**ADMINISTRATIVE PRE-REVIEW CHECKLIST and APPROVAL COMMENT FORM**

**UVA RELYING on Non-UVA IRB**

**IRB of Record:       UVA Study Tracking#**\_\_\_ \_\_\_ **IRB RA Tracking #**\_\_\_\_\_\_  None-*refer to AG 2-36.*

**Study previously open at UVA with IRB-HSR as IRB of Record?** No  Yes-If Yes: **IRB-HSR/UVA Study Tracking#**\_\_\_\_\_\_

*Do not download the study, retain the current IRB-HSR/ UVA Study Tracking # and enter an event to transfer the study to the non- UVA IRB***. (see AG 2-37)**

**PI Name:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Confirm PI Staff/Faculty at UVA**  Yes

**Outside Sponsor**  **NA Yes If yes: Sponsor**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Funded by Grant from FDA or other non- common rule agency?** **No Yes GIRB #** \_\_\_*List Sponsor in database*

**Training Current?  Yes  No If no, who? \_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (If No, notify study team)

**Original approval date: Reviewing IRB**      \_\_\_\_\_\_\_**Expiration date: Reviewing IRB**-

**Last continuation approval date (If applicable):  N/A or Date:**

**Will the UVA IRB-HSR serve as the HIPAA Privacy Board?**  No  Yes-*If yes, complete Appendix A*

*(Note: UVA IRB will serve as HIPAA Privacy board for NCI CIRB studies)*

**Is the study federally funded or regulated by FDA?  Yes  No**

***If YES,*** *check Federally Regulated on Regulatory page*

***If NO,*** *does the Reviewing IRB apply the federal regulations to all research regardless of funding source?*

*(Unchecked the FWA box)*  **Yes  No**

***If YES,*** *will the Reviewing IRB report UPs, serious or continuing non-compliance to federal agencies, regardless of funding source?*  **Yes  No** *If NO, check box on main page of IRB online (UVA to Report UP et al to Feds).*

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| --- | --- | --- | --- | --- | --- |
| **Q#** | **Note** | **Q#** | **Note** | **Q#** | **Note** |
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| **IND Exempt (drug/biologic)**  **Must make this determination if using Gadolinium** | NA\* | Yes | No | *If No, IND#* *NAME:*  *If yes, check FDA Regulated on Reg page in IRB online* |
| **IND Exempt**  **(NON-drug: isotope/supplement)** | NA\* | Yes | No | *NAME:* *Send protocol to SOM CTO to determine if a drug.*  *If YES, do NOT check: Invest Drug/Biologic on Reg page. Data should not be sent to FDA.* |
| **IDE Exempt** | NA\* | Yes | No | *If no and device does not have an IDE # send protocol to SOM CTO for SR/NSR opinion*  NSR  SR - IDE # |

*\*Check N/A if the study does not involve the evaluation of a device, a drug, biologic or other products such as isotopes or supplements.*

See FDA [FDA Regulated Studies](https://research.virginia.edu/sites/vpr/files/2019-08/fda_regulated_studies.docx) Studies for additional info

**Reminder:**

NOTE: If Question in protocol builder pertaining to enrolling Non-English speaking subjects is YES, and question to use short forms is no– Confirm with study team if consent is being fully translated or whether creation of UVA Short Forms is necessary.

NOTE  if Question in Protocol builder pertaining to using LAR is YES then verify in the Non UVA Initial Approval that they approved LAR use.

NOTE  Sponsor should not be IND/IDE Holder. Ask study team who is taking on the liability of being sponsor and/or providing funding. Funder may not be the same as the sponsor.

**ADDITIONAL COMPLIANCE APPROVAL(S)/REVIEWS  NONE**

If any of the items below are applicable, check below and on regulatory page of IRB ONLINE. Forward any approvals/requirements to the Reviewing IRB

| **ANCILLARY APPROVAL/REVIEW** | **STATUS** | **IRB ONLINE COMMENT*: If on file, add below to the event comment field*** |
| --- | --- | --- |
| HIRE | On file  Pending | HIRE Committee approval on file. |
| RDRC | On file  Pending | RDRC approval on file |
| SOM CTO  UVA PI held IND/IDE | On file  Pending | SOM CTO approval on file for UVA PI held IND/IDE  Check UVA PI of IND/IDE on Regulatory page in IRB Online |
| SOM-CTO  PI of Multi-site Trial | On file  Pending | SOM CTO approval on file for PI of multisite trial.  Check PI of Multi-site Trial on Regulatory page in IRB Online |
| SOM-CTO  Review regarding SR/NSR status | On file  Pending | SOM CTO review on file regarding SR/NSR status. Their opinion is (INSERT). Full IRB to determine if device is SR or NSR. If SR, an IDE will be required. *IRB may consult with SOMCTO regarding IDE exempt status, but this is not required.* |
| SOM-CTO Review Need for IND/IDE | On file  Pending | SOM CTO determined an IND/IDE is ***PICK ONE*** required/ not required. |
| SOM-CTO Review Need for IND/IDE held by outside PI | On file  Pending | *For studies involving investigational device enter:*  SOM CTO review on file regarding need for an IDE.  SOM CTO determined an IND is ***PICK ONE*** required/ not required. |
| SOM CTO-  Outside academic investigator serving as Sponsor | On file  Pending | SOM CTO review of sponsors’ protocol on file as outside academic investigator is serving as sponsor. |
| PRC Exemption/ Approval | On file  Pending | PRC exemption/ Approval (INSERT NUMBER) on file |
| MRI Physicist Approval  Use of Gadolinium | On file  Pending | MRI Physicist Approval –Use of Gadolinium on file |
| IBC# | On file  Pending | IBC# (INSERT NUMBER) on file. |
| IBC Approval | On file  Pending | *IBC approval on file for use of hazardous/toxic material in this protocol* |
| InfoSec Approval | On file  Pending | InfoSec approval on file. |
| Departmental Scientific Review Committee | On file  Pending | Departmental Scientific Review Committee from (INSERT NAME) approval on file. |
| Gene Transfer Study | On file  Pending | Approval from SOM CTO, IBC and RAC committee on file. IBC# (insert #) on file. |
| Investigational Drug Services(IDS) Feasibility Approval | On file  Pending | Approval from IDS on file. |
| Investigational Drug Services(IDS) Waiver | On file  Pending | Waiver from IDS on file. |
| New Medical Device | On file  Pending | New Medical Device Application Form on file |
| Laser Safety Officer Approval | On file  Pending | Laser Safety Officer Approval on file |
| SBS | On file  Pending | SBS review on file for use of FERPA regulated data |
| COI identified with UVA researcher(s) | On file  Pending | ***If yes, is there a COI Management plan from the COI Committee?***  **Yes  No** If yes, Send the plan to the IRB of Record**.**  Completed --Add comment: COI Management plan on file. |
| GRIME: If this study will target UVA Medical Students as subjects, GRIME approval is required | On file  Pending | GRIME approval on file to enroll UVA medical students |
| GMEC: If this study will target UVA medical residents or fellow as subjects, GMEC approval is required | On file  Pending | GMEC approval on file to enroll UVA medical residents or fellows |
| UVA PI of IND/IDE? | Yes No | If Yes, check UVA PI of IND/IDE on Regulatory page in IRB Online. |
| Specimen Banking at UVA | Yes No | If Yes, check Specimen Banking at UVA on Regulatory page in IRB Online. |
| Funded by Federal Government or study has/will have a Certificate of Confidentiality? | Yes No | If Yes, check “Certificate of Confidentiality without Expiration Date on Regulatory Page of IRB Online. |
| Not funded by Federal Government and study has a Certificate of Confidentiality | Yes No | If Yes, check “Certificate of Confidentiality with or without Expiration Date on Regulatory Page of IRB Online. |

**Administrative Staff Completing Form:       Date**

**Appendix A: UVA IRB serving as the HIPAA Privacy Board**

**HIPAA**

|  |
| --- |
| HIPAA- De-identified and / or no health information,(no consent) |
| HIPAA- Identifiable-External Disclosure-Tracking Required ( no consent)  *Tracking instructions found at U/ IRB/IRBHSR/Administrative FAQ’s /HIPAA/ HIPAA TRACKING INSTRUCTIONS* |
| HIPAA- Limited Data Set (no consent) |
| HIPAA-Identifiable-External Disclosure-Tracking Required-**screening log only** ( no consent for screening log disclosure)  *Tracking instructions found at U/ IRB/IRBHSR/Administrative FAQ’s /HIPAA/ HIPAA TRACKING INSTRUCTIONS*   * *If Yes to Screening Log,* ***click Screening Log (If LDS- complete DUA section) on Regulatory Page*** |
| HIPAA-Identifiable-Internal Use-No Tracking Required( no consent) |
| **Does the study include sharing data/ specimens outside of the UVA HIPAA covered entity without the written authorization of the subject?** Yes No  *Nutrition services employees are part of UVA HIPAA covered entity***.** Yes No  *If sending names to Center for Survey Research for health related research- answer YES*  *If yes, see* [*Sending or Receiving Data and/ or Specimens*](https://research.virginia.edu/irb-hsr/sending-or-receiving-specimensdata) *to determine required steps & documentation* |
| If UVA serving as the HIPAA Privacy Board, the Recruitment template must be complete-click the applicable check boxes *under “Identifying” and “Contacting” on the Regulatory page of IRB online* |
| **Does this study include Waiver of HIPAA Authorization for the main study and involve Unaffiliated Investigators, other than Nutrition Services employees, or who has not obtained approval from the SOM via the SOM Volunteer Form but who will receive identifiable health information?**  *If yes, see Unaffiliated Investigator, Access to PHI, Waiver of Consent/HIPAA Authorization* Yes No |

**NOTE: IRB-HSR will ONLY grant Waiver(s) of HIPAA Authorization (if applicable)**

**\*Populated template in database may need to be revised to remove reference to Waiver of Consent. \***

**CONTACTING**

**2.** Contacting: Not Health Care Provider-Waiver of HIPAA Authorization

*Pre 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.*

**Is the IRB-HSR the HIPAA Privacy Board?**  YES NO

**If YES add:**

The IRB-HSR has granted a 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.

***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.

2018 Common Rule

*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.*

**Is the IRB-HSR the HIPAA Privacy Board?**  YES NO

**If YES 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.

***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.

Reviewer Comments:

**5.** Waiver of HIPAA Authorization- Main Study

* *Excludes a waiver for identifying /contacting.*
* *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.*

***If PHI and LDS add***: Health information meets the criteria of a limited data set. DUA sent to PI.

***If PHI and Identifiable***: This protocol has been granted a waiver of HIPAA authorization under 45CFR 164.512(i)(2) for the main study. The following HIPAA identifiers will be collected: ***INSERT.***  The minimum necessary PHI to be collected includes ***INSERT***

Subjects may not be contacted by any method (email, phone, in person etc.) to obtain more information for this study without additional IRB-HSR approval. No identifiable health information will be taken or shared outside of the UVA HIPAA covered entity.

**7.** Waiver of HIPAA Authorization-Questionnaires

***PICK ONE:*** Identifiable health information will not be collected in this study**. OR *if includes identifiable health information add*** This protocol has been granted an alteration of HIPAA Authorization under 45CFR164.512(i)(2) to obtain oral HIPAA authorization for questionnaires. The IRB determined that obtaining written HIPAA authorization would be impracticable because***: insert***

**8.** Waiver of Documentation of HIPAA Authorization-Main Study

***PICK ONE:*** Identifiable health information will not be collected in this study**. OR *if includes identifiable health information add*** This protocol has been granted a alteration of HIPAA Authorization under 45CFR164.512(i)(2) to obtain oral HIPAA authorization for the main study. The IRB determined that obtaining written HIPAA authorization would be impracticable because***: insert.***

**Unaffiliated Investigator, Access to PHI, Waiver of HIPAA Authorization  Yes  No**

*If yes, complete section below and add language to assurance form*

**Does the work being done by the unaffiliated investigator meet the criteria for Waiver of HIPAA authorization?** Yes No

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:*
2. *An adequate plan to protect the identifiers from improper use and disclosure;*
3. *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*
4. *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.*
5. *The research could not practicably be conducted without the waiver or alteration and*
6. *The research could not practicably be conducted without access to and use of the protected health information*

**IF NO, do not complete any additional info on this page. Go to section entitled: Waiver of Documentation of Consent/alteration of HIPAA Authorization.**

**IF YES, insert ALL of the following statements into the Comment Field of the Event.**

* This protocol has been granted a waiver of HIPAA authorization under 45CFR 164.512(i)(2) for the work being done by the unaffiliated investigator.
  + The following HIPAA identifiers will be shared with the unaffiliated investigator:
  + The PHI, deemed to be the minimum necessary to share with the unaffiliated investigator includes
  + Study team must track disclosures to the Unaffiliated Investigator in EPIC.

**On Regulatory Page mark the following:** HIPAA- Identifiable-External Disclosure- Tracking Required (no consent)