main page when approval is processed– note on Approval Overview page * If applicable, make sure PI of Multi-site Study is checked when approval is processed– note on Approval Overview page | **Pre-review Notes:** | **Approval form comments:**  Non-UVA IRB approval from **(add name of outside IRB/ethics committee)** is on file.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Non-UVA IRB approval may be needed in the following circumstances:   * Study is an **international** study * Study is **DoD funded** and study involves DoD personnel, data, or specimens   See appendix B for various scenarios. |
| **Outside Institution OK if no IRB exists**? If yes,   * Obtain documentation from outside institution verifying they approve of UVA personnel doing research at their institution * If applicable, make sure PI of multi-site study is checked when approval is processed– note on Approval Overview page * (e.g. Culpeper Regional Hospital) | **Pre-review Notes:** | **Approval form comments:**  Outside institutional approval from **(add name of outside institution)** is on file. |

|  |  |  |
| --- | --- | --- |
| **Device new to the UVA Health** added?If yes, note on Approval Overview page that New Medical Device Monitoring form is needed. | **Pre-review Notes:** | **Approval form comments:**  New Medical Device Monitoring form is on file.  ­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  This is needed if use of a medical device is occurring for the first time at UVA Health. If the device will not be used within UVA Health, New Medical Device Form is not needed (Examples: device used in Mem Gym; device used in local nursing home, device used in an Engineering dept.).  The Food and Drug Administration (FDA) defines a medical device as any instrument, apparatus, or other article that is used to prevent, diagnose, mitigate, or treat a disease or to affect the structure or function of the body, with the exception of drugs. This means that the FDA classifies common hospital products such as catheters, thermometers, patient restraints and syringes as medical devices. Certain types of software are also considered a device. If there are questions on how to complete the form, investigator should contact Clinical Engineering at 982-3857. The link for completing the New Medical Device Request Form online can be found on the IRB-HSR website at the following location: <https://research.virginia.edu/irb-hsr/forms-irb-hsr> |

|  |  |  |
| --- | --- | --- |
| **Procedures added requiring InfoSec approval?**  Answer Yes if any of the following procedures are being added:   * Collect or store identifiable\* data onto an individual use device (e.g. smart phone app, tablet, laptop) * Collect or store identifiable\* data via web based format (e.g. online consent, online surveys) Only exception is sharing or storing of data by sponsor or CRO in which data will be sent and stored in an encrypted fashion (e.g. Secure FS=X, Secure FTP, HTTPS, PGP) * Collect or store to a server NOT included in the list of HIPAA Compliant servers.   (see Data Security Plan for list of HIPAA compliant servers) | **Pre-review Notes:** | **Approval form comments**  InfoSec approval on file. |
| **GRIME: UVA Medical Students as Subjects**   * If this study will enroll UVA Medical Students as subjects, GRIME approval is required | **Pre-review Notes:** | **Approval form comments:**  GRIME approval on file for enrolling UVA medical students as subjects. |
| **GMEC: UVA Medical Residents or Fellow as Subjects**   * If this study will enroll UVA medical residents or fellow as subjects, GMEC approval is required | **Pre-review Notes:** | **Approval form comments:**  GMEC approval on file for enrolling UVA medical residents or fellows as subjects. |

| Certificates of Confidentiality | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |

|  |  |  |
| --- | --- | --- |
| **Certificate of Confidentiality** added? If yes: | **Pre-review Notes:** | **Approval form comments:**  ***(Insert applicable wording):*** Certificate of Confidentiality/Certificate of Confidentiality approval is on file.   * Check: Certificate of Confidentiality without expiration date * Additional information is at the following link: <https://research.virginia.edu/irb-hsr/certificates-confidentiality> |

| Compensation/Reimbursement | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| Is compensation or reimbursement being **added or significantly altered**? If yes,   * Make sure the appropriate template sections were included and completed correctly. * Make sure the payment amount is free of undue influence. * Make sure the compensation section on the “Funding Page” has been updated – note on Approval Overview page * Make sure the information matches between the IRB protocol/application template and the consent * Make sure the difference between compensation (payment) and reimbursement is clear (if applicable). | **Pre-review Notes:** | **Approval form comments:**  ***(insert applicable information regarding payment/reimbursement addition or change)***.  A **reimbursement** is used when the subject is paid back for travel expenses such as mileage, lodging, food while traveling. Receipts or mileage must be submitted for a reimbursement. Compensation is "payment" for things such as time, discomfort, inconvenience.  If study team needs instructions on how to process a reimbursement send them to the "Goods and Services Procurement Guide" at <https://procurement.virginia.edu/payables/accounts-payable-basics>. They may also call the Procurement Help Desk at 924-4212.  Reimbursements are not reportable to the IRS as income, but will be withheld if the subject owes money to the state. The study team may want to speak to procurement regarding the typical turnaround time for reimbursements, so that accurate information is in the consent form.  For additional information, refer to:   * Protocol Builder * “Research Participant Compensation Procedure” under Special Issues on the IRB website * Special Issues FAQ “Is there a procedure for how to compensate research trial participants” |
| Was a **method of payment other than a check via oracle**, requested? If yes,   * Make sure the justification is adequate; if not adequate, explain to study team why the payment addition cannot be approved w/ the justification provided. | **Pre-review Notes:** | **Approval form comments:**  None  Information related to this issue can be found under the Special Issues FAQ “When is it justifiable to provide compensation using an alternative method of payment (gift card, petty cash, etc.) while still collecting tax information” |
| Has study team stated that they cannot **obtain SS#** for compensation? If yes,   * Make sure the justification is adequate; if not adequate, explain to study team why the payment addition cannot be approved w/ the justification provided. | **Pre-review Notes:** | **Approval form comments:**  None  Information related to this issue can be found under the Special Issues FAQ “When is it justifiable to provide compensation if the tax information (name, address, social security number of recipient) cannot be collected”. |
| Is new payment **pro-rated?** If not,   * Make sure it is appropriate NOT to be pro-rated, and is not coercive. | **Pre-review Notes:** | **Approval form comments:**  None |

| Drugs, Biologics, and Devices | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| ***If the study is NOT regulated by the FDA*** | **Pre-review Notes:** | **Approval form comments:**  ***pick one of the following:***  --This study is not regulated by the FDA as it does not involve research on a drug, biologic or device.  *(Use the following option if it is noted in the letter from SOM CTO as the study involves a supplement/isotope in which the intent of the study does not include evaluating the supplement’s/isotope’s ability to diagnose, cure, mitigate, treat or prevent disease)*  --This study is not regulated by the FDA because it has been determined that the product as used in this study does not meet the criteria of a drug.  **If the modification is being sent to the Full Board for them to make a determination, DO NOT cite items above until the approval is processed.** I |
| Was a **drug or biologic (to be used for research purposes)** added? This question refers to investigational drugs/biologics and approved drugs/biologics being used in an unapproved manner. If yes,   * Make sure the appropriate template section(s) were added to the application, protocol and consent. * Note on Approval Overview page which check box or boxes need to be ticked on the Regulatory page in the database * (e.g. check Approved Drugs/ Biologics or investigational drug/ AND FDA Regulated. See [FDA Regulated Studies](https://research.virginia.edu/sites/vpr/files/2019-08/fda_regulated_studies.docx)  for additional information * If an IND was added, update the IND/IDE screen when submission is processed. | **Pre-review Notes:** | **Approval form comments:**  ***If drug/biologic is exempt from an IND per 21CFR212.2(b) write:*** *This study is regulated by the FDA.* Drug/biologic determined to be exempt from IND requirements according to 21CFR312.2(b).  ***If the board determined that the drug/biologic is NOT exempt write:*** This study is regulated by the FDA. The board determined that an IND is required. IND# required ***OR (enter #)*** on file.  **If the modification is being sent to the Full Board for them to make a determination, DO NOT cite items above until the approval is processed.** In the Receipt Protocol Modification event write: The SOM CTO opinion on the need for an IND is on file. The board needs to determine if an IND is required.  The SOM CTO has determined that the protocol is choose one   * exempt from an IND because (INSERT REASON e.g. the study will not increase risk to subjects) * exempt from an IND because the product being given is not considered to be a drug * not exempt from an IND.   A separate drug information section should be added to either the application or the protocol if developed from Protocol Builder for EACH drug or biologic added. Refer to the Modification Templates tab, Protocol Builder, and the appropriate AG for additional information related to the addition of a drug or biologic. Information can also be found on the website at the following link: <https://research.virginia.edu/irb-hsr/investigational-drugs-and-biologics>  If the protocol involves research of a drug or biologic already approved by the FDA for the indication, dose, and route to be used in this protocol, the boxes for “Approved Drug, Device or Biologic” AND ”Investigational Drug, Biologic” need to be ticked to indicate that an approved drug or biologic is being investigated.  **OPTIONAL:** You may elect to use the expedited or full board Administrative Pre-review checklist when a drug or biologic is being added. If you elect to do this be sure to apply the above information that is highlighted in gray. |
| Was a **device added** for which the safety and efficacy is being evaluated? If yes,   * Using the Device Questions in Protocol Builder determine which template section(s) need to be completed. Add the section(s) to the protocol and consent as applicable, and then send the document(s) back to the study team for completion. If the study utilizes an IRB Application, create a Word document containing all of the appropriate template sections. If the study is part of a UVA faculty member’s investigational device application, make sure the UVA PI held IDE section of the DSMP is added. * Note on Approval Overview page which check box or boxes need to be ticked on the Regulatory page in the database. See [FDA Regulated Studies](https://research.virginia.edu/sites/vpr/files/2019-08/fda_regulated_studies.docx)  for additional information * If the study has an outside sponsor, find out if the sponsor has already obtained an IDE number or if there is information from the sponsor documenting their opinion as to why an IDE number is not needed. * If there is no outside sponsor, make sure the PI has made the initial determination about whether or not the study is exempt from device regulations. Also make sure SOM CTO has provided their opinion on the need for an IDE and note on Approval Overview page. * If no outside sponsor and not exempt, make sure the PI has made the initial determination regarding significant/non-significant risk. Also send protocol to SOM CTO for opinion on need for IDE and to full board to determine if device is SR vs. NSR. * If an IDE was added, update the IND/IDE screen in the database when the submission is processed – note on Approval Overview page. * If an SR/NSR determination is needed ( study is not exempt from IDE) make sure SOM CTO letter is received – note on Approval Overview page. * New Medical Device Monitoring Form should be noted under “Other Approvals” if device is new to the UVA Health * If the device is exempt from 21CFR812.2(c)(3), complete the row below related to exempt devices. * Make sure the costs section of the consent is updated as applicable | **Pre-review Notes:** | **Approval form comments:**  ***If applicable:*** New Medical Device Monitoring Form is on file for ***(insert name of device)***  ***If device is NOT exempt and SR:***  This study is regulated by the FDA [***if applicable***, under IDE# ***(insert IDE #)*]**. The Full Board determined the (insert name of device) to be significant risk per 21CFR812.3(m). An IDE # from the FDA is required prior to IRB approval to enroll subjects. The sponsor is required to follow the FDA regulations found at 21CFR812.3(m)  ***OR*** IDE approval from FDA required for ***(insert name of device)***. Device determined to be of Significant Risk.  ***If device is NOT exempt and NSR:***  This study is regulated by the FDA. The Full Board determined the (insert name of device) as used in this protocol to meet the criteria of non-significant risk per 21CFR812.3(m). No IDE application required, however the sponsor is required to follow the FDA regulations "abbreviated IDE requirements" at 21CFR 812.2(b).  **If the modification is being sent to the Full Board for them to make a determination, DO NOT cite items above (except the comment related to the New Medical Device Application) until the approval is processed.** In the Receipt Protocol Modification event for devices reviewed by the board write: The SOM CTO opinion on the need for an IDE is on file. The board needs to determine if the device is SR or NSR.  The researcher may be evaluating a device that has never obtained FDA approval, or he/she may be evaluating a device which is FDA approved, but for a different indication than that being evaluated in the study.  A separate device information section should be added for EACH device added to either the Application or the protocol if developed from Protocol Builder template.  If the investigator feels that the device meets the criteria of a non-significant risk device, the protocol will need to be reviewed by the full board to determine if the device is NSR.  For additional information refer to AG 3-13 and/or the Device Decision Tree, located at the following path on the U:drive: \\IRB\IRB-HSR\Administrative FAQ's\Algorithms. Information can also be found on the website at the following link: <https://research.virginia.edu/irb-hsr/investigational-medical-devices>  **OPTIONAL:** You may elect to use the expedited or full board Administrative Pre-review checklist when a device is being added. If you elect to do this, ,make sure to apply the above information that is highlighted in gray. |
| Is the device being evaluated **exempt** from 21CFR812.2(c)(3)? If yes,   * If all of the sub-bullets below apply, Expedited Category #1 will be utilized for Expedited studies and should be noted on the Approval Overview page (Regulatory page).   + All other procedures in the study fall under an expedited category   + Study is minimal risk   + If the study involves an in-vitro diagnostic device, the results will not be given back to the subject. * Also note on Approval Overview other items to be ticked on the Regulatory page (see notes). See [FDA Regulated Studies](https://research.virginia.edu/sites/vpr/files/2019-08/fda_regulated_studies.docx)  for additional information * If study is a full board study Expedited category #1 will not be used – simply add the appropriate approval form comments. * If the study is not exempt from IDE regulations the protocol must be sent to the SOM CTO for their opinion, and to the full board to determine SR vs NSR device status. See AG 3-13 for steps to be taken. | **Pre-review Notes:** | **Approval form comments:**  ***If research is on a non-approved device and is exempt from 21CFR812.2(c)(3) write:***  Device (***insert name)*** determined by the IRB to be exempt from IDE requirements according to 21CFR812.2(c) (3).  ***If research is on an approved device being used in an approved manner write:*** Device has FDA approval and is being used according to FDA labeling.    ***If applicable:*** This study now meets the criteria of Expedited Category #1.  ***If applicable (use for approved device being used in an approved manner):*** Device has FDA approval and is being used according to FDA labeling.  ***If applicable:*** New Medical Device Monitoring Form is on file for ***(insert name of device)***  If research is on a non-approved device:   * Investigational Device: Exempt will need to be checked on the Regulatory page   If research is on an approved device being used in an approved manner:   * Approved Drug, Device or Biologic AND Investigational Device will need to be checked on the Regulatory page   + - ***NOTE:*** *If the device is being evaluated, the FDA classifies an approved device being used in an approved manner as an ‘Investigational Device’.* *Therefore, both approved and investigational Device should be checked to designate that the study is of an approved device which is being investigated.*   **Exempt Criteria**   * a legally marketed device when used in accordance with its labeling * a diagnostic device if it complies with the labeling requirements in §809.10(c) and if the testing:   + is noninvasive;   + does not require an invasive sampling procedure that presents significant risk;   + does not by design or intention introduce energy into a subject; and   + is not used as a diagnostic procedure without confirmation by another medically established diagnostic |
| Does this modification add the use of a **“research use only”** device?   * If yes and the results will be used to diagnose or treat a subject, the device falls under FDA regulations. Follow the instructions under rows 2/3 of this table). * If yes, but the results will NOT be used to diagnose or treat subjects, and the study meets the criteria of an Expedited study, expedited Category #4 will be used. If the study is a FB study, the modification can be expedited UNLESS there are other pieces of the modification that would increase risk. * Note on Approval Overview (Regulatory page) that “Research Use Only Device” needs to be ticked * Also note on Approval Overview other items to be ticked on the Regulatory page (see notes). See [FDA Regulated Studies](https://research.virginia.edu/sites/vpr/files/2019-08/fda_regulated_studies.docx)  for additional information | **Pre-review Notes:** | **Approval form comments:**  **For expedited studies where expedited category #4 applies:**  The device (insert name of device) being used in this protocol is a Research Use Only device. It is not being evaluated for safety and efficacy but is being used in an unapproved manner. The FDA device regulation 21CFR812 does not apply to this protocol.  The FB does NOT determine SR/NSR status for RUO devices when FDA regs do not apply. In addition, since the device is not regulated under FDA regulations, expedited category #1 is not used. |
| Does the modification add the **use of (and not evaluation)** a device in an unapproved manner?   * FOR EXPEDITED STUDIES: If the device has FDA approval for ANY indication and is not being used to diagnose or treat a subject, Expedited Category #4 should be noted on the approval, and Device: Unapproved USE only; no evaluation should be noted on the Approval Overview. * FOR EXPEDITED STUDIES: If the device does NOT have FDA approval for ANY indication, the modification will need to be reviewed by the full board as Category #4 does not apply. * If sent to the full board, note the following on the Approval Overview (regulatory) page: If the board determines that the study is still minimal risk, tick Expedited Category #9 and change the study TYPE on the main page to FULL COMMITTEE * FOR FULL BOARD STUDIES: the modification needs to be sent to the full board. The board will not determine IDE exemption or SR/NSR status as the device is being used and not evaluated. | **Pre-review Notes:** | **For expedited studies with no FDA approval for any indication:**  The IRB needs to determine if this study is still minimal risk. If so determined, future continuations may be expedited.  **For expedited studies where expedited category #4 applies:**  The device (insert name of device) being used in this is not being evaluated for safety and efficacy but is being used in an unapproved manner. The FDA device regulation 21CFR812 does not apply to this protocol. |
| Is there an **IND/IDE for this study that is held by someone outside of UVA** other than a commercial sponsor? If yes,   * SOM CTO should be noted in “Other Approvals” section above | **Pre-review Notes:** | **Approval form comments:**  Noted above under “Other Approvals” |
| Was the **FDA Verification of Approval** section added?   * If yes, and 3 or more questions are answered NO, refer protocol to David Driscoll (if PI is from SOM) or Dave Hudson (if PI does not work for SOM) and the IRB Chair for review. | **Pre-review Notes:** | **Approval form comments:**  FDA Verification of Approval has been provided for ***[insert name of drug/device/biologic].***  ***(insert applicable name)*** David Driscoll/Dave Hudson notified. No additional review required. |

| Genetic Research/Specimen Banking | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| Is **Genetic Research and/or testing for HLA status** being added? If yes,   * Click on the Modification Templates tab in Protocol Builder, and review the appropriate genetic research table to make sure all relevant template sections are included in the Application or IRB protocol and consent. * Make sure the information regarding genetic research matches between the Application or IRB protocol (if applicable) and consent. * If there is an IRB application, you will need to provide the appropriate template sections to the study team for them to submit and complete. See notes on right for more information. * If there is an IRB protocol, make sure the “Risks of Genetic Research” item is present in the expected risks table in the DSMP. * Make sure the risk of accidental disclosure/loss of confidentiality is mentioned in both the IRB protocol (if applicable) and the consent. * Note on Approval Overview (Regulatory section) that Genetic Research needs to be ticked. * Verify banking is not mandatory if the study has a potential for therapeutic benefit. | **Pre-review Notes:** | **Approval form comments:**  Genetic Research / testing for HLA status ***(insert as appropriate)*** is being added with this modification***. If useful, add a brief description of the genetic research***. Results ***will*** OR ***will not*** be shared with subjects.  **If reviewed by the full board, DO NOT cite the comments above until the approval is processed.** In the RECEIPT protocol modification event, write: ***If applicable***, The IRB to determine if mandatory banking is acceptable.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Reviewing the genetic/HLA testing questions and help text in Protocol Builder may be helpful as you conduct your pre-review. If the study previously included genetic research and/or HLA testing, there may not be any additional template sections to add, but the clean/full templates may still be helpful in determining if all necessary information has been added, particularly since relevant information is sometimes deleted before the documents are submitted to the IRB.   * If there is an IRB application, the only template associated with the application is a short Genetic Research section. * The consent will be a little more challenging. You are going to need to find out what type of genetic research is being added, and provide the consent sections that apply. You can do this either by reviewing the Protocol Builder questions using the “Major” HSR Question Report function.   The Genetic Research link under Special Issues on the website may be helpful: <https://research.virginia.edu/irb-hsr/genetic-research> |
| Does this modification add a type of **genetic research that is considered greater than minimal risk**? If yes, and the study did not previously include this type of genetic testing:   * The modification will require review by the full board * If the study is currently approved as an Expedited study, it will become a full board study, and you will need to review the Protocol Approval Types table. | **Pre-review Notes:** | **Approval form comments:**  Nothing specific needs to be added beyond the comments that will be included from the row above, and the Protocol Approval Types table.  Full board review is DNA/RNA or sequence analysis results will go in the subjects’ medical records, will be shared with the subjects’ health care providers, or will be shared with the subjects or their parent/guardian.  See above for website link for Genetic Research. |
| Is there a possibility that data from this study may someday be used for a **Genome-Wide Association Study**? If yes,   * Make sure the GWAS template section has been added to the consent. * Make sure the Approval Overview notes that “Genetic Research” needs to be ticked on the regulatory page (if not ticked already) * If the modification adds a request for **GWAS certification,** notify the IRB Director. | **Pre-review Notes:** | **Approval form comments:**  None specific.  This applies to studies funded by the NIH that include analysis of the entire genome.  Researchers can find additional information about this at the following sites:  [IRB-HSR Website on GWAS](https://research.virginia.edu/irb-hsr/genomic-data-sharing-gds)  [NIH GWAS website](http://grants.nih.gov/grants/gwas/)  There is also a GWAS page under Special Issues on the website: <https://research.virginia.edu/sites/vpr/files/2019-08/SPECIMEN_Banking.docx> |
| Is **Specimen Banking** being added to a study that did not previously include banking? If yes,   * Click on the Modification Templates tab in Protocol Builder and review the appropriate table to make sure all relevant template sections are included. * Make sure the information matches between the IRB protocol/application template and consent. * Make sure the risk of loss of confidentiality is mentioned as an expected risk in the DSMP in the IRB protocol (if applicable) and the consent. * If specimens are being banked long term at UVA, note on Approval Overview that the following needs to be added to the Main Page in IRB online: “This protocol includes specimen banking at UVA. Verify a database # is included with closure form before closing this study.” * If information on who will be responsible for storing specimens is present, make sure roles or titles are used as opposed to individual names. * If someone outside UVA will have control over the specimens, make sure the related question(s) are answered YES if there is an IRB protocol. * If participants can withdraw their specimens or request that they be destroyed, make sure the appropriate language is present in the “Changing your mind later” section of the consent. * Note on Approval Overview (Regulatory page) that specimen banking needs to be ticked. | **Pre-review Notes:** | **Approval form comments:**  Specimen banking is being added with this modification.  The specimen banking section is ONLY needed if specimens are being stored at UVA long term.  Additional information regarding specimen banking can be found on the website under Special Issues.  Link: <https://research.virginia.edu/sites/vpr/files/2019-08/SPECIMEN_Banking.docx> |

**Populations Requiring Additional Protections**

|  | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| Study already Includes Enrollment of a Population requiring additional protections | **Pre-review Notes:** | If the modification is being sent to the Full Board, *In the RECEIPT event, insert:*  Populations requiring additional protections being recruited include (INSERT). The study currently requires (INSERT TYPES OF PROTECTIONS CURRENTLY IN PLACE). The board needs to determine if the current protections continue to be appropriate given this modification. |
| Children | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| **If children are being added to a study previously approved for adults only**:   * If the study will administer radiation to minors, HIRE approval is required. * Go to the Modifications Template tab in Protocol Builder to make sure all appropriate template sections have been added to the IRB protocol/application and/or consent. Pay close attention to headings and signature lines. * If there are short forms, make sure they are updated to include the necessary signature lines. * If the study will administer radiation to minors, HIRE approval is required. *( In the past, HIRE approval was not required if standard radiation language was used)* * Note applicable regulations on Approval Overview page – if full board, make sure the regulations you cite match the completed scientific reviewer’s checklist you receive following the meeting. * If modification is sent to the full board, note on Approval Overview page that the text about the Board’s determinations regarding enrollment of children needs to be deleted after the meeting. | **Pre-review Notes:** | **Approval form comments:**  Do NOT include references to 21CFR if protocol has no drug/device  Children are approved to enroll in this protocol per ***(select applicable regulation)***  45CFR46.404/21CFR50.51 ***If applicable***, specify ARM of study  45CFR46.405/21CFR50.52 ***If applicable***, specify ARM of study  45CFR46.406/21CFR50.53 ***If applicable***, specify ARM of study  45CFR46.407/21CFR50.54 ***If applicable***, specify ARM of study  This protocol requires the signature of (***select applicable regulation)***  One parent per 45CFR46.408(b)/ 21CFR50.55 (e )(1)  Both parents per 45CFR46.408(b)/ 21CFR50.55 ( e)(2)  No parent per 45CFR46.408 (c)/ 21CFR50.55/( e)  **If the modification is being sent to the Full Board, DO NOT cite the items above until the approval is processed.** In the RECEIPT protocol modification event, write: Populations requiring additional protections being recruited include children. The board needs to determine the number of parents signatures and if assent is required (written or verbal). ***If applicable,*** The board needs to determine the approval criteria for each arm of the study.  If the study involves a placebo arm, a protocol may be approved under one or more of the approval criteria listed below. If this is the case, please note which arm is being approved under each criteria.  See Appendix C for tips on which regulation(s) to use and the appropriate # of parent signatures.  Information about Children can also be found at the following link on the website under Special Issues. <https://research.virginia.edu/irb-hsr/vulnerable-subjects-children-minors> |
| If the **age range** of the children is changing:   * Use the Modification Templates tab to view the current template and to make sure all necessary updates have been made. | **Pre-review Notes:** | **Approval form comments:**  The age range of subjects in this study is changing from X ***(note original age range)*** to X ***(note new age range)***.  If any of the scenarios below apply, add additional comments as appropriate.  If the age range changes in a way that:   * the risk/benefit ratio may be affected * another regulation may need to be cited than the one already approved * assent requirements might be different than what was originally approved * the number of parent signatures may be different for the new population   Send to the full board, and note that the board will need to make whatever determinations are appropriate. |
| Is **assent** required?   * If Written assent is required, confirm that consent/assent forms are appropriate * If either verbal assent is being requested, or no assent is needed, add the applicable comments listed under “Approval Form comments”. * If PI or sponsor is requesting written assent, note this in the receipt protocol modification comments.   **Age of Majority Consent**  Does the study meet the following criteria:   * Enrolling minors requiring parental consent and either of the following two criteria applies:   + Study is longitudinal and requires continued active participation of the subject after the minor reaches the age of majority   + Study data or samples obtained from the subject will continue to be used after the minor reaches the age of majority and a Waiver of Consent not requested for continued use of data/specimens for subjects reaching Age of Majority.   NOTE- Age of majority is 18 in Virginia. If subjects enrolled outside of Virginia study team must-verify age of majority in other state(s).  **YES** *An Age of Majority Consent Addendum and an Age of Majority Cover Letter are required.*  **NO** *Waiver of Consent/Waiver of HIPAA Authorization can be applied so long as*  *• This study will enroll minors under parental permission.*  *• If data or specimens are collected from the minor they will be banked for future research and used after the minor reaches the age of majority.*  *• This study does NOT require continued active participation of the subject after the minor reaches the age of majority making obtaining consent from the subject after they reach the age of majority impracticable.* | **Pre-review Notes:** | **Approval form comments:**  Do NOT include references to 21CFR if protocol has no drug/device  ***If assent is required:*** This protocol requires the ***(pick one)***: verbal/written assent of the child per 45CFR46.408(a)/21CFR20.55  ***If assent is NOT required:*** No assent required per 45CFR46.408(a)/21CFR50.55 because:  subjects are too young to understand the research and its ramifications.  the study provides the potential for therapeutic benefit and the treatment is not available outside of this protocol.  subjects are unconscious or have impaired decision making capacity and unable to provide assent.  ***If no assent required or verbal assent is approved***, add the following applicable statement(s) to the main page comment field in IRB online:  No assent required– therapeutic – treatment not available outside of protocol  No assent required – children not capable of giving assent  No assent form required – no subjects aged 7 to < 15  No assent form required – obtaining verbal assent  **Approval form comments:**  *An Age of Majority Consent Addendum and an Age of Majority Cover Letter were created.*  **Approval form comments:**  This protocol has been granted a waiver of consent under 45CFR46.116 ADD ADDITIONAL REGULATIONS FROM ADMIN FORM AS APPLICABLE-E.G. DOD, FDA, and a waiver of HIPAA authorization under 45CFR 164.512(i)(2) for the continued use of data/specimens collected under parental/guardian permission. The IRB determined that obtaining consent/authorization would be impracticable because the study team no longer has contact with the subject.  The tick box for Waiver of Consent/HIPAA Authorization- Age of Majority should be checked in IRB online.  **If the modification is being sent to the Full Board, DO NOT cite the items above until the approval is processed.**  If the study is not therapeutic, there should be an assent form. The board will not typically require written assent if the study is therapeutic.  See Appendix C for tips regarding assent. |
| If minors were added and **study is more than minimal risk with no benefit (requiring two parent signatures)**:   * Make sure an Advocate for Ward of State has been appointed if wards of states will be enrolled. * Note on Approval Overview (Regulatory page) that “Ward of State Advocate” needs to be ticked when hard copies are processed. * Note final versions of short forms on Approval Overview | **Pre-review Notes:** | **Approval form comments:**  ***If study approved under 45CFR406 or 407 choose the appropriate sentence below:***  Children who are Wards of State have been excluded from this protocol  Children who are Wards of State will be included in this protocol per 45CFR46.409/21CFR50.56. The advocate is ***(INSERT NAME)***. If approved under 407, Wards of state can be included in research only if the research is:   1. Related to their status as wards, OR 2. Conducted in schools, camps, hospitals, institutions, or similar setting in which the majority of children involved as subjects are not wards.   If subjects are being enrolled at UVA, Wards are generally included |

| Pregnant women/Fetus/ Neonates | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| If the modification adds the enrollment of **pregnant women or fetuses:**   * Pregnant women, fetus, in vitro fertilization box should be checked on Regulatory Page – note in Approval Overview section of this form. * If modification is sent to the full board, note on Approval Overview page that the information about the board determining the appropriateness of pregnant women/fetuses needs to be deleted when the approval is processed. | **Pre-review Notes:** | **Approval form comments:** Enrollment of pregnant women/fetuses approved under 45CFR46.204.  **If the modification is being sent to the Full Board, DO NOT cite the comments above until the approval is processed.** In the RECEIPT protocol modification event, write: The board needs to determine if it is appropriate to enroll pregnant women/fetuses in this study.  When conducting the pre-review, it may be helpful to utilize the Scientific Reviewer’s checklist for Pregnant Women, Fetuses, and Neonates.  Information can be also found on the website under Special Issues:  <https://research.virginia.edu/irb-hsr/vulnerable-subjects-pregnant-women> |
| If the modification adds enrollment of **neonates:**   * If viable neonates are included, “Children” must also be checked above with reviewer completing both checklists * Other Populations requiring additional protectionsshould be checked on Regulatory Page, writing in Neonates in box. Note in Approval Overview section of this form. * If modification is sent to the full board, note on Approval Overview page that the information about the board determining the appropriateness of neonates needs to be deleted when the approval is processed. | **Pre-review Notes:** | **Approval form comments:** Enrollment of neonates approved under 45CFR46.205  ***Also complete Children section above.***  ***Note to staff- there is no FDA equivalent for this regulation***  **If the modification is being sent to the Full Board, DO NOT cite the comments above until the approval is processed.** In the RECEIPT protocol modification event, write: The board needs to determine if it is appropriate to enroll neonates in this study.  When conducting the pre-review, it may be helpful to utilize the Scientific Reviewer’s checklist for Pregnant Women, Fetuses, and Neonates. Link:  <https://research.virginia.edu/irb-hsr/irb-board-members>  Information can also be found on the website under Special Issues:  <https://research.virginia.edu/sites/vpr/files/2019-08/vulnerable_pop_pregnant_fetus_checklist.doc> |
| If the modification adds research involving, after delivery, **the placenta, the dead fetus, or fetal material:**   * Other populations requiring additional protections should be checked on the Regulatory Page, writing in placenta, dead fetus or fetal material in box. Note in Approval Overview section of this form. * If modification is sent to the full board, note on Approval Overview page that the information in the event about the board determining the appropriateness of adding this population needs to be deleted when the approval is processed. | **Pre-review Notes:** | **Approval form comments:** Research involving after delivery, the placenta, the dead fetus or fetal material approved under 45CFR46.206.  ***Note to staff- there is no FDA equivalent for this regulation***  DoD Directive 3216.02 *( if funded by DoD and study involves Fetal Tissue Research*)  **If the modification is being sent to the Full Board, DO NOT cite the comments above until the approval is processed.** In the RECEIPT protocol modification event, write: The board needs to determine if it is appropriate to allow this protocol to contain research involving, after delivery, the placenta, the dead fetus, or fetal material.  When conducting the pre-review, it may be helpful to utilize the Scientific Reviewer’s checklist for Pregnant Women, Fetuses, and Neonates. Link:  <https://research.virginia.edu/irb-hsr/irb-board-members>  Information can also be found on the website under Special Issues:  <https://research.virginia.edu/sites/vpr/files/2019-08/vulnerable_pop_pregnant_fetus_checklist.doc> |
| If the modification adds enrollment of **neonates:**   * Other populations requiring additional protectionsshould be checked on Regulatory Page, writing in Neonates in box. Note in Approval Overview section of this form. * If modification is sent to the full board, note on Approval Overview page that the information about the board determining the appropriateness of neonates needs to be deleted when the approval is processed. | **Pre-review Notes:** | **Approval form comments:** Enrollment of neonates approved under 45CFR46.205  **If the modification is being sent to the Full Board, DO NOT cite the comments above until the approval is processed.** In the RECEIPT protocol modification event, write: The board needs to determine if it is appropriate to enroll neonates in this study.  When conducting the pre-review, it may be helpful to utilize the Scientific Reviewer’s checklist for Pregnant Women, Fetuses, and Neonates. Link:  <https://research.virginia.edu/irb-hsr/irb-board-members>  Information can also be found on the website under Special Issues:  <https://research.virginia.edu/sites/vpr/files/2019-08/vulnerable_pop_pregnant_fetus_checklist.doc> |
| If the modification adds research involving, after delivery, **the placenta, the dead fetus, or fetal material:**   * Other populations requiring additional protection should be checked on the Regulatory Page, writing in placenta, dead fetus or fetal material in box. Note in Approval Overview section of this form. * If modification is sent to the full board, note on Approval Overview page that the information in the event about the board determining the appropriateness of adding this population needs to be deleted when the approval is processed. | **Pre-review Notes:** | **Approval form comments:** Research involving after delivery, the placenta, the dead fetus or fetal material approved under 45CFR46.206.  **If funded by DoD, and study involves Fetal Tissue Research, add:**  and DoD Directive 3216.02  **If the modification is being sent to the Full Board, DO NOT cite the comments above until the approval is processed.** In the RECEIPT protocol modification event, write: The board needs to determine if it is appropriate to allow this protocol to contain research involving, after delivery, the placenta, the dead fetus, or fetal material.  When conducting the pre-review, it may be helpful to utilize the Scientific Reviewer’s checklist for Pregnant Women, Fetuses, and Neonates. Link:  <https://research.virginia.edu/irb-hsr/irb-board-members>  Information can also be found on the website under Special Issues:  <https://research.virginia.edu/sites/vpr/files/2019-08/vulnerable_pop_pregnant_fetus_checklist.doc> |

| Prisoners | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| If the modification adds enrollment of **prisoners** OR prisoners are enrolled:   * Prisonersbox should be checked on Regulatory Page – note in Approval Overview section of this form. | **Pre-review Notes:** | **Study team must submit:**   * Modification Request Form stipulating that they wish to enroll Prisoners * Protocol Appendix: Research with Prisoners * Consent Addendum: Prisoner Subjects Population * Letter of cooperation from the correctional facility/facilities/ where the prisoner(s) are housed   **Approval form comments:** Enrollment of prisoners approved under 45CFR46Subpart C.  **If DHHS funded, add:** by 46.306(a)(2) Category [**i, ii, iii, or iv].** DHHS Secretarial Approval on file.  *(see AG 3-34 for additional info)*  **If study will be carried out inside the Bureau of Prisons add:** 28CFR812.512  **For all studies add:** 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 protocol. The IRB members discussed the additional protections necessary for this population.  The Prisoner Representative concurred with the permission for prisoners to enroll as subjects in the research.  **If the modification is being sent to the Full Board, DO NOT cite the comment above until the approval is processed.**  ***In the RECEIPT protocol modification event, write***:  Study team requests inclusion of prisoners.  NOTE:   * If the modification requires full board review, the Prisoner Representative must be present at the meeting and complete the i [Research Involving Prisoners Checklist](https://research.virginia.edu/sites/vpr/files/2020-04/IRB%20Member%20Populations%20Requiring%20Additional%20Protections%20Checklist%20-%20Prisoners.doc) . * If the modification meets expedited review criteria, and consent has not been waived, the Checklist will be completed by a designated IRB member which may or may not be the Prisoner Representative. If the Prisoner Representative does not complete the checklist the IRB must have written confirmation from the Prisoner Representative that they agree the study/ the changes to the study is no more than minimal risk * If the study does not involve an interaction/ intervention (e.g. chart review under waiver of consent) the Prisoner Representative and the checklist are NOT required. * If funded by DoD, involvement of prisoners of war is prohibited per Directive 3216.2. * If study will be carried out inside the Bureau of Prisons, must follow 28CFR812.512 * If study is funded by DHHS and involves an interaction/ intervention (e.g not done under a waiver of consent) the research must be reviewed and approved by the DHHS Secretary via OHRP. *See AG 3-34 for additional information.*   Information can also be found on the website under Special Issues: <https://research.virginia.edu/irb-hsr/vulnerable-subjects-prisoners> |

| Impaired Decision-Making Capacity | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| Does the modification add enrollment of subjects with impaired decision-making capacity? If yes,   * Go to the Modification Templates tab, and make sure the required template sections have been added and completed appropriately. * If the study is sponsored, make sure the information being added is consistent with the sponsor’s protocol and/or that the sponsor agrees with the addition of this subject population. * If use of LAR is not needed, note on Approval Overview (Main Page): Use of LAR is not needed since subjects have only mild impairment of decision making capacity?. * Mental Impairmentbox should be checked on Regulatory Page – note in Approval Overview section of this form. * If modification is sent to the full board, note on Approval Overview page that the text about the board’s determination regarding enrollment of subjects with impaired decision making capacity needs to be deleted after the meeting. | **Pre-review Notes:** | **Approval form comments:**  ***(If applicable):*** Use of a Legally Authorized Representative approved under 45CFR46.116 and if applicable: 21CFR56.111 ***(or if not approved, document the board’s rationale for not approving the use of the LAR)***.  **If the modification is being sent to the Full Board, DO NOT cite the comment above until the approval is being processed.**  In the RECEIPT protocol modification event, write: Populations requiring additional protections should being recruited include subjects with impaired decision making capacity. The board needs to determine if the use of a LAR is appropriate for this study.  The use of a LAR is only required if an ADULT is not able to give consent for him/herself in research due to:   * Impaired decision-making capacity * Suffering from a serious or life-threatening disease   IRB review for use of LAR in minors is handled in a different section of this review form. In Virginia, for non-therapeutic research, the use of a LAR is only allowed if the research is no more than a minor increase over minimal risk to the human subject.  Refer to AG3-15 and to the [Surrogate consent/ Use of LAR](https://research.virginia.edu/irb-hsr/surrogate-consent-use-legally-authorized-representative-lar) on the IRB-HSR website for more information. |

| Employees/Students | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| Does the modification add enrollment of **employees/students as** subjects? If yes,   * Go to the Modification Templates tab, and make sure the required template sections have been added and completed appropriately. * If the study is sponsored, make sure the information being added is consistent with the sponsor’s protocol and/or that the sponsor agrees with the addition of this subject population. | **Pre-review Notes:** | **Approval form comments:**  ***(If applicable):*** Study modified to target employees/ student for enrollment.  In the RECEIPT protocol modification event, write: Vulnerable populations being recruited include employees and students.  NOTE:  **Verify the Employee / Student template section has been added to the application**  **Complete the checklist for employees/students** |

| **Miscellaneous** | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| [Blood/ Specimens Added](#Text57) |  |  |
| Is taking of blood/specimens being added? If yes,   * Make sure the volume of blood/specimen to be taken for each visit is clear * Make sure the total amount of blood/specimens to be taken is listed * If any new sections need to be added to the application or protocol, make sure they have been added. * If there is no IRB protocol, determine if you need to provide the study team with a template section from the Application to be completed. * If the amount of blood being taken exceeds the expedited criteria, the modification will need to be reviewed by the full board. If the study is currently approved as an Expedited study, complete the applicable row in the Protocol Approval Types and Categories table. | **Pre-review Notes:** | **Approval form comments:** None specific. Add whatever information is relevant.  There are several possible sections that may need to be added. Use the master protocol template to see what sections are applicable. |
|  |  |  |

| COVID 19 Treatment/Vaccine Study |  |  |
| --- | --- | --- |
| Study involves treatment/vaccine for COVID-19 | **Pre-review Notes:** | If YES, verify the language regarding the PREP act is in the consent (What if you are hurt section) |

|  |  |  |
| --- | --- | --- |
| **Grants and Contracts** |  |  |
| Does Grants and Contracts need to be contacted by the study team?   * If yes, notify the investigator to consult grants and contracts regarding the need for a contract/MTA/or other type of agreement. | **Pre-review Notes:** | **Approval form comments:** Nothing specific. If you know that Grants & Contracts has been contacted, you may want to indicate that the study team has contacted them.  If an exchange is occurring, the P.I. may need to contact Grants and Contracts. Examples include:   * financial support or supplies (drugs, devices) in exchange for data * services (ex. tissue analysis) in exchange for professional recognition * specimens being shipped outside of UVA |
| International Site |  |  |
| **Does the study have an international site?** | **Pre-review Notes:** | Yes  No  If YES, must approve mod with conditions and require IRB approval from international site as a condition of approval along with any other conditions ( e.g. translated consent) |
| Has a site outside of the US been added to the study (UVA PI is overall PI)? | **Pre-review Notes:** | Yes  No  If NO, are all of the reviewing IRB for each site accredited?  Yes  No  If NO, does each IRB have policies and procedures in place to address items listed in section 25.2.1.2 of the UVA HRPP SOP)?  Yes  No *Answer must be YES* |
| Laser Added |  |  |
| Does the modification include the addition of the use of a laser?   * If yes, requires approval from the Laser Safety Officer (EHS)   Marianne Yencken 243-1725 | **Pre-review Notes:** | **Approval form comments:**  Use of a laser was added with this modification. Laser Safety Office Approval on file. |

|  |  |  |
| --- | --- | --- |
| Major change- new C of C required |  |  |
| If the study is NOT funded by the Federal Government and if a major change in the research is done after the Certificate of Confidentiality is granted, the study team must re-apply for another certificate.  Significant changes include: major changes in the scope or direction of the research protocol, changes in personnel having major responsibilities in the project or changes in the drugs to be administered ( if any) and the persons who will administer them.  *IF YES, study team to submit the C of C approval.* | **Pre-review Notes:** | **Approval form comments:**  Due to significant changes in the protocol the study team has submitted a new approval for the certificate of confidentiality.  OR  The NIH grant sponsoring the study was funded after December 13, 2016 (CoC is automatically issued through a term and condition of the award).  Additional information may be found at <https://grants.nih.gov/grants/policy/coc/faqs.htm> |

|  |  |  |
| --- | --- | --- |
| Revisions required by PAM |  |  |
| Does this modification contain revisions requested by the post approval monitoring group? If yes:   * Send the revisions to the person who conducted the PAM audit to make sure all revisions they needed have been incorporated. * Delete the PAM comment from the comment field on the Main page in IRB Online. | **Pre-review Notes:** | **Approval form comments:**  In follow-up to a post approval monitoring audit report dated ***(insert date)***, the following revisions were made: ***(add relevant information)*** |

|  |  |  |
| --- | --- | --- |
| **New procedures and/or visits** added |  |  |
| Were new procedures and/or visits added? If yes,   * Make sure all new procedures are clearly defined as either research related or completed as part of clinical care (regardless of participation in the study). * If there is an IRB protocol, make sure any new procedures added for research purposes only are added under the “What will be done in this protocol” section. * Make sure consent clearly states whether subject will be responsible for cost of any of the new procedures. * If payment seems appropriate, make sure compensation for new procedures/additional visits is present, or ask study team to clarify why there isn’t any additional payment. | **Pre-review Notes:** | **Approval form comments:**  None specific- add an appropriate description of the new procedures and/or visits. |
| **Number of Subjects Changed** |  |  |
| Was the number of subjects changed? If yes:   * make sure the Application, IRB protocol (if applicable) and consent *(if applicable*) were updated. * make sure the comment field on the main page in IRB Online is updated when approval is processed – note new # on Approval Overview page | **Pre-review Notes:** | **Approval form comments:**  The number of subjects at UVA was changed to ***(insert new #)***. |
| **Optional Procedures** Added |  |  |
| Were any optional procedures added?   * If YES, make sure the consent (s) have checkboxes for the optional procedures in order for the subject to indicate whether or not they wish to participate in the optional portions of the protocol | **Pre-review Notes:** | **Approval form comments:**  Consent was modified to include add optional procedure checkboxes to document subjects choices regarding participation in optional procedures. |
| **Pregnant Partner** |  |  |
| Is a Pregnant Partner addendum consent being added? If yes:   * Make sure applicable UVA template sections have been included. * Note Pregnant Partner consent and version date on Approval Overview page. | **Pre-review Notes:** | **Approval form comments:**  A Pregnant Partner addendum consent was added with this modification.  Sponsors do not always include Pregnant Partner consents. If an amendment includes text indicating that pregnancy information will be collected from partners of male subjects, the IRB will want a Pregnant Partner consent to be created. There is a sample Pregnant Partner consent at the following location: \\IRB\IRB-HSR\WEBSITE\Forms on website |
| **Randomization** |  |  |
| Was randomization added? If yes,   * Make sure the method and probability of receiving each treatment is described in both protocol and consent. | **Pre-review Notes:** | **Approval form comments:**  None specific – describe randomization method as appropriate. |
| Security Issues/InfoSec approval |  |  |
| If any of the following items are being added to the protocol, obtain approval from InfoSec.   * Collect or store IDENTIFIABLE\* data onto \*\* an individual use device\*\*\* * Collect or store IDENTIFIABLE data via web based format (e.g., online consent, online surveys) via a non-UVA server. Only exception is sharing or storing of data by sponsor or CRO in which data will be sent and stored in an encrypted fashion (e.g. Secure FX, Secure FTP, HTTPS, PGP). * Collect or store to a server NOT included in the list of HIPAA compliant servers\*\*\*\* | **Pre-review Notes:** | **Approval form comments:**  InfoSec approval on file. |
| **Short Forms** |  |  |
| If Short Forms are being added for subjects who do not speak English:   * Make sure the current templates found on the website under “Forms – Consent forms for non-English speaking subjects” were used to create the short forms, and that all necessary information is present. * Delete the template version date in the footer of the short form. * Add the current document version date in the footer. * Make sure all necessary signature lines are present. Pay close attention to signature lines if children or subjects with impaired decision making capacity are enrolling. * If the interpreter's signature line is not on the other consents (e.g. main consent), add the interpreter's signature line. | **Pre-review Notes:** | **Approval form comments:**  ***[Insert language(s)]*** *s*hort form(s) were added with this modification.  Information about consenting subjects who do read, speak, or understand English can be found at the following website link: <https://research.virginia.edu/irb-hsr/consent-short-forms-non-english-speaking-subjects>  <https://research.virginia.edu/irb-hsr/consenting-subjects-who-do-not-read-speak-or-understand-english> |
| **Translation of the Consents to other Languages** |  |  |
| Before the consents are translated to other languages for subjects who do not speak English:   * If the interpreter's signature line is not on the other consents (e.g. main consent), add the interpreter's signature line to the English version of the consents. | **Pre-review Notes:** | **Approval form comments:**  ***[Insert language(s)]*** *The consent(s)* were translated to [*name the language*]. *The translation certificate (dated xx) is on file.*  <https://research.virginia.edu/irb-hsr/consenting-subjects-who-do-not-read-speak-or-understand-english> |

|  |  |  |
| --- | --- | --- |
| **Sponsorship or funding change** |  |  |
| Did the sponsorship or funding of the study change with the modification? If yes*,* make sure:   * the sponsorship/funding change is documented in the application, protocol and/or consent (if applicable) * the funding page in IRB Online is updated when the modification is processed – note on Approval Overview page * If Department of Defense is new sponsor, verify appropriate regulations have been used to review protocol and that these regulations are documented. Research monitor required if full board/ additional regs for use of fetal tissue/ prisoners of war/ waiver of consent * If DoD funded and study involves DoD personnel, data or specimens, we need approval from DoD IRB/ other federal IRB. * If new sponsor is a foundation- confirm a contract or grant is in place. | **Pre-review Notes:** | **Approval form comments:**  The sponsor/funding source ***(insert as appropriate)***for this study has changed to ***(insert new sponsor/funding information)***. |

|  |  |  |
| --- | --- | --- |
| Status change |  |  |
| Was there a change in the current status of the study?   * If yes, make sure the Main Page in IRB Online is updated when approval is processed - note new status on Approval Overview page.   Re-opening not allowed if IRB study file has been destroyed.  Review to determine if a Continuation review is required.   * A review is required if the protocol was closed and missed a continuation review (s). * A review may also be required if the protocol required Full Board review but received an expedited continuation because the protocol was closed to enrollment in either in FU or data analysis   REFER TO AG 3-33 FOR ADDITIONAL INFORMATION | **Pre-review Notes:** | **Approval form comments:**  With this modification, the status of this study was changed to (***insert new status).***  If the status is changed **TO** closed to enrollment**, follow up only**; OR closed to enrollment, **performing data analysis**;  Regulatory page: **add Category 8A or 8C**  If the status is changed **FROM** closed to enrollment**, follow up only**; OR closed to enrollment, **performing data analysis** TO another status;  Regulatory page: **uncheck Category 8A or 8C** |

|  |  |  |
| --- | --- | --- |
| **Student Health Data (FERPA Regulated)** |  |  |
| If Student information (e.g. health, grade, test scores… etc.) that is regulated by FERPA is added, the following steps must be taken   1. Verify written approval from director of applicable office if the PI is not director of office from which student regulated data will be obtained 2. Obtain written review from IRB-SBS   If data will be obtained from Student Health, one member of the study team must be a permanent staff member of Student Health. | **Pre-review Notes:** | **Approval form comments:**  Student Health data regulated under FERPA added to the protocol.  Written review from IRB-SBS on file.  ***If PI of protocol is not a permanent staff member of Student Health add:***  Written approval from director of INSERT NAME OF APPLICABLE OFFICE on file. |

|  |  |  |
| --- | --- | --- |
| [**Study Site Outside State of Virginia added and study includes subjects under the age of 21 or subjects have impaired decision-making capacity**](#StudySiteOutsideStateofVirginia) |  | **See Study Site Outside State of Virginia added and study includes subjects under the age of 21 or subjects have impaired decision-making capacity.** |
| Submission Documents |  |  |
| Were any documentsreceived?   * If yes, this will either need to be noted in the approval form comment field, or in a separate receipt event. * If the item is going to be entered as a separate “receipt” event, state under “Reviewer Notes” that a receipt will be needed for the item(s) when hard copies are processed. * If questionnaires are being added to a study that does not have a consent form, complete the Waiver of Documentation of Consent and Alteration of HIPAA Authorization for Verbal Authorization tables. | **Pre-review Notes:** | **Approval form comments:**  ***Include only if there will not be a separate receipt event:***  The following document(s) was/were submitted with this modification (***include name(s) and date(s) of document(s)***  *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  Submission documents include but are not limited to documents such as letters or questionnaires |

|  |  |  |
| --- | --- | --- |
| [Sub-study](#SubStudy) |  |  |
| **If the sub-study is being added that does not require a separate IRB # / UVA Study Tracking (refer to the SPECIAL ISSUES on website:** [**Sub-studies**](https://research.virginia.edu/sites/vpr/files/2019-08/Substudies.docx)**):**   1. Sub-study procedures are embedded into the existing main/parent protocol:    1. Verify that ALL applicable sections of the main/parent protocol and application are updated; new sections are added (e.g. Specimen section)    2. Verify if a separate sub-study consent is required OR if the original consent may be updated to add sub-study procedures. 2. Sub-study is submitted under the existing IRB number but a separate sub-study protocol document is submitted:    1. It is preferred that the main/parent protocol refer to the sub-study protocol, however it is not required    2. All applicable sections of the IRB application will need to be revised to include information about the sub-study.    3. Verify if sub-study procedures added require that new sections be added to the main/parent protocol, application and/or consent. (e.g. if a blood draw is added that was not previously present).    4. Verify if a separate sub-study consent is required OR if the original consent may be updated to add sub-study procedures.   If this is an expedited study, verify if added sub-study procedures are covered under existing approval categories or if a new expedited category needs to be added. Update REGULATORY PAGE accordingly | **Pre-review Notes:** | **Approval form comments:**  **A sub-study was added that involves the following: describe**  **If parent/main study is expedited, add any additional expedited review categories required to cover sub-study procedures and add the following**  **The following categories were added to cover sub-study activities: (list per regulatory page)**  **If additional waivers are required to cover sub-study recruitment or activities add the following:**  **The following waivers were added to cover sub-study activities (list per regulatory page)** |
| Taping Added |  |  |
| Is video/audiotaping and/or photography being added? If yes:   * Open the Modification Templates tab in Protocol Builder and make sure the current template section(s) have been appropriately completed. | **Pre-review Notes:** | **Approval form comments:**  ***(insert as applicable):*** Videotaping/audiotaping/photographing of subjects was added with this modification. |
| **Title Change** |  |  |
| Was there a title change**?**   * If yes, make sure the consent(s), short forms (if applicable), and IRB protocol (if applicable) were updated, and that the title matches on all documents. | **Pre-review Notes:** | **Approval form comments:**  The title of the study was changed. |

|  |  |  |
| --- | --- | --- |
| **Deception** |  |  |
| Is **Deception** added**?**   1. If yes, a Debriefing Script is required. 2. To be granted an alteration of consent, deception studies must meet the requirements of [45 CFR 46.116 (c) or (d)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116). Note that the FDA has no provisions for waiver of informed consent related to the use of deception in research. Thus, it is highly unlikely that FDA-regulated research would involve deception. In non-FDA regulated research, a waiver/alteration of informed consent is allowed if: 3. Research involves the study of public programs (45 CFR 46.116(c)), **OR** 4. Research meets **all** of the following criteria from 45 CFR 46.116(d):  * The research involves no more than minimal risk to the subjects. * The research could not practicably be carried out without the waiver or alteration, * If the research involves using identifiable private information or identifiable bio-specimens, the research could not practicably be carried out without using such information or bio-specimens in an identifiable format. * The waiver or alternations will not adversely affect the rights and welfare of the subjects. * When appropriate, subjects or their legally authorized representative will be provided with additional pertinent information after participation.   **IF YES, *Insert the following:***  The protocol grants waiver of consent for deception per: (45 CFR 46.116(c)), **OR** 45 CFR 46.116 (d) | **Pre-review Notes:** | **Approval form comments:**  ***(insert as applicable):*** The protocol grants waiver of consent for deception per: 45 CFR 46.116(c), **OR** 45 CFR 46.116 (d).  Debriefing Script on FILE  *If yes, a Debriefing Script is required.*  When the convened IRB reviews research involving deception and/or incomplete disclosure, the minutes document the IRB made the findings in accordance with 45CFR46.11  **If reviewed by the full board, DO NOT cite the comments above until the approval is processed.** In the RECEIPT protocol modification event, write: The study team requests waiver of consent for the use of deception. |

| Personnel Changes | **Tick applicable items below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| **Change in Principal Investigator?**  If yes, see Appendix A for additional information and make sure:   * New PI/ Department chair have signed current protocol or Investigator’s Agreement * PAM and SOM CTO are notified via e-mail (if applicable) when approval is processed (note on Approval Overview page; print e-mail when hard copies are processed; if additional e-mail correspondence is received stating that no PAM review is needed, print that e-mail as well) * Investigator’s Experience section has been updated (if applicable) * Verify that the new PI has current human subjects training. * If applicable: All applicable areas in the consent have been changed * If there are short forms, make sure the short forms have been updated. * If a person is being added verify they have no financial conflict of interest with the study. * If the COI committee has provided a COI Management Plan, the IRB should conduct review to determine acceptability. May be reviewed by expedited review procedures if the study meets the expedited review criteria | **Pre-review Notes:** | **Approval form comments:**  PI change. Signed Investigator’s Agreement (or updated IRB protocol) ***(add whichever is applicable)*** from new PI and Dept. Chair on file. (***If applicable add)*** PAM has been notified regarding the PI change so they may determine if an audit is needed. (***If applicable add):*** SOM CTO notified of change in PI. [***see instructions below]***  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  To determine when PAM must be notified see [Appendix A](#_Appendix_A:_)  SOM CTO must be notified if YES is marked on the regulatory page for SOM CTO |
| If **UVA personnel (other than a new PI)** are being added:   * Make sure the personnel change form was submitted. * If the personnel are already in the database, make sure the information in the database is current – people often move from one department to another, so information in the database may not match what is on the personnel change form * Verify that the personnel being added have current human subjects training by clicking on “People – Training” in the database or going to [www.citiprogram.org](http://www.citiprogram.org) * If study personnel will have access to patients or identifiable health information verify that all UVA personnel are from a department within the UVA HIPAA covered entity or that they have a dual appointment that includes a dept. within the HIPAA covered entity or verify they have approval to serve as a volunteer within the UVA HIPAA covered entity * If a person is being added verify they have no financial conflict of interest with the study. * If the COI committee has provided a COI Management Plan, the IRB should conduct review to determine the acceptability of the plan. The review may be done by expedited review criteria if the protocol meets the expedited review criteria. .   If a person being added does not have a paid appointment under one of the departments within the HIPAA covered entity, he/she cannot identify, contact, or conduct the study without consent. See recruitment appendix for details. |  | **Approval form comments:**  ***(Insert name of person)*** was added to this protocol as ***(insert position new personnel will hold)***.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  All researchers (including offsite collaborators) must be listed with the protocol if they will: intervene with subjects by performing research procedures, or by manipulating the environment for research purposes; or have access to their identifiable data   * participate in the recruitment and/or selection of subjects; * participate in the informed consent process; * collect or report subject identifiable data; or * have access to subject identifiable study data.   The exception to this is if this is a multisite study and they are listed on their local protocol under their own IRB approval.  *The UVA HIPAA Covered Entity includes the following areas:The UVA HIPAA Covered Entity includes the following areas:*  UVA Health including the School of Medicine & the School of Nursing, the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Core Laboratory and University Physicians Group (UPG)  Identifiable health info may also be shared with the following areas without tracking the disclosure as agreements are in place to protect the information:   * VP Office of Research * Nutrition Services (Morrison’s) * UVA Center for Survey Research   It does not include Engineering departments, the Curry School, or the College of Arts and Sciences. |
| If **Unaffiliated/non-UVA personnel** are being added under the UVA IRB-HSR approved protocol, make sure the following are submitted:   * Personnel change form(s) * Signed Unaffiliated Investigator Agreement(s) * Certificate(s) of human subjects training * Revised protocol to add or update non-UVA personnel section * If applicable, make sure Outside IRB approval or documentation from administration of outside institution (if there is no IRB) has been received and is noted on the Approval Overview.   **If identifiable and the person has not received approval from the SOM via the SOM Research Volunteer Form :**   * + Note on Approval Overview page that Unaffiliated Investigator should be ticked on regulatory page   + If PHI will be disclosed prior to consent also check HIPAA Tracking   + Must have Data Agreement with Contracts office in place prior to sharing data.   **If Limited Data Set :**   * Note on Approval Overview page that Unaffiliated IA and DUA ( protocol specific) and Data Use Agreement Type ( Recipient outside UVA) needs to be ticked * If data being shared with unaffiliated investigator meets the criteria of a Limited Data Set, verify the contract includes a HIPAA Data Use Agreement. * Agreement required via Contracts office to share the data * Any electronic data must be reviewed by the IS Data Support Office ([researchdata@hscmail.mcc.virginia.edu](mailto:researchdata@hscmail.mcc.virginia.edu)) prior to sharing of data to confirm data meets criteria of LDS.   **If De-identified :**   * Any electronic data must be reviewed by the IS Data Support Office ([researchdata@hscmail.mcc.virginia.edu](mailto:researchdata@hscmail.mcc.virginia.edu)) prior to sharing of data to confirm data meets criteria of de-identified. * MTA required to share data. | **Pre-review Notes:** | **Approval form comments:**  Signed Unaffiliated Investigator’s Agreement and current training certificate(s) are on file for the Non-UVA personnel (***list names***).  Non- UVA personnel ***will/will not*** have access to identifiable health information from UVA patients prior to consent.  ***If non- UVA personnel will have access to identifiable health info prior to consent add:*** Study team will track disclosures in EPIC.  ***If applicable insert as appropriate:*** Outside IRB approval/documentation from administration of outside institution is on file.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  If the study is being conducted under a Waiver of Consent/ Waiver of HIPAA Authorization, and identifiable health information will be shared with the unaffiliated investigator, TRACKING of the disclosure is required. Discuss with IRB Director.  Non-UVA faculty, staff, and students should NOT be added if all of the following apply:   * the individual is the PI at another site that UVA has a contract with * the individual is under the oversight of a PI at another site that UVA has a contract with * the study will be approved by the outside IRB, ethics board etc. * the outside institution has a Federal Wide Assurance (FWA) number |

| Protocol Approval Types and Categories | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| Does the modification change the study type from **Exempt to Expedited**? If yes,   * Instruct the researcher to go into Protocol **B**uilder, answer the questions, and complete the templates. * When e-copies of are received, change the “submission number” to the IRB-HSR # that was given when the study was exempt, and conduct a full pre-review. * Note the following on the Approval Overview page:   **Main Page**:   * + Study Type changing to Expedited   + Enter meeting date and expiration date,   + Number of subjects   + Any other relevant items   **Regulatory Page**:   * + Expedited Category(ies)   + Any other relevant items   **Funding Page:**   * If sponsored or subjects are being compensated, note | **Pre-review Notes:** | **Approval form comments:**  This study (previously approved as an Exempt study now meets the criteria of an expedited study under **[*list category(ies)]***  See Appendix D for a listing of the exempt and expedited categories. Reference Protocol Review Process FAQ on website titled “Does my study meet Exempt or Expedited Approval Criteria” and AG 3-1 for additional information.  A study cannot be exempt if:  1. The study involves the following types of research:   * Review of records if the information gathered from those records is recorded in such a way that it can be linked back to the subject (either directly or through use of a code) * Surveys or interviews given to minors * Any procedure that may cause a subject either physical or psychological discomfort or is perceived as harassment above and beyond what the person would experience in daily life * Deception * Observation of minors if the investigator participates in the activities being observed unless there is a federal statute covering the activity.   2. The sponsoring agency requires that the proposed research receive full or expedited review even when the activities would otherwise qualify for exemption. |
| **Does the modification change the study type from full board to expedited AND:**   * **all interventions fall under an expedited criteria (other than #9) and** * **the minimal risk determination is made by a single IRB member (mod NOT sent to full board for review) ?**   **If yes:**   * **Change the study TYPE on the main page from full board to expedited.** * Note applicable items on the Approval Overview page. * Choose all applicable expedited criteria (may not use criteria # 9) * If there is a protocol from the Protocol Builder template, replace the full board DSMP with the expedited DSMP in the protocol * If there is an application, replace the full board DSMP in the application with the expedited DSMP. * If applicable, add other relevant template sections that are missing or are being significantly altered. | **Pre-review Notes:** | See Appendix D for a listing of the expedited categories. Reference Protocol Review Process FAQ on website titled “Does my study meet Exempt or Expedited Approval Criteria” and AG 3-2 for additional information.  *If the IRB member determines the protocol does not involve an* [*FDA regulated device*](https://research.virginia.edu/irb-hsr/fda-regulated-studies) *and the protocol meets the criteria for minimal risk, follow the instructions below.*  **Approval form comments:**  ***If study regulated under Pre 2018 Common Rule:***  The IRB determined that the study is no more than minimal risk to subjects and that future continuations may be reviewed by an expedited review process under Category **[*list category(ies)]. List all applicable expedited categories- may not use expedited category #9)***  ***If study regulated under 2018 Common Rule:***  The IRB determined that the study is no more than minimal risk and meets the following expedited criteria **[*list category(ies)]. List all applicable expedited categories- may not use expedited category #9) .*** Continuation reviews are not required, however the study team will be required to submit an IRB Update to the IRB-HSR on an annual basis. |
| **Does the modification change the study type from full board to expedited AND:**   * **all interventions fall under an expedited criteria and** * **the full board determined the study is minimal risk?**   **If yes:**   * **Change the study TYPE on the main page to expedited** * Note applicable items on the Approval Overview page. * Choose all applicable expedited criteria excluding #9 * If there is a protocol from the Protocol Builder template, replace the full board DSMP with the expedited DSMP in the protocol * If there is an application, replace the full board DSMP in the application with the expedited DSMP. * If applicable, add other relevant template sections that are missing or are being significantly altered. | **Pre-review Notes:** | See Appendix D for a listing of the expedited categories. Reference Protocol Review Process FAQ on website titled “Does my study meet Exempt or Expedited Approval Criteria” and AG 3-2 for additional information.  *If the board determines the protocol does not involve an* [*FDA regulated device*](https://research.virginia.edu/irb-hsr/fda-regulated-studies) *and the protocol meets the criteria for minimal risk, follow the instructions below.*  **Approval form comments:**  **If study regulated under Pre 2018 Common Rule**  The board determined that the study is no more than minimal risk to subjects and that the study is approvable under expedited category # (INSERT NUMBER- do NOT include #9) Continuation reviews will be conducted via an expedited review process.  **2018 Common Rule**  The board determined that the study is no more than minimal risk to subjects and that the study is approvable under expedited category # (INSERT NUMBER- do NOT include #9). Continuation reviews are not required per the 2018 Common Rule, however the study team must submit an IRB Update to the IRB-HSR on an annual basis. |
| **Does the modification change the study type from full board to expedited AND:**   * **all interventions do NOT fall under an expedited criteria and** * **the full board determined the study is minimal risk?**   **If yes:**   * **Do not change the study TYPE on the main page. Must remain as Full Committee.** * Note applicable items on the Approval Overview page. * Choose expedited criteria # 9. * If there is a protocol from the Protocol Builder template, replace the full board DSMP with the expedited DSMP in the protocol * If there is an application, replace the full board DSMP in the application with the expedited DSMP. * If applicable, add other relevant template sections that are missing or are being significantly altered. | **Pre-review Notes:** | See Appendix D for a listing of the expedited categories. Reference Protocol Review Process FAQ on website titled “Does my study meet Exempt or Expedited Approval Criteria” and AG 3-2 for additional information.  *If the board determines the protocol does not involve an* [*FDA regulated device*](https://research.virginia.edu/irb-hsr/fda-regulated-studies) *and the protocol meets the criteria for minimal risk, follow the instructions below.*  **Approval form comments: Pre 2018 and 2018 Common Rule**  The board determined that the study is no more than minimal risk to subjects and that the study is approvable under expedited category #9. Continuation reviews will be conducted via an expedited review process. |
| **Does the modification change the study type from expedited to full board?**  **If yes,**   * Change study TYPE on main page to Full Committee * Note applicable items on the Approval Overview page * If there is an IRB protocol, replace the expedited DSMP with the full board DSMP template. * If there is no IRB protocol, complete the full board “sponsored study” DSMP template. * If applicable, add relevant template sections that are missing or are being significantly altered. | **Pre-review Notes:** | **Approval form comments:**  This study (previously approved as an expedited study) now meets the criteria of a full board study.  *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  **You also need to delete any expedited criteria which is now not applicable.**  **(e.g. if now drawing more than 50 Cc of blood in subjects who are non- healthy- delete Expedited Criteria 2b.)** |
| **Does the modification add or change an Exempt Criteria?** If yes,   * Note on Approval Overview Page which exempt criteria are being added/changed, and then update the database. * The email and documents should be saved electronically under IRB/IRB-HSR/ Current Protocols and Consents/Approved Exempt Applications and upload applicable documents to IRB Pro * In the Receipt protocol modification event in IRB Online document that the modification does not affect the Exempt status. | **Pre-review Notes:** | **Approval form comments:**  This study now meets the criteria of an exempt study under ***(list exempt criteria)*** OR Exempt Criteria ***(list exempt criteria)*** is being added with this modification***.***  See Appendix D for a listing of the exempt criteria. Reference AG 3-1 for additional information. |
| **Does the modification add or change an Expedited Category**? If yes,   * Note on Approval Overview Page which expedited category is being added/changed. Additional category will need to be listed in comment field on main page. | **Pre-review Notes:** | **Approval form comments:**  This study now meets the criteria of an Expedited study under ***(list category)*** OR Expedited Category ***(list expedited category)*** is being added with this modification***.***  See Appendix D for a listing of the expedited categories. Reference AG 3-2 for additional information. |

| Recruitment/Advertising/Prescreening Plans | | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- | --- |
| **TYPE OF RECRUITMENT MATERIAL ADDED WITH THIS MODIFICATION** | | | |
| **Advertising** | | | **Direct Contact by a UVA Researcher** |
| Public Cable Service Announcement  Poster /Flyers/Brochure  Newspaper/Journal Ads  Internet (non-UVA)  Television | Radio  UVA Health System Subject Recruitment Website  Social Networking: Facebook, Twitter, etc.  Other indirect contact (describe): | | Recruitment letters/emails  Telephone Contact Script  Other direct contact (describe): |
| Were advertisements, phone scripts, letters, or any other type of **recruitment material** submitted with the modification? If yes,   * If the current “Recruitment and Consenting” appendix is present, make sure it is completed correctly * If a new type of recruitment material is being added that will require waivers not previously documented to be added to the assurance, the current recruitment template should be completed. In these situations, add the current template to the IRB protocol, or if there is an IRB Application, send the current appendix to the study team to complete. If a type of recruitment material previously approved is simply being modified (i.e. revising a phone script that was previously approved), DO NOT ask the study team to complete the current template. * Make sure all proper IRB advertising templates are utilized if necessary. * If there is more than one group of subjects enrolling in the study (i.e. physicians and patients of physicians/controls and non-controls), make sure identification and/or contacting of EACH group is documented. * Note on the Approval Overview any updates that need to be made to the Adverts page in the database. * Any “Advertising” or “Direct Contact by a UVA Researcher” item(s) checked at the beginning of this table will also need to be ticked on the Adverts page in the database. * If the recruitment materials will be approved with this modification,   + refer to AG 3-9 for guidance in reviewing the recruitment material.   + Update the ADVERTS page in IRB Online   + If a UVA Health System Clinical Trials Website ad is approved, refer to AE 3-9 for instructions regarding how to post this ad. * If the recruitment materials will not be approved with this modification, forward the recruitment materials to be reviewed along with the Routing Form to IRBHSR [ads@virginia.edu](mailto:ads@virginia.edu) | | **Pre-review Notes:** | **Add this comment ONLY if the advertisement is to be approved with the modification approval**  **Approval form comments:**  The following types of recruitment/advertising materials were reviewed and approved with this modification: ***(insert items as checked above***  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  You may wish to review the process for advertisements if you are not already familiar with it. All recruitment materials should be processed according to the AG. The address is: <https://research.virginia.edu/irb-hsr/advertising-human-research-study-subjects-0> |
| Does the modification add **identifying** potential subjects via some type of chart review/database review with identifiers being collected, or patient’s contact info given to study team by a health care provider without patients’ knowledge? If yes,   * Note on Approval Overview (Regulatory Page) that # 1- “Identifying – Waiver of Consent” needs to be ticked. * If the study involves more than one group of subjects, make it clear in the approval form comment which group you are referring to (if not applicable for all subjects). | | **Pre-review Notes:** | **Approval form comments:**  *Pre 2018 Common Rule*  This protocol has been granted a waiver of consent to identify potential subjects via 45CFR46.116.  The tick box for this question should be checked if a, b, or c is checked under question 1 of the current recruitment appendix.  Reviewer Comments:  ***If any of the following apply,*** tick the appropriate box(es) below and add: Also granted waiver of consent under ***(insert applicable wording from ticked boxes below)***  1)  **Funded by DoD**  **Add*:*** 32CFR219.117(c)  2)  **Testing of an in-vitro device involved**  **Add:** FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using leftover Human Specimens that are Not Individually Identifiable.  3)  **Includes drugs or devices- emergency use**  **Add*:*** 21CFR50.23  4)  **Includes drugs or devices (rare- consult w/ IRB Director) Add:** 21CFR50.24  2018 Common Rule  *Recruitment 1a, b or c is checked. If the study involves more than one group of subjects (controls vs. non- controls, patients vs. health care providers) make it clear in the wording below- which group you are referring to if not applicable for all subjects.*  **Funded by a non-Common Rule Agency besides the FDA(e.g. Dept of Justice)? *If yes,*** ***add***  This protocol has been granted a Waiver of Consent to identify potential subjects via INSERT APPLICABLE REG. (Department of Justice: 28CFR46)  *NOTE:FDA does not require waiver of consent for screening, recruiting or determining eligibility. Consent must be obtained before any clinical procedures that are performed solely to determine eligibility or for drug washout.* |
| Does the modification add **contacting** potential subjects by a person who is NOT a member of their health care team? If yes,   * Note on Approval Overview (Regulatory Page) that # 2 “Contacting: Not Health Care Provider – Waiver of Consent/Waiver of HIPAA Authorization” needs to be ticked. * If the study involves more than one group of subjects, make it clear in the approval form comment which group you are referring to (if not applicable for all subjects). | | **Pre-review Notes:** | **Approval form comments:**  *Pre 2018 Common Rule*  This protocol has been granted a waiver of consent via 45CFR46.116 and a waiver of HIPAA Authorization via 45CFR164.512(i)(2) to contact potential subjects via direct contact by a person who is not their health care provider. Direct contact may include phone, letter, direct e-mail, or approaching potential subjects while at UVA. The following HIPAA identifiers may be collected: name, medical record number, date of birth, and contact information appropriate to the recruitment plan. The minimum necessary PHI to be collected includes only those items related to the inclusion/exclusion criteria. ***If subjects over the age of 89 will be enrolled add:*** For subjects over the age of 89, their date of birth and age will not be recorded. All will be recorded as >89 years of age.  The tick box for this question should be checked if a or b is checked under question 2 of the current recruitment appendix.  ***If any of the following apply,*** tick the appropriate box(es) below and add: Also granted waiver of consent under ***(insert applicable wording from ticked boxes below)***  1)  **Funded by DoD**  **Add*:*** 32CFR219.117(c)  2)  **Testing of an in-vitro device involved**  **Add:** FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using leftover Human Specimens that are Not Individually Identifiable.  3)  **Includes drugs or devices- emergency use**  **Add*:*** 21CFR50.23  4)  **Includes drugs or devices (rare- consult w/ IRB Director)**  **Add:** 21CFR50.24  2018 Common Rule  *Recruitment 2 a or b is checked. If the study involves more than one group of subjects (controls vs. non- controls, patients vs. health care providers) make it clear in the wording below- which group you are referring to if not applicable for all subjects.*  **Funded by a non-Common Rule Agency besides the FDA (e.g. Dept of Justice)? *If yes,*** ***add***  This protocol has been granted a Waiver of Consent to contact potential subjects via INSERT APPLICABLE REG. (Department of Justice: 28CFR46)  *NOTE:FDA does not require waiver of consent for screening, recruiting or determining eligibility. Consent must be obtained before any clinical procedures that are performed solely to determine eligibility or for drug washout.*  **For all studies add:**  The IRB-HSR has granted Waiver of HIPAA Authorization via 45CFR 164.512(i)(2) to contact subjects by direct contact by a person who is not their health care provider. Direct contact may include phone, letter, direct email or approaching potential subjects while at UVA. Phone, letter or emails will be approved by the IRB-HSR prior to use. The following HIPPA identifiers may be collected: Name, medical record number, date of birth and contact information appropriate to the recruitment plan. The minimum necessary PHI to be collected includes only those items related to the inclusion/ exclusion criteria. |
| Does the modification add **contacting** potential subjects by a person who IS a member of their health care team? If yes,   * Note on Approval Overview (Regulatory Page) that # 3- “Contacting by Health Care Provider – Waiver of Consent” needs to be ticked. * If the study involves more than one group of subjects, make it clear in the approval form comment which group you are referring to (if not applicable for all subjects). | | **Pre-review Notes:** | **Approval form comments:**  *Pre 2018 Common Rule*  This protocol has been granted a waiver of consent via 45CFR46.116 to contact potential subjects via direct contact by a person who is their health care provider. Direct contact may include phone, letter, direct e-mail, or approaching potential subjects by a healthcare provider while at UVA.  The tick box for this question should be checked if c is checked under question 2 of the current recruitment appendix.  ***If any of the following apply,*** tick the appropriate box(es) below and add: Also granted waiver of consent under ***(insert applicable wording from ticked boxes below)***  1)  **Funded by DoD**  **Add*:*** 32CFR219.117(c)  2)  **Testing of an in-vitro device involved**  **Add:** FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using leftover Human Specimens that are Not Individually Identifiable.  3)  **Includes drugs or devices- emergency use**  **Add*:*** 21CFR50.23  4)  **Includes drugs or devices (rare- consult w/ IRB Director)**  **Add:** 21CFR50.24  2018 Common Rule  *Recruitment 2 a or b is checked. If the study involves more than one group of subjects (controls vs. non- controls, patients vs. health care providers) make it clear in the wording below- which group you are referring to if not applicable for all subjects.*  **Funded by a non-Common Rule Agency besides the FDA (e.g. Dept of Justice)? *If yes,*** ***add***  This protocol has been granted a Waiver of Consent to contact potential subjects by direct contact by a person who is their health care provider via INSERT APPLICABLE REG. (Department of Justice: 28CFR46)  Direct contact may include phone, letter, direct email or approaching potential subjects while at UVA.  Phone, letter or emails will be approved by the IRB-HSR prior to use.  *NOTE: FDA does not require waiver of consent for screening, recruiting or determining eligibility. Consent must be obtained before any clinical procedures that are performed solely to determine eligibility or for drug washout.* |
| Does the modification add **pre-screening** **questions** (i.e. asking questions for study eligibility)? If yes,   * Note on Approval Overview (Regulatory page) that # 6 Waiver of Documentation of Consent- Pre-screening Questions needs to be ticked. * Add/update Protocol: Recruitment section for pre-screening. | | **Pre-review Notes:** | **Approval form comments:**  *Pre 2018 Common Rule*  Waiver of documentation of consent granted under 45CFR46.117(c) for pre-screening questions. Pre-screening form to assess study eligibility submitted.  ADD ADDITIONAL AGENCIES BELOW IF APPLICABLE  If funded by DOD add: and 32CFR219.117(c)  If funded by the FDA add: and 21CFR56.109(c)  2018 Common Rule  **If funded by DoD add:**  This protocol has been granted a waiver of documentation of consent for pre-screening questions under 32CFR219.117(c)  **Funded by a non-Common Rule Agency besides the FDA (e.g. Dept of Justice)? *If yes,*** ***add***  This protocol has been granted a Waiver of Documentation of Consent for pre-screening questions via INSERT APPLICABLE REG.  *NOTE: FDA does not require waiver of consent for screening, recruiting or determining eligibility. Consent must be obtained before any clinical procedures that are performed solely to determine eligibility or for drug washout.* |
| Does the modification add **minimal risk pre-screening procedures** (i.e. fasting prior to first study visit)? If yes,   * Note on Approval Overview (Regulatory page) that # 7 -Waiver of Documentation of Consent- Minimal Risk Pre-Screening Procedures needs to be ticked. | | **Pre-review Notes:** | **Approval form comments:**  *Pre 2018 Common Rule*  Waiver of documentation of consent granted under 45CFR46.117(c) for minimal risk pre-screening procedures.  If funded by DOD add: and 32CFR219.117(c)  If funded by the FDA add: and 21CFR56.109(c)  *2018 Common Rule*  This protocol has been granted a waiver of documentation of consent for minimal risk pre-screening procedures under 45CFR46.117(c).  ***If funded by DOD add*** and 32CFR219.117(c). |
| Does this study previously has no written consent and now add the use of **written consent(s)**? If yes,   * Note on Approval Overview (Regulatory page) that # 10 -Written Consent needs to be ticked. | | Pre-review Notes: | **Approval form comments:**  **Written consent will be obtained for this study.** |

| Scientific Changes | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| FOR UVA INVESTIGATOR-INITIATED STUDIES ONLY: Was an **AE trend or newly identified risk** that is potentially serious, life-threatening, or could result in temporary or permanent disability noted/added with this modification?   * *If yes, this constitutes an unanticipated problem.* * *Contact IRB staff member responsible for reviewing adverse events.* * *Ensure appropriate changes have been made to the consent.* | **Pre-review Notes:** | **Approval form comments:**  None |
| Does this modification involve a change in the inclusion/ exclusion criteria that would allow **enrollment of a new subject population**? (e.g. different stage of cancer diagnosis, addition of children)? If yes:   * Obtain scientific review to determine if the modification needs to go to the full board (unless it is obvious that it should be reviewed by the full board OR the study is expedited and will clearly remain expedited). | **Pre-review Notes:** | **Approval form comments:**  None |
| If an **MRI with gadolinium** is being added for use other than BRAIN imaging:   * Click on the Modification Templates tab in Protocol Builder, and make sure all the appropriate template sections have been completed. * Obtain MR Physicist (Jaime Mata) approval of justification for use of gadolinium. | **Pre-review Notes:** | **Approval form comments:**  An MRI with gadolinium for research purposes is being added with this modification. MR Physicist approval on file for use of gadolinium  Different types of gadolinium have different FDA approved uses. Current information can be found on Micromedex Solutions (in the UVA Health System website).  If there is an IRB protocol, several sections will need to be added to the protocol. If there is an IRB Application, it should include the Gadolinium section.  A guidance document for use of gadolinium in research can be found on the website under Special Issues.  Regulatory Page: check Gadolinium box; provide the name of Gadolinium  MR Physicist: Gadolinium-YES |

| Screening Log | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| Is a **screening log being added**? If yes,   * Make sure the screening log has been submitted and check to see if there are any HIPAA identifiers on it. If the form contains HIPAA identifiers that designates the information being shared as identifiable, suggest that study team talk to the sponsor to see if the HIPAA identifier(s) can be removed so that they don’t have to track disclosures. Tracking requires a substantial amount of additional work for the study team. * Add the Waiver of Consent/Waiver of HIPAA Authorization section to the IRB protocol /application. * Note on Approval Overview (Regulatory page) that # 4- Waiver of Consent – Screening log needs to be ticked. | **Pre-review Notes:** | **Approval form comments:**  *Pre 2018 Common Rule*  A waiver of consent has been granted for the screening log under 45CFR46.116.  If funded by DOD add: and 32CFR219.117(c)  If funded by the FDA add: and 21CFR56.109(c)  Information may be shared outside of UVA in a variety of ways. It may be done by the sponsor viewing data during a monitoring visit or with a screening log that is sent to the sponsor. The important point is if identifiable data is shared with anyone outside of UVA prior to a potential subject signing a consent form.   A Screening Log is a log that is shared with an outside entity (usually the sponsor) that would include potential subjects who may have not yet signed a consent form. Some sponsors also have documents they call enrollment logs. Per IRB-HSR guidance, an enrollment log is a document that records all subjects who have already signed a consent form. Regardless of what the sponsor calls this form, the IRB-HSR is only asking about a form in which information will be shared about subjects who have NOT yet signed a consent form. This may be done by different methods (e.g. hard copy form faxed to sponsor, electronic data entry)  If the screening log includes any HIPAA identifiers the study personnel may be required to "Track" the disclosure each time the screening log is seen by sponsor personnel. The study team will be notified of this requirement with IRB approval. To "track" the disclosure study personnel will go to EPIC and track the disclosure required for each subject on the screening log. (If study team has difficulty with this link, they may call Health Information Services at 924-5229).  2018 Common Rule  **Funded by a non-Common Rule Agency besides the FDA (e.g. Dept of Justice)? *If yes,*** ***add***  This protocol has been granted a Waiver of Consent to use a screening log via INSERT APPLICABLE REG. (Department of Justice: 28CFR46)  *NOTE:FDA does not require waiver of consent for screening, recruiting or determining eligibility. Consent must be obtained before any clinical procedures that are performed solely to determine eligibility or for drug washout.*  **For all studies add:**  ***PICK ONE:***  Identifiable health information will not be collected in this study**. *If de-identified health information and if subjects over the age of 89 will be enrolled add****:* For subjects over the age of 89, their date of birth and age will not be recorded. All will be recorded as >89 years of age.  ***If PHI and LDS add***: Health information meets the criteria of a limited data set. A HIPAA data use agreement sent to PI. **OR** HIPAA data use agreement will be obtained by the School of Medicine Office of Grants and Contracts/OSP.  ***If PHI and Identifiable add***: This protocol has been granted a waiver of HIPAA authorization under 45CFR 164.512(i)(2) for a screening log. Tracking instructions sent to PI. The following HIPAA identifiers will be collected: **INSERT.**  The minimum necessary PHI to be collected includes **INSERT**.  No identifiable health information from the screening log will be taken or shared outside of the UVA HIPAA covered entity. |
| Is the data being collected for the screening log either **de-identified** or **without any health Information**? If yes,   * Note on Approval Overview (Regulatory page) that HIPAA- De-identified and/or no health information (no consent) needs to be ticked when hard copies are processed. | **Pre-review Notes:** | **Approval form comments:**  ***(insert as applicable)*** Data being recorded on the screening log is de-identified and/or contains no health information.  If the screening log itself does not contain health information but is being shared with the sponsor as the screening log for a particular study such as a colon cancer study, **the inclusion of health information is implied**. |
| If **health information** is being collected, do the HIPAA identifiers being recorded meet the criteria of a **limited data set**? If yes,   * Add instructions to the Approval Overview page as applicable | **Pre-review Notes:** | **Approval form comments:**  HIPAA identifiers recorded on the screening log meet the criteria of a limited data set. DUA sent to PI.  Tick the boxes below that apply to the study being modified  Recipient outside UVA. Outside entity will get LDS identifiers: dates, address info. and/or code, but not key to code   * Tip: SOM Grants and Contracts office to also obtain a HIPPA DUA with outside recipient in contract.   *On Regulatory Page mark the following:*  *HIPAA- Limited Data Set*  *Data Use Agreement: Protocol Specific*  *Data Use Agreement Type- Recipient Outside of UVA*  *Also send an e-mail to SOM Grants and Contracts office to let them know a HIPAA DUA with the outside recipient is needed. To determine who to contact, view Partner Offices on the HRPP Website.*  No Recipient outside UVA. LDS identifiers will be kept at UVA but not shared outside of UVA. (Tip: Outside entity will not even receive a code with the data).  *Add comment to main page comment field* "DUA with sponsor not required since data will not be released with identifiers or a code"  *On Regulatory Page mark the following:*  *HIPAA – Limited Data Set*  *Data Use Agreement: Protocol Specific*  *Data Use Agreement Type- PI* |

|  |  |  |
| --- | --- | --- |
| Is **identifiable health information** being collected on the screening log? If yes,   * Note on Approval Overview (Regulatory Page) that HIPAA – Identifiable – External Disclosure – Tracking Required (no consent) needs to be ticked. | **Pre-review Notes:** | **Approval form comments:**  This protocol has been granted a waiver of HIPAA authorization under 45CFR 164.512(i)(2) for a screening log. Tracking instructions sent to PI. The following HIPAA identifiers will be collected:  The minimum necessary PHI to be collected includes:  Study team to track disclosures in EPIC. They may contact Health Information Services to obtain information regarding the process to follow to track disclosures.  *On Regulatory Page mark the following:*  *HIPAA – Identifiable – External Disclosure –Tracking Required (no consent)* |
| If **identifiable** data is being collected for the screening log, it will meet the criteria **Waiver of HIPAA authorization.**   * Add applicable approval form comments. | **Pre-review Notes:** | **Approval form comments:**  This protocol has been granted a waiver of HIPAA authorization under 45CFR 164.512(i)(2) for a screening log. The following HIPAA identifiers will be collected:  The minimum necessary PHI to be collected includes:  No identifiable health information from the screening log will be taken or shared outside of the UVA HIPAA covered entity. |

| Sending Data/Specimens Outside of UVA | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| Does the modification add **data/specimens to be shipped outside of UVA**? If yes,   * Add the applicable sections to IRB Protocol/application * Database protocol: Central Registry/ Database outside of UVA * Non- database protocol: Ensure the Data Transfer section in the Data Security Plan is completed.   + Ensure the protocol has the current version of the “Appendix: Legal/Regulatory”. Which includes the “Sharing of Data/Specimens” section. * If there is a consent, make sure the consent mentions the blood/specimens being shipped outside of UVA * Instruct the study team to contact Grants and Contracts/OSP regarding the need for a contract/agreement. * Add items on the Approval Overview page (for example, Specimen Banking, HIPAA info., or Data Use Agreement information) * For more information see [Sending Data/ Specimens](https://research.virginia.edu/irb-hsr/sending-or-receiving-specimensdata) | **Pre-review Notes:** | **Approval form comments:** None specific. Describe what is being shipped outside of UVA and to whom. Also mention what the outside site will do with the samples, and state if samples will be identifiable, linked and coded, LDS, or de-identified when they go outside of UVA. If samples are being sent without consent/authorization see Waiver of Consent/ HIPAA authorization sections of this document for additional wording . |

| Waiver of Consent/Waiver of HIPAA Authorization | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| Is a **Waiver of Consent** for part or all of the main study being added? If yes,   * Make sure criteria listed in the notes section on the right are met. * Note on Approval Overview (Regulatory page) that Waiver of consent/HIPAA Authorization- Main Study needs to be ticked (item 5 under “Enrolling”) when submission is processed. * Add the Waiver of Consent/Waiver of HIPAA Authorization section to the IRB protocol (or if there is an IRB Application, have the study team fill this section out). * If more than one category applies for the waiver of consent (de-identified, limited data set, identifiable), note on approval overview (Main page) that a comment needs to be added to describe the situation (e.g. Waiver of consent granted for identifiable data kept at UVA, DUA obtained for LDS going to University “x”). * Waiver of consent NOT ALLOWED for data or specimens collected after 1/25/15 if used to generate large scale genomic data or to be submitted to an NIH Genomic data set. | **Pre-review Notes:** | **Approval form comments: ( Click applicable checkboxes on the Regulatory page to obtain applicable wording.**  This protocol has been granted a waiver of consent under 45CFR46.116 for ***(insert as applicable)***  the main study  *other- insert*:  ***If any of the following apply,*** tick the appropriate box(es) below and add: Also granted waiver of consent under ***(insert applicable wording from ticked boxes below)***  1)  **Funded by DoD**  **Add*:*** 32CFR219.117(c)  2)  **Testing of an in-vitro device involved**  **Add:** FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using leftover Human Specimens that are Not Individually Identifiable.  3)  **Includes drugs or devices- emergency use**  **Add*:*** 21CFR50.23  4)  **Includes drugs or devices (rare- consult w/ IRB Director)**  **Add:** 21CFR50.24  Protocol (or part of the protocol) must meet the criteria below for waiver of consent to be granted:   * The research involves no more than minimal risk to the subjects. * The research could not practicably be carried out without the waiver or alteration, * If the research involves using identifiable private information or identifiable bio-specimens, the research could not practicably be carried out without using such information or bio-specimens in an identifiable format. * The waiver or alternations will not adversely affect the rights and welfare of the subjects. * When appropriate, subjects or their legally authorized representative will be provided with additional pertinent information after participation. |

|  |  |  |
| --- | --- | --- |
| Is the data being collected either **de-identified** or without any health Information? If yes,   * Note on Approval Overview (Regulatory page) that HIPAA- De-identified and/or no health information (no consent) needs to be ticked when the submission is processed. | **Pre-review Notes:** | **Approval form comments:**  ***(insert as applicable)*** Data being collected is de-identified and/or contains no health information.  ***If subjects over the age of 89 will be enrolled, add:*** For subjects over the age of 89, their date of birth and age will not be recorded. All will be recorded as >89 years of age. |
| If **health information** is being collected, do the HIPAA identifiers being recorded meet the criteria of a **limited data set**? If yes,   * Send Data Use Agreement to PI * Fill out the boxes to the right, and add instructions to the Approval Overview page as applicable | **Pre-review Notes:** | **Approval form comments:** DUA sent to PI. Meets the criteria of a limited data set.  Tick the boxes below that apply to the study being modified  Recipient outside UVA. Outside entity will get LDS identifiers: dates, address info. and/or code, but not key to code   * Tip: SOM Grants and Contracts office to also obtain a HIPAA DUA with outside recipient in contract.   *On Regulatory Page mark the following:*  *HIPAA- Limited Data Set*  *Data Use Agreement: Protocol Specific*  *Data Use Agreement Type- Recipient Outside of UVA*  *Also send an e-mail to SOM Grants and Contracts office to let them know a HIPAA DUA with the outside recipient is needed. To determine who to contact go to the SOM Grants and Contracts office website under HRPP website/ Partner Offices.*  No Recipient outside UVA. LDS identifiers will be kept at UVA but not shared outside of UVA. (Tip: Outside entity will not even receive a code with the data).  *Add comment to main comment field* "DUA with sponsor not required since data will not be released with identifiers or a code"  *On Regulatory Page mark the following:*  *HIPAA – Limited Data Set*  *Data Use Agreement: Protocol Specific*  *Data Use Agreement Type- PI* |
| Is **identifiable health information** being collected? If yes,   * Fill out boxes to the right, and add instructions to the Approval Overview page regarding tracking instructions as applicable. | **Pre-review Notes:** | **Approval form comments:**  None specific. If approval form comments are not adequately covered based on the other questions in this table, then add text to further explain the situation.  Internal- Identifiers not given to or seen by anyone from outside entity – no additional documentation required  *On Regulatory Page mark the following:*  *HIPAA – Identifiable – Internal Use – No Tracking Required (no consent)*  External – give PI Tracking Instructions  *On Regulatory Page mark the following:*  *HIPAA – Identifiable – External Disclosure –Tracking Required (no consent)* |
| If **identifiable** data is being collected, does the protocol or part of the protocol meet the criteria for **Waiver of HIPAA authorization**?   * If yes, add applicable approval form comments. * If the study involves more than one group of subjects (i.e. control vs. non controls, patients vs. health care providers) make it clear in the approval comment wording which group you are referring to if not applicable for all subjects. * If no, see Waiver of Documentation of consent/alteration of HIPAA Authorization table below. | **Pre-review Notes:** | **Approval form comments:**  This protocol has been granted a waiver of HIPAA authorization under 45CFR164.512(i)(2) for ***(insert as applicable)*** the main study OR other (specify)  The following HIPAA identifiers will be collected:  The PHI deemed to be the minimum necessary for ***(insert as applicable)*** this protocol OR this part of the protocol includes  (***insert protected health information from privacy plan section of protocol).***  ***If waiver of HIPAA authorization is being granted for the entire study add:*** Subjects may not be contacted by any method (email, phone in person, etc.) to obtain more information for this study.  No identifiable information will be taken or shared outside of the UVA HIPAA covered entity.  **Criteria for waiver of HIPAA Authorization is as follows:**   * The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals base in, at least, the presence of the following elements:   1. An adequate plan to protect the identifiers from improper use and disclosure;   2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless thee is a health or research justification for retaining the identifiers or such retention is otherwise required by law;   3. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart. * The research could not practicably be conducted without the waiver or alteration * The research could not practicably be conducted without access to and use of the protected health information   For additional information, see U/IRB/IRB-HSR/Administrative FAQ's**/** Sources for regulations and guidance regarding when waiver of consent and waiver of HIPAA authorization are required. |

| Waiver of Documentation of Consent/Alteration of HIPAA Authorization | **Tick applicable boxes below** | **Approval Form Comments and Notes (in purple)** |
| --- | --- | --- |
| Is Waiver of Documentation of consent being added for the **main study (or part of the main study)**? If yes,   * Make sure the criteria for waiver of documentation of consent is met. * Make sure the template sections from the Modification Templates table in IRB online have been added to the IRB protocol, or if there is an IRB Application, that the appropriate template sections have been submitted and properly completed. * Note on Approval Overview (regulatory) page that Waiver of Documentation of Consent/HIPAA Authorization – Main Study needs to be ticked. | **Pre-review Notes:** | **Approval form comments:**  Waiver of documentation of consent granted under 45CFR46.117(c) for ***(insert as applicable)***the main study OR specify part of study.  If funded by DOD add: and 32CFR219.117(c)  If funded by the FDA add: and 21CFR56.109(c)  Criteria for waiver of documentation of consent:   * The only record linking the subjects and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality OR * The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. |
| Is Waiver of Documentation of Consent being added for **questionnaires**? If yes,   * Make sure the criteria for waiver of documentation of consent is met (criteria outlined above). * Make sure the template sections from the Modification Templates table in IRB online have been added to the IRB protocol, or if there is an IRB Application, that the appropriate template sections have been submitted and properly completed. * Note on Approval Overview (regulatory) page that Waiver of Documentation of Consent/HIPAA Authorization – Questionnaires needs to be ticked. | **Pre-review Notes:** | **Approval form comments:**  Waiver of documentation of consent granted under 45CFR46.117(c) for questionnaires being administered.  If identifiable health information is not being collected add: Identifiable health information will not be collected.  If funded by DOD add: and 32CFR219.117(c)  If funded by the FDA add: and 21CFR5 6.109(c) |
| Is **identifiable health information** included on the questionnaire or with data being collected for the main study? If yes,   * Determine if the study or questionnaire qualifies for alteration of HIPAA authorization to allow for verbal/oral authorization. See criteria in notes section to the right. * Add the appropriate approval form comments based on whether or not the questionnaire/study qualifies for alteration of HIPAA authorization. * If study does NOT qualify for alteration of HIPAA authorization, provide the study team with the HIPAA Authorization Stand Alone form located under “forms” on the IRB website. | **Pre-review Notes:** | **Approval form comments:**  ***If questionnaire/study does NOT qualify:*** Study team will obtain a signature from each subject on the HIPAA Authorization form.  ***If questionnaire/study does qualify:*** Alteration of HIPAA Authorization granted under 45CFR164.512(i)(2) to obtain an oral HIPAA authorization for ***(insert as applicable)*** questionnaires/the study.  The IRB determined that obtaining written HIPAA Authorization would be impracticable because ***(insert as applicable)***  study (or providing questionnaire responses) will be conducted over the phone or via e-mail, making obtaining written HIPAA authorization impracticable.  study will be conducted in a public area with oral consent under DHHS regulations.  the sample size required is so large that including only those samples/records/data for which written authorization can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.  of ethical concerns created by the risk of creating additional threats to privacy by having to link otherwise de-identified data with identifiers in order to contact individuals to seek authorization.  other: ***explain:***  Criteria for alteration of HIPAA authorization:   1. The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based in at least the presence of the following elements:  * an adequate plan to protect the identifiers from improper use and disclosure * an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and * adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.  1. The research could not practicably be conducted without the waiver or alteration, and 2. The research could not practicably be conducted without access to and use of the protected health information. |

# Appendix A: Additional Information for PI Changes

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study Status** | **Submission must be updated and signed by new PI?** | **Consent(s) must be updated?** | **Updated Investigator Agreement?** | **PAM Review** | **PRC approval if protocol was approved by the PRC** |
|  |  |  |  |  |  |
| **Database Study** | YES | YES  ( if consent exists and still enrolling subjects) | YES | NO | YES |
| If not exempt or database and Open to Enrollment or Temporarily Closed to Enrollment | YES | YES | YES | YES \* | YES |
| **If not exempt or database and** **Closed to Enrollment, Subjects Being Treated** | YES | NO | YES | YES | YES |
| **If not exempt or database and** **Closed to Enrollment, Follow Up Only or Data Analysis** | YES | NO | YES | NO | YES |

**\* A PAM audit does not need to be initiated if no subjects have enrolled or if the PAM auditors determine this study team has a history of exceptional audits.**

**NOTE: If a PI change is occurring in a large number of protocols, it may be determined that post approval monitoring will only be done initially on 20% of the protocols. If the results are determined to be exceptional or satisfactory no additional audits are required. If however, if at least one of the protocols has a marginal rating audits will be conducted on an additional 10% of the protocols.**

# Appendix B: Outside IRB/Multi-site study Examples

**Examples of when a study is considered multi-site.**

NOTE: These examples apply to studies that are becoming multi-site. If the study is ALREADY a multi-site study w/ SOM CTO approval, you won’t need to get SOM CTO approval again w/ the modification unless a new IND or IDE is being added and the study is not commercially sponsored. In addition, if your study matches the example in the 3rd bullet below, the IRB does not require documentation of approval from the clinic each time a modification is submitted.

* Dr. Uva Researcher has written a protocol and obtained funding for the protocol from the NIH. The study will be carried out at UVA, the University of Mississippi and Martha Jefferson Hospital in Charlottesville. The work at each site will be performed by employees of that site. Each site will have its own Principal Investigator for the protocol, who will obtain IRB approval at that site. All data will be submitted to the PI at UVA for analysis.
  + Study team will need to submit the following documents to UVA IRB-HSR:
    - Approval from UVA School of Medicine Clinical Trials Office
  + Study team will need to keep a copy of outside IRB approvals on file. The UVA School of Medicine Clinical Trials Office will review files annually to confirm the study team has all applicable IRB approvals on file. The study team will not be required to submit the outside IRB approvals to the IRB-HSR. They will also NOT be required to submit a modification to the IRB-HSR to open enrollment at a new site.
* Dr.Uva Researcher has written a protocol and obtained confirmation from a drug company that they will supply free drug for the study. The drug company will not receive data prior to publication and is not functioning as the sponsor. The study will be carried out at UVA, the University of Mississippi and Martha Jefferson Hospital in Charlottesville. The work at each site will be performed by employees of that site. Each site will have its own Principal Investigator for the protocol, who will obtain IRB approval from their site. All data will be submitted to the PI at UVA for analysis.
  + Study team will need to submit the following documents to UVA IRB-HSR:
    - Approval from UVA School of Medicine Clinical Trials Office
  + Study team will need to keep a copy of outside IRB approvals on file. The UVA School of Medicine Clinical Trials Office will review files annually to confirm the study team has all applicable IRB approvals on file. The study team will not be required to submit the outside IRB approvals to the IRB-HSR. They will also NOT be required to submit a modification to the IRB-HSR to open enrollment at a new site.

**Examples of when study is NOT considered multi-site. Outside IRB approval may or may not be needed depending on the scenario**

* Dr.Uva Researcher has written a protocol and obtained funding for the protocol from the NIH. The study will be carried out at UVA and the Rochester New York Free Clinic. Employees of the Free Clinic will collect the data and send it to Dr. Researcher at UVA. The Free Clinic does not have an IRB.
  + Study team will need to submit the following documents to UVA IRB-HSR:
    - Documentation from the administration of the Free Clinic confirming they approve of this work being done at the Free Clinic.
    - Unaffiliated Investigators Agreement for each employee of the Free Clinic working on this protocol, as well as documentation of CITI training
    - In order to add other sites to this protocol, study team will need to submit a modification to the IRB-HSR
* Dr. Uva Researcher has written a protocol and obtained funding for the protocol from the NIH. The protocol will be carried out by employees of UVA who will travel to a hospital in Brazil to collect the data.
  + Study team will need to submit the following document to UVA IRB-HSR:
    - IRB approval (or approval from other appropriate entity if there is no IRB) from the hospital in Brazil.
* Dr. Uva Researcher has written a protocol and received departmental funds to carry out the study. The protocol will be carried out by employees of UVA who will travel to surrounding county fairs to collect the data.
  + No approval documents need to be submitted to the UVA IRB-HSR:
* Dr. Uva Researcher has a joint appointment at UVA and Encompass Health Rehabilitation Hospital. He will be collecting data from both institutions. IRB-HSR would review protocol because Dr. Uva Researcher is a UVA employee
  + Study team will need to submit the following documents to UVA IRB-HSR:
    - Documentation from the administration of Encompass Health Rehabilitation Hospital confirming they approve of this work being done at Encompass Health Rehabilitation Hospital or copy of outside IRB approval if required by Encompass Health Rehabilitation Hospital.
* Dr. Uva Researcher has a protocol with a sub-investigator who is an employee of Encompass Health Rehabilitation Hospital. The sub-investigator at Encompass Health Rehabilitation Hospital who is not a UVA employee will collect data as a LDS and send to the UVA Researcher. The UVA Researcher will not monitor the site at Encompass Health Rehabilitation Hospital - therefore seeing no identifiable data.
  + Study team will need to submit the following documents to UVA IRB-HSR:
    - Documentation from the administration of Encompass Health Rehabilitation Hospital confirming they approve of this work being done at Encompass Health Rehabilitation Hospital or copy of outside IRB approval if required by Encompass Health Rehabilitation Hospital
    - Unaffiliated Investigator Agreement and confirmation of CITI training from sub-investigator at Encompass Health Rehabilitation Hospital
    - Copy of DUA from Encompass Health Rehabilitation Hospital signed by Dr. Uva Researcher
* Dr. Uva Researcher has written a protocol and obtained funding from the University of Virginia Research and Development committee. Specimens and data will be collected by a sub-investigator, Dr. Iam International at the University Hospital of Timbuktu. Dr. Iam International is not an employee of UVA. The specimens will be sent to Dr. Uva Researcher for hematocrit testing.
  + Study team will need to submit the following documents to UVA IRB-HSR:
    - IRB Approval from University Hospital of Timbuktu
* Dr. Uva Researcher has written a protocol and obtained funding from the University of Virginia Research and Development committee. Specimens and data will be collected by a sub-investigator, Dr. Iam International at the University Hospital of Timbuktu. Dr. Iam International has an affiliation with UVA and is an employee of UVA. The specimens will be sent to Dr. Uva Researcher for hematocrit testing.
  + Study team will need to submit the following documents to UVA IRB-HSR:
    - IRB Approval from University Hospital of Timbuktu

# Appendix C: Regulations regarding enrollment of children

Regulations starting with **21CFR apply only if the protocol is regulated by the FDA** (has an IND or IDE).

**45CFR404:**

404 is rarely applicable for a study requiring full board review. This regulation is used when it is determined that the research:

* involves minimal risk
* the permission of one parent is required

In addition, adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians per 45CFR46.408 (see below)

**45CFR405:**

This regulation is used when it is determined that the research:

* involves greater than minimal risk but benefits subject or monitoring procedure is like to contribute to subjects well-being *45CFR46.405/21CFR50.52*
* the permission of one parent is required.*45CFR46.408(b)/21CFR50.55(e)(1)*

**In addition:**

* The risk is justified by the anticipated benefit to the subject
* The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches
* Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians per 45CFR46.408 ( see below)

***IRB-HSR Guidance:*** *Protocols including genetic testing would fall under this category if results will not be given back to subject, parents, subject’s physician and/or placed in medical record.*

**ASSENT for 404 and 405**

Assent should be solicited unless:

* the capability of some or all of the children is so limited that they cannot reasonably be consulted (if all subjects are under 7, this is appropriate) OR
* the intervention or procedure involved in the research/clinical investigation holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research

**45CFR406:**

This regulation is used when it is determined that the research:

* involves greater than minimal risk, does not directly benefit subject, but will yield knowledge of subject’s condition; or the monitoring procedure is not likely to contribute to the well-being of the subject and

45CFR46.406/21CFR50.53

* permission of two parents is required, unless one is one parent is deceased, unknown, incompetent or not reasonable available.

*45CFR46.408(b)/21CFR50.55(e)(2)*

**In addition**

* The risk represents a minor increase over minimal risk
* The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations
* The intervention or procedure is likely to yield generalizable knowledge about the subjects’ disorder or condition which is of vital importance for the understanding or amelioration of the subjects’ disorder or condition AND
* Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians as set forth in 45CFR46. 408
* Assent is required if enrollment of children is approved under 406.

**45CFR407:**

This regulation is used when it is determined that the research would not otherwise be approvable, but it offers an opportunity to alleviate a serious problem affecting health of children and is to be conducted with ethical principles; assent by child should be solicited if he/she is capable of meaningful assent, and permission of two parents is required, unless one is deceased, unknown, incompetent or not reasonably available.

# Appendix D: Exempt Criteria and Expedited Categories

**Exempt Categories for the Pre 2018 Common Rule and the 2018 Common Rule may be found on the IRB-HSR Website at**

[Exempt Criteria](https://research.virginia.edu/sites/vpr/files/2019-10/exemptcriteria.docx)

**EXPEDITED CATEGORIES**

|  |  |  |
| --- | --- | --- |
| **EXPEDITED CATEGORIES** | | **TIPS** |
| 1 | 1. Clinical studies of drugs and medical devices only when conditions (a) or (b) is met: 2. Research on drugs for which an investigational new drug application is not required. 3. Research on medical devices for which    1. an investigational device exemption (IDE) application is not required; or    2. the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. | * Choose EITHER a or b- do not include both in comment field. * a. Research on marketed drugs that significantly increases the risks associated with the use of the drug is not eligible for expedited review. * B. Choose EITHER i or ii- do not enter BOTH in the comment field. * Used for a study involving a drug or device study where an IND/IDE is not required. |
| 2 | 1. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:    1. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period, and collection may not occur more frequently than two times per week; or    2. From other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than two times per week. | * Only list a/b in comment field if they are applicable to current study. |
| 3 | Prospective collection of biological specimens for research purposes by noninvasive means. | * ***TIP****- see* [*review category*](https://research.virginia.edu/sites/vpr/files/2019-10/Expedited%20Review.doc) *for examples.* |
| 4 | Collection of data through non-invasive procedures (not involving general anesthesia or sedation) employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. | * Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. * ***TIP****: see* [*review category*](https://research.virginia.edu/sites/vpr/files/2019-10/Expedited%20Review.doc) *for examples* * Note: For Guidance on Determination of Intensity of Exercise, go to IRB/IRB-HSR/Administrative FAQs/Expedited Studies/Guidance on Determination of Intensity of Exercise |

|  |  |  |
| --- | --- | --- |
| 5 | Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment and/or diagnosis). | * ***TIP:*** *According to* [*OHRP Request for Comment*](http://www.hhs.gov/ohrp/requests/com102607.html)  *this category may include “research involving materials that were previously collected for either the non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research. Also see* [*Admin question*](https://research.virginia.edu/irb-hsr/when-can-expedited-category-5-be-used) *for further information* * *Note to staff- if study involves an IND or IDE- consult with IRB Director regarding use of this expedited category for the study* |
| 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 limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. | * ***TIP****: see* [*review category*](https://research.virginia.edu/sites/vpr/files/2019-10/Expedited%20Review.doc) *for additional explanation* |
| 9 | Continuing review no drug or device where 2-8 don't apply and minimal risk established by full board. | * Use this category when the full board determined future continuation can be expedited. |
| 9 (HUD) | Continuing review no drug or device where 2-8 don't apply and minimal risk established by full board. (Humanitarian Use Device) | * Use this category when the full board determined future continuation can be expedited. |

**Full Board Meeting Day: MODIFICATION Meeting Date:**

|  |  |  |
| --- | --- | --- |
| **IRB/UVA Study Tracking # and**  **PI Name** | **Committee Member Conflicts** | **Scientific Reviewer** |
| **/** |  |  |

***Complete Within One Week PRIOR to the Meeting***

**Review Checklists: (Only for any NEW Populations Requiring Additional Protections Added with Modification):**

NA  Children  Impaired Decision Making  Pregnant Females/Fetuses/Neonates  Prisoners  Students/Employees

**Any Pending Items?**   No  Yes If Yes, list \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Complete the two columns to the left prior to the meeting and the three columns to the right during the meeting***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Board Decisions at time of meeting** | | | | | |
| **Applicable?** | |  |  |  |  |
| **Yes** | **No** | IND exempt  *Answer YES if investigating safety & efficacy of an approved drug or biologic SOM CTO opinion* | Yes | No | If no- Is IND# on file? YesNo |
| **Yes** | **No** | IDE exempt?  *Answer YES if investigating safety and efficacy of an approved device. SOM CTO opinion* | Yes | No | If no-  SR  NSR  If SR- is IDE# on file? YesNo |
| **Yes** | **No** | Children- # of parent signatures/ assent  *Consent/assent submitted with:*  *one two signature lines* | One | Two | *If multiple arms- need to consider each arm.* |
| **Yes** | **No** | Children- Assent  *Submission includes request for No Assent,*  *Written Assent  Verbal Assent* | Yes | No | If yes:  Written  Verbal |
| **Yes** | **No** | Minors enrolled under parental permission & will be continued interaction with minors in the study after they turn 18.  Age of Majority Consent submitted? Yes No  *Age of Majority Consent required?* | Yes | No | *If No and minors will be enrolled under parental permission and identifiable data/specimens will continue to be used after minor turns 18 in which there will be no continued interaction with minors provide. Check #11 Waiver of Consent: Age of Majority* |
| **Yes** | **No** | Wards of State to be enrolled.  Are two parent signatures required-? | Yes | No | If yes, name of advocate: |
| **Yes** | **No** | Surrogate: is there benefit to subjects? | Yes | No | If No- is there no more than a slight increase over Minimal Risk? Yes  No |
| **Yes** | **NA** | STUDY CURRENTLY EXPEDITED AND REGULATED UNDER **PRE2018 Rule:**  Did the IRB determine the study continues to meet minimal risk criteria? | Yes | No | If yes, are there any changes to the Expedited Criteria for this study?  Yes  No  If YES, what Expedited Criteria are applicable?  *Enter in IRB Online when approved.* |
| **Yes** | **NA** | STUDY CURRENTLY EXPEDITED /NOT REGULATED BY THE FDA AND/OR REGULATED UNDER **2018 Rule:**  Did the IRB determine the study continues to meet minimal risk criteria? | Yes | No | If yes, see instructions on section under Minimal Risk Determination .  Study falls under Expedited Category(s) #:        **C**ontinuation reviews not required.  Study DOES NOT fall under Expedited Categories.  Continuation reviews per Expedited Category # 9. |
| **Yes** | **No** | Does study meet the criteria for:   * Waiver of Consent/Alteration * Waiver of Documentation of Consent * Exception from Informed Consent? | Yes | No | If yes, which one/ which arm:  Waiver of Consent/Alteration:  Waiver of Documentation of Consent:  Exception from Informed Consent: |
| **Yes** | **No** | Mandatory Banking approved? | Yes | No | If yes, add reason for approval to Assurance Form |
| **OTHER:** | | | | | |

Approved  Approved with Suggestions  Approvable with Conditions  Deferred  Disapproved

For( #):Against(#): Abstain(name): \_\_\_\_\_\_Absent (name):

|  |  |  |
| --- | --- | --- |
| **Enrollment:** | | |
| **Did the board have concerns regarding the ability of the study team to meet enrollment goals?**  *If YES, note the following in main comment field*: Board had enrollment concerns with (enter year) modification. | **Yes** | **No** |

**Administrative Staff Completing at Time of FB Review:**

**Waiver of Consent/ Waiver of Documentation of Consent**

**Waiver of Consent/Alteration of Consent - Main Study- DHHS Regulations**

|  |  |
| --- | --- |
| **CRITERIA** | **PROVIDE STUDY SPECIFIC JUSTIFICATION BELOW** |
| The research involves no more than minimal risk to the subjects **because:** |  |
| The waiver or alterations will not adversely affect the rights and welfare of the subjects because: |  |
| The research could not practicably be carried out without the waiver or alteration because |  |

**Waiver of Documentation of Consent- Main Study- DHHS Regulations**

|  |  |
| --- | --- |
| **CRITERIA** | **PROVIDE STUDY SPECIFIC JUSTIFICATION BELOW** |
| That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; |  |
| That the research presents no more than minimal risk of harm to subjects because and involves no procedures for which written consent is normally required outside of the research context. |  |

|  |
| --- |
| **Minimal Risk Determination** |
| |  |  |  |  | | --- | --- | --- | --- | | IRB determined study is Minimal Risk , is not FDA Regulated and meets an Expedited Criteria # 2-8  *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  IRB determined study is Minimal Risk, is not FDA Regulated and does NOT meet an Expedited Criteria # 2-8 | Yes  Yes | No  No | *If YES:*  *Regulatory page: check applicable expedited criteria*  *Change TYPE on main page to Expedited*  **Approval form comments:**  The board determined that the study is no more than minimal risk to subjects and that the study is approvable under expedited category # (INSERT NUMBER). Continuation reviews are not required per the 2018 Common Rule, however the study team must submit an IRB Update to the IRB-HSR on an annual basis.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *If YES:*  *Regulatory page: check Expedited Cat # 9 Continuing review-no drug/device-where 2-8 don’t apply. Leave TYPE on main page as FULL COMMITTEE*  **Approval form comments:**  The board determined that the study is no more than minimal risk to subjects. Continuation reviews will be conducted via an expedited review process per expedited criteria # 9. . | |