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

**2018 Common Rule: New Full Board Protocols**

**PI Name:** **UVA Study Tracking or** **IRB-HSR #**

**Training Current? Yes No If no, who?      Committee Member Conflict? No Yes**

*NOTE: CIRTification training allowed for Community Engaged Research*

**# of Subjects: at UVA       Age of Subjects        Single site Multi-site  International  Collaborative Site(s)**

**If multi-site/investigator-initiated the following are submitted: NA: Sponsors Protocol:  Yes  No/ SOM CTO Review  Yes  No**

**Outside Sponsor**  **NA Yes If yes: Sponsor** **Update to Current Templates? No Yes If yes: complete page 9.**

**If study involves identifiable health information, is at least one member of study personnel employed by UVA HIPAA Covered Entity?  Yes  No** *At UVA this 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 Laboratory.*

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

**Review Checklists:  NA**

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

* *If viable neonates are included, “Children” must also be checked above with reviewer completing both checklists.*

*\*\* If conducting pre-review and need additional guidance, please refer to Appendix B\*\**

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| **Q#** | **Note** | **Q#** | **Note** | **Q#** | **Note** |
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| **IND Exempt (drug/biologic)?** | NA\* | Yes | No | *If No, IND#* *NAME:*  *Is FDA Letter granting IND/IDE# or exemption on file?* NAYes No |
| **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.*  *Is FDA Letter granting IND/IDE# or exemption on file?* NAYes No |
| **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 #  *If yes, is FDA Letter granting exemption on file?* NAYes No |
| **RUO Device** | NA\* | Yes | No |  |
| **IVD**  **See** [**IVD Learning Shot**](https://hrpp.irb.virginia.edu/learningshots/Full-Board-In-Vitro-Diagnostic-Devices/presentation_html5.html) | NA | Yes | No | *If yes and the IVD meets any of the following criteria, send to SOM CTO for review:*  IVD not approved by the FDA  IVD is a companion device that is not covered by an IND  IVD is a laboratory developed test that will be used on non-UVA subjects |
| *\*Check NA if the study does not involve the evaluation of a device or does not include the evaluation of a drug, biologic or other products such as isotopes or supplements.* See [FDA Regulated Studies](https://research.virginia.edu/sites/vpr/files/2019-08/fda_regulated_studies.docx) for additional info | | | | |

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| N/A | **PENDING Protocol** | Version Date: |
| N/A | **PENDING IRB-HSR Application** | Version Date: |
| N/A | **Data Security Plan** | Version Date: |
| N/A | **INVESTIGATOR BROCHURE** | Version Date: |
| N/A | **PENDING Adult Consent:** | Version Date: |
| N/A | **PENDING Parental Permission** | Version Date:   1  2 |
| N/A | **PENDING Adult/Parental Permission** | Version Date:   1  2 |
| N/A | **PENDING Assent:** *Verbal* No Yes | Version Date: |
| N/A | **PENDING Age of Majority Consent** | Version Date: |
| N/A | **PENDING English/Non-English short form** | Version Date: |
| N/A | **PENDING Translated Consent** | Version Date: **(**insert language**)** |
| N/A | **PENDING English Version of Translated Consent** | Version Date: |
| **N/A** | **PENDING: Other-Specify** | Version Date: |

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| **ADDITIONAL APPROVALS/REVIEWS**  NONE  ***If any of the approval items below are applicable- they should be checked below and on the regulatory page of IRB Online.*** | |
| Cancer Center Protocol Review Committee **(PRC)** | NA  PRC Exempt OR  Pending Approval  On file If ON FILE and study is PI Initiated: Review PRC Letter:   * If high-risk check PRC Audit and PRC Review of Mods Requested in REGULATORY ITEMS. * If PRC Exempt, Check PRC Exempt in REGULATORY ITEMS. |
| **HIRE** Review | NA  Pending Approval  On file.  If “On file” is checked, will Template D wording for a radiation dose of >50mSv/year be used? Yes No  *If YES, add the following wording into the receipt event:*  This protocol will deliver a radiation dose >50 mSv/year. The radiology representative on the IRB must review this protocol to determine a risk-benefit analysis. |
| Institutional Biosafety Committee **(IBC) IBC # only** | NA  Pending IBC #  On file |
| Institutional Biosafety Committee approval for **(IBC)** use of recombinant DNA (Gene Transfer) , biological vectors or infectious agents | NA  Pending Approval  On file |
| **RDRC** | NA  Pending Approval  On file |
| **Gadolinium Use for Research** ( MR Physicist approval of justification) | NA  Pending Approval  On file |
| SOM CTO-**PI of Multi-site** | NA  Pending Approval  On file |
| SOM CTO **Need for IND/IDE- SR vs NSR status**  *(IRB-HSR may determine IDE Exempt status without review*  *by SOM CTO )* | NA  Pending Review  On file |
| SOM CTO **IND/IDE held by Outside PI** | NA  Pending Approval  On file |
| SOM CTO **UVA PI of IND/IDE** | NA  Pending Approval  On file |
| SOM CTO-**Outside academic investigator serving as Sponsor** (overarching sponsor protocol requires review) | NA  Pending Approval  On file |
| SOM CTO-**IVD** | NA  Pending Approval  On file |
| **New Medical Device Form** | NA  Pending Application  On file |
| **Laser:** Laser Safety Officer Approval | NA  Pending Approval  On file |
| **Information Security (InfoSec)** | NA  Pending Approval  On file |
| **Investigational Drug Services (IDS) Email Notification** | NA  Pending Approval  On file |
| **IDS Waiver Application (signed)** | NA  Pending Approval  On file |
| **ESCRO committee:** viable embryos/embryonic stem cells | NA  Pending Approval  On file |
| **Export Control- Sanctioned Countries** | NA  Pending Approval  On file |
| **SOM/Market Share Study?**  If PI is in SOM and FDA approval section-3 or more questions answered NO-refer study | NA  Referred to David Driscoll *No response needed*  *For additional info- see Admin FAQ/ Legal/Market Share Study* |
| **Use of Student Data**: Director of applicable office if PI is not director of office from which student regulated data will be obtained | NA  Pending Approval  On file |
| **Use of Student Data**:  IRB-SBS review if student regulated data will be obtained | NA  Pending Approval  On file |
| **PI is an RN from the Professional Nursing Staff Organization** –**Nursing Research Department** | Yes  No If Yes, an IRB member who is an RN employed by the health system must vote on the protocol. |
| **PI is an Emeritus Professor/ Retired Faculty** | Yes  No  If Yes, is a copy of their non-expired departmental appointment letter to conduct research on file?( A clinical appointment is not sufficient)  Yes  No |
| **Outside IRB approval/Institutional Letter of Approval**  Data or specimens coming to UVA  \* see below for Collaborative Site Analysis Studies | NA  Pending Approval  On file |
| **Collaborative Site Analysis Studies:**  If data/ specimens are being sent to UVA does the study team state in the DSMP section for Collaborative Site Analysis studies that they will receive a copy of the sending site’s IRB approval and an MTA will be in place prior to UVA receiving the data/specimens? | NA  Yes  No  IF YES, the IRB does not require a copy of the outside IRB approval to approve the study. |
| **Certificate of Confidentiality Approval** | NA  Yes  No  If study is not funded by Federal Government and C of C will be required by IRB-HSR, notify study team to submit application ASAP. C of C approval will be required prior to study being opened to enrollment.  *Only studies with a GRANT from the FDA are funded by the Federal Government.*  *Studies funded by Department of Justice have a different process*.  For additional information see <https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm> |
| Does the study involve **Community Based Research?** | Yes  No If Yes, an IRB member or consultant with experience with community based research must review the study. |
| **Scientific Review by Department /Committee** | NA  Yes  No Name of Review Committee: |
| **Genomic Data study funded by NIH?**  *Waiver of consent not allowed if data/specimens collected after 1/25/15* | Yes  No |
| **Study does not have an IND/IDE# and could be considered minimal risk** | Yes  No |
| **Gene Transfer Study:**  Are IBC# and IBC approval on file?  (IBC will notify SOM Dean if ad hoc scientific review committee is required & will not provide IBC approval without it.) | Yes  No |
| **Research conducted outside of Virginia and enrolling subjects less than 21 years of age or subjects who have impaired decision-making capacity.** | Yes  No  *If Yes, is documentation on file from General Counsels’ office regarding implications of applicable state statutes?*  Yes  No |
| **Does the study involve mandatory specimen banking?** | Yes  No If yes, do you confirm the study has no potential for therapeutic benefit?  If NO, is the future research limited to a similar disease process?  If YES- insert the following statement into Receipt Comment:  The IRB to determine if mandatory banking is acceptable. |
| **Does the study involve deception and/or incomplete disclosure?** | Yes  No  *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 |
| **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  No  *If Yes, an Age of Majority Consent Addendum and Age of Majority Cover Letter are required.*  *If study team is requesting a waiver to NOT obtain an Age of Majority consent for subjects who turn 18 while in the study, check # 11 under Waiver of Consent on Regulatory page in IRB Online* |
| **UVA Medical Students as Subjects- GRIME**  If study will enroll UVA Medical Students, GRIME approval is required | NA  Pending Approval  On file |
| **UVA Medical Residents or Fellow as Subjects- GMEC**  If this study will enroll UVA medical residents or fellow GMEC approval is required | NA  Pending Approval  On file |
| **Department of Justice**  Is the study funded by the Department of Justice? | Yes  No If YES, follow 28CFR46 and submit Privacy Certificate (See HRPP SOP)(see HRPP SOP) |
| **Transfer of IRB of Record from non UVA IRB to the IRB-HSR for an Active Study** | Yes  No If YES – Complete page:  1 . Verify new templates created via Protocol Builder and application uses Option A or B for DSMP  2. Changes to the following page on this form: *Make in IRB Online When Approved by IRB*: *Update to Current Templates/Transition of sIRB to IRB-HSR for an Active Study*  *3. Update Approval/Expiration dates on Main page in IRB Online*  Verify if:  --any version dates in IRB Online need to be de-activated.  --need to upload applicable new documents to IRB Pro (e.g. protocol, consents, investigator brochures, questionnaires)  --a consent addendum is needed to notify currently enrolled subjects of new contact info.  --updates to sponsorship are needed |
| **COVID 19 Treatment / Vaccine Study** | Yes  No If YES, verify the language regarding the PREP act is in the consent (What if you are hurt section) |

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| **REGULATORY ITEMS**  NONE  ***If any of the items below are applicable- they should be checked below and the on regulatory page of IRB Online.*** |
| Approved Drug/ Device/Biologic (Research On) |
| Assent Required-Verbal |
| Assent Required-Written |
| Certificate of Confidentiality without expiration date  *Check this box if study is funded by Federal Government and collects identifiable information OR has an IND/IDE*  *OR if CofC approved after Jan 12, 2021.* |
| Consent Observation |
| Data to FDA |
| Device: Unapproved USE only; no evaluation |
| Financial Conflict of Interest |
| FDA Regulated *See* [*FDA Regulated Studies*](https://research.virginia.edu/sites/vpr/files/2019-08/fda_regulated_studies.docx) *or additional guidance* |
| Gadolinium Use NAME:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Gene Transfer Study |
| HDE |
| HIPAA- De-identified and / or no health information,(no consent) |
| HIPAA- Identifiable-External Disclosure-Tracking Required ( no consent)  Add Tracking Instructions to Assurance Form  *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)  Add Tracking Instructions to Assurance Form  *Tracking instructions found at U/ IRB/IRBHSR/Administrative FAQ’s /HIPAA/ HIPAA TRACKING INSTRUCTIONS* |
| HIPAA-Identifiable-Internal Use-No Tracking Required( no consent) |
| IND Exempt (Drug/Biologic) |
| IND Exempt (Non-Drug/Biologic) |
| Investigational Device; Evaluation (if checked , check, Exempt, NSR or SR below) |
| Investigational Device: Exempt |
| Investigational Device- NSR |
| Investigational Device-SR *Add IDE# and information to IND/IDE page of IRB online if available.* |
| Investigational Drug or Biologic *Add IND # and information to IND/IDE page of IRB online if available.* |
| PI of Multi-site Study |
| PRC Audit (see AG 5-12) |
| PRC Review of Mod’s Required |
| PRC Exempt (see AG 5-20) |
| Research Use only Device |
| Screening Log (If LDS- complete DUA section on Regulatory Page) |
| Surrogate Consent; Use of Legally Authorized Representative (LAR) |
| Specimen Banking at UVA |
| Specimen Banking outside of UVA |
| Tracking for HIPAA |
| UVA PI of IND/IDE |
| Unaffiliated Investigator Agreement(s) |
| Ward of State Advocate |

**REGULATORY PAGE- WAIVER CRITERIA**

**IDENTIFYING**

**1.** Identifying- Waiver of Consent

*Recruitment 1a, b or c is checked. If the study is 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.

*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.*

Reviewer Comments:

**CONTACTING**

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

*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.

*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.

Reviewer Comments:

**3.** Contacting by Health Care Provider- Waiver of Consent

*Recruitment 2 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 contact potential subjects by direct contact by a person who is their health care provider via INSERT APPLICABLE REG.

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.*

Reviewer Comments:

**ENROLLING**

**4.** Waiver of Consent-Screening Log

* *Excludes a waiver for identifying /contacting.*
* *See Waiver of Consent section (page 22) for additional guidance and info on what to enter in IRB Online.*
* *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 use a screening log 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.*

**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.

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

* *Excludes a waiver for identifying /contacting/screening.*
* *See Waiver of Consent section (page 22) for additional guidance and info on what to enter in IRB Online.*
* *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.*
* *Waiver of consent NOT ALLOWED for research involving 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.*

This protocol has been granted a waiver of consent under 45CFR46.116 for the main study.

***Add additional regulations from admin form as applicable-e.g. DoD, FDA.***

***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. 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.

**6.** Waiver of Documentation of Consent- Pre-Screening Question

*For additional guidance: see Waiver of Documentation of Consent section (page 23).*

**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.*

**7.** Waiver of Documentation of Consent- Minimal Risk Pre-Screening Procedures

*For additional guidance see Waiver of Documentation of Consent section (page 23) .Per the FDA Information Sheet on Screening Test Prior to Study Enrollment this includes asking subjects to consent to a drug “wash out” period.*

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).

**8.** Waiver of Documentation of Consent/HIPAA Authorization-Questionnaires

*For additional guidance see Waiver of Documentation of Consent section (page 23) .*

This protocol has been granted a waiver of documentation of consent under 45CFR46.117(c).  ***If funded by DOD add*** and 32CFR219.117(c). ***PICK ONE:*** Identifiable health information will not be collected in this study**. OR *if includes identifiable health information add*** and 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 criteria from Admin Review Form.***

***Add additional regulations as applicable-e.g. FDA.***

**9.** Waiver of Documentation of Consent/HIPAA Authorization-Main Study

*For additional guidance see Waiver of Documentation of Consent section ( page 23).*

This protocol has been granted a waiver of documentation of consent under 45CFR46.117(c).

***If funded by DOD add*** and 32CFR219.117(c).

***PICK ONE:*** Identifiable health information will not be collected in this study**. OR *if includes identifiable health information add*** and an 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 criteria from Admin Review Form***

***Add additional regulations as applicable-e.g. FDA.***

**10.** Written Consent

*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.*

Written consent will be obtained for this study.

**11.** Waiver of Consent: Age of Majority Consent

This protocol has been granted a waiver of consent under 45CFR46.116  ***If funded by DOD add*** and 32CFR219.117(c).ADD ADDITIONAL REGULATIONS FROM ADMIN FORM AS APPLICABLE-E.G., 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.

Check this option if study team answered YES to the following question in Protocol Builder

*Does the study meet all of the following criteria?*

* *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.*

**Administrative Staff Completing Form at Pre-review:       Date**

**\*\* See last page of this document for additional guidance on receipt of Electronic Document Final Copies\***

**Enter into the Receipt Event Comment Field using the template below.**

N=\_\_ Ages ( )

***If an update to current templates***, This submission is for review of an update to current templates of the protocol and consent(s).

The purpose of this study is to ….

***If applicable,*** This study involves emergency research and an exception from informed consent (EFIC).

***If applicable,*** The IRB-HSR may serve as the single IRB of record for non- UVA sites. Overall N= INSERT #. ***If applicable*** include name of Data Coordinating Center.

**If applicable**, With future modifications, the IRB-HSR may become the single IRB of Record for non UVA sites.

The sponsor of the study is ***OR***  There is no outside sponsor for this study.

***If applicable,*** The following deviations exist between the Protocol and how the study will be conducted at UVA:  ***List differences***

***If applicable,*** The study is being sponsored by Grant #....

***If applicable,*** This study has been reviewed and approved by the PRC ***ENTER #***

***If applicable,*** The New Medical Device application is on file for...

***If applicable,*** Investigational Drug Services (IDS) email notification on file

***If applicable,*** MR Physicist approval on file for use of gadolinium

***If applicable,*** This is DOD related research.

***If the study is NOT regulated by the FDA 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 SOMCTO 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 applicable,*** This protocol is being conducted under IND#/IDE# ***ENTER #/Enter Drug/ Device Name.*** FDA letter granting IND#/IDE# is on file.

***If applicable,*** This protocol has been granted an IND/IDE exemption from the FDA. FDA letter on file.

***If applicable,*** The device (enter device name) has received FDA 510 K Clearance; FDA letter is on file.

***If applicable,*** The opinion of the SOM CTO is that the protocol is ***choose one option from below.*** The board needs to determine if the protocol is exempt from FDA drug regulations.

* 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.

***If applicable,*** The opinion of the SOM CTO is that the protocol is ***choose one*** exempt from an IDE/ not exempt from an IDE and non-significant risk/ not exempt from an IDE and significant risk. The board needs to determine if the protocol is exempt from FDA device regulations. If not exempt determine if SR or NSR.

***If applicable,*** The IRB is to determine if the study is minimal risk. If so determined, the study does not fall under expedited criteria # 2-8, therefore if study determined to be minimal risk, continuation reviews will be reviewed by an expedited review process per Expedited Category # 9.

***If applicable,*** The IRB is to determine if the study is minimal risk. If so determined, the study falls under expedited category(s) #       and per the 2018 Common Rule, continuation reviews are not required.

***If applicable,*** ***If RUO device being used but will not diagnose or treat insert:*** The IRB needs to determine if this study is minimal risk.

***If applicable,*** ***If RUO device being used AND WILL diagnose or treat insert:*** The IRB needs to determine if the Research Use Only (RUO) device (INSERT NAME) being used to diagnose or treat the subjects in this protocol is exempt from IDE regulations. If not exempt, the IRB needs to determine if the device is SR or NSR.

***If applicable, (FDA regulated or not funded by Federal Government)*** As this study is federally funded, the study is automatically covered by a Certificate of Confidentiality.

***If applicable, (FDA regulated or not funded by Federal Government)*** An application for a Certificate of Confidentiality is on file ***OR*** is needed.

***If applicable,*** Protocol includes specimen banking ***pick one:*** at UVA/with sponsor.

***If applicable,*** The IRB to determine if mandatory banking is acceptable.

No populations requiring additional protections are being recruited ***OR*** Populations requiring additional protections to be recruited include:

***If applicable,*** Prisoners are anticipated to enroll. IRB members must review additional protections required. ***If study is funded by DHHS add:*** The board needs to determine if a letter to DHHS secretary is required.  *NOTE TO STAFF: Arrange for Prisoner Representative to be “present” at meeting. Review HRPP SOP Section 12.6 regarding additional requirements if the research will be conducted WITHIN the Bureau of Prisons.*

***If applicable,*** The board needs to determine the # of parent signatures and if assent is required (written or verbal).

***If minors and multiple arms add:*** The board needs to determine the approval criteria for each arm of the study.

***If applicable,*** The board needs to determine if use of a LAR is appropriate for this study.

***If applicable,*** Site is requesting the use of a ***insert name of language*** short form

***If applicable,*** This study will be monitored by a DSMB. OR This study will not be monitored by a DSMB.

***If applicable****,* SOM CTO David Driscoll notified OR Dave Hudson notified (if study is not from SOM) for additional review for use of FDA approved product.

***If applicable****,* Protocol involves a Screening Logwhich: contains only de-identified data **OR** requires a DUA for releasing a Limited Data Set **OR** requires tracking for releasing Identifiable health information.

***If applicable:*** The study team requests waiver of consent for the use of deception.

**If applicable:** The study team requests waiver of consent/waiver of HIPAA authorization for (INSERT APPLICALBE INFORMATION: e.g. entire study/specimens collected in the past/clinical data/specimens collected from minors under parental permission that will continue to be used after the minor reaches the age of majority. )

No compensation **OR** Compensation via Oracle OR Compensation via alternative route, tax information to be collected. **OR** Compensation via alternative route and tax information will not be collected.

***If applicable,*** On file with submission: [e.g. protocol: *version date*: Investigators Brochure *Insert drug name and version date*) survey, IND safety reports…]

|  |  |  |
| --- | --- | --- |
| **Changes to Make in IRB Online When Approved by IRB: Update to Current Templates/Transition of sIRB to IRB-HSR for an Active Study** | | |
|  |  | |
| **NEW VERSION DATES:** | | |
| Protocol:  IRB /CIRB Application:  Consent(s):  Other, (specify):  Other, (specify): | Investigator’s Brochure:  Consent addendum:  Assent:  English/Spanish Short Forms: | |
| **MAIN PAGE:** | | |
| Title changed?  Revised Sponsor protocol #:  Change in protocol status? (If yes, enter new status):  *Re-opening not allowed if IRB protocol 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 and either in FU or data analysis .*  REFER TO AG 3-33 FOR ADDITIONAL INFORMATION | | # of UVA subjects changed to:  IRB protocol retired?  *If checked write “IRB protocol retired on [date of modification approval]” in comment section of main page*. *Deactivate IRB protocol when approval is processed.*  Other: |
| **REGULATORY PAGE:** | | |
| Specify any updates that need to be made on this page: | | |
| **IND/IDE PAGE:** | | |
| Specify any new IND/IDE information: | | |
| **FUNDING PAGE:** | | |
| Change in sponsor:  Change or addition of grant #: | Compensation change or addition: | |
| **PEOPLE PAGE:** | | |
| Add the following individual(s) to the following position(s): | Delete the following individual(s) from the following position(s): | |
| **ADVERTS PAGE:**  Specify any updates that need to be made on this page: | | |
| **Add the following to comment field of event approval**:  Modification: Protocol and Consent updated to current templates. | | |
| **REVIEWER NOTES:** | | |

**Full Board Meeting Day: NEW PROTOCOL Meeting Date:** \_\_\_     \_\_\_\_\_\_\_\_\_\_\_

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

**Training Current?**  Yes  No If no, who?      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Review Checklists:**  NA  Children  Impaired Decision Making Capacity  Pregnant Females/Fetuses Neonates  Prisoners Students/Employees

SEE PAGE 12/13 if any item above checked

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Applicable? Board Decisions at time of meeting.** | | | | | |
| **Yes** | **No** | IND exempt?  *Answer YES if investigating safety & efficacy of an approved drug/biologic . SOM CTO opinion?* | Yes | No | If no- Is IND# on file? YesNo  If IND exempt check FDA Regulated on Reg page  If study has IND# enter FDA Regulated and Data to FDA on Reg Page. |
| **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  If IDE exempt check FDA Regulated on Reg page  If study has IDE# enter FDA Regulated and Data to FDA on Reg Page. |
| **Yes** | **No** | Children- # of parent signatures  *Current consent/assent has one two signature lines* | One | Two | *Complete page 12* |
| **Yes** | **No** | Children- Assent required?  *Submission includes request for*  *No Assent,*  *Written Assent  Verbal Assent* | Yes | No | If yes:  Written  Verbal |
| **Yes** | **No** | Minors enrolled under parental permission & there 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 | *Answer should be YES ( age of majority consent submitted.* |
| **Yes** | **No** | Minors enrolled under parental permission & there will NOT be continued interaction with minors in the study after they turn 18 does the study team wish to continue to use data/specimens after subject reaches Age of Majority under Waiver of Consent? | Yes | No | *If YES 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** | Pregnant Women, Fetuses and or Neonates to be enrolled  Does the research meet the review criteria per subpart B | Yes | No |  |
| **Yes** | **No** | Use of Surrogate/LAR : is there therapeutic benefit to subjects? | Yes | No | If no- is this no more than a slight increase over Minimal Risk?  Yes  No |
| **Yes** | **No** | Study does not have an IND/IDE# and the IRB determined study is minimal risk (MR). | Yes | No | If yes, see instructions under *Additional Pages*  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   *Required if study includes deception.*   * 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? :  PROVIDE JUSTIFICATION ON NEXT PAGE |
| **Yes** | **No** | Gene Transfer Study  IS IBC# and IBC Approval on file | Yes | No | Must be YES  Send final documents with all approvals to VPR office. |
| **Yes** | **No** | Mandatory Banking approved? | Yes | No | If yes, add reason for approval to Assurance Form |
| **Yes** | **No** | Additional items to verify at meeting***?*** | | | |

**VOTE**:  Approved  Approved with Suggestions  Approvable with Conditions  Deferred  Disapproved

***EFIC studies must be deferred until initial report of community consultation is reviewed by the full IRB.***

***If Approved: approved for  1 year,  Other***

***If mod to update to current templates approve until current expiration date.***

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

**Risk Level:**   Minimal Risk  More than Minimal Risk PROVIDE JUSTIFICATION FOR BOTH ON NEXT PAGE

**Is the PI from the Professional Nursing Staff Organization?**  No  Yes

If YES, did an RN employed by the health system vote on the protocol?  No  Yes If YES list Name

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

**Full Board Meeting Day: NEW PROTOCOL**

**Risk Justification**

Minimal Risk Justification:

Greater than Minimal Risk Justification

Study involves investigational drug, device or biologic

Study involves invasive procedures

Study involves administration of radiation.

Other

**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 Consent-Age of Majority- 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. |  |

**Waiver of Consent- Main Study- FDA Emergency Research Regulations**

|  |  |
| --- | --- |
| The IRB must find that obtaining informed consent is not feasible because: | **PROVIDE STUDY SPECIFIC JUSTIFICATION BELOW** |
| 1. the subjects will not be able to give their informed consent as a result of their medical condition; |  |
| 1. he intervention involved in the research must be administered before consent from the subjects' legally authorized representatives is feasible |  |
| 1. and there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research. |  |

**Full Board Meeting Day: NEW PROTOCOL**

Enrollment of Children, Prisoners or Pregnant Women, Fetuses, Neonates

**One Parent Consent (404)**

|  |
| --- |
| **In order to allow only one parent consent, the IRB must find that the study is minimal risk.**  ***Provide study specific justifications by completing one of the following below:*** |
| This study is minimal risk because:  Single Arm Study    For Arm 1: Describe( e.g. investigational study drug arm):    For Arm 2: Describe (e.g. placebo arm): |

**One Parent Consent (405)**

|  |
| --- |
| **In order to allow only one parent consent, the IRB must find that there is greater than minimal risk but there is a potential for benefit.**  ***Provide study specific justifications by completing one of the following below:*** |
| This study is greater than minimal risk and has a potential for benefit because :  Single Arm Study  Greater than Minimal Risk:  Potential for Benefit:  For Arm 1: Describe:  Greater than Minimal Risk:  Potential for Benefit:  For Arm 2: Describe:  Greater than Minimal Risk:  Potential for Benefit: |

**Two Parent Consent (406)**

|  |
| --- |
| **Studies that involve greater than minimal risk, do not directly benefit the subject but yield knowledge of subject’s condition require 2 parent consent. Provide study specific justifications by completing one of the following below:** |
| This study represents a minor increase over minimal risk because, does not benefit subjects and will provide the following knowledge of the subjects condition:  Single Arm Study  Greater than Minimal Risk:  No Potential for Benefit:  Knowledge to be gained:  For Arm 1: Describe:  Greater than Minimal Risk:  No Potential for Benefit:  Knowledge to be gained:  For Arm 2: Describe:  Greater than Minimal Risk:  No Potential for Benefit:  Knowledge to be gained: |

**Two Parent Consent (407)**

|  |
| --- |
| **Studies that involve greater than minimal risk, do not directly benefit the subject but yield knowledge of subject’s condition require 2 parent consent. Provide study specific justifications below.** |
| This study is otherwise not approvable but offers the following opportunity to alleviate a serious problem:  Single Arm Study  Greater than Minimal Risk:  No Potential for Benefit:  Not otherwise approvable but offers the opportunity to alleviate the following serious problem:  For Arm 1: Describe:  Greater than Minimal Risk:  No Potential for Benefit:  Not otherwise approvable but offers the opportunity to alleviate the following serious problem:  For Arm 2: Describe:  Greater than Minimal Risk:  No Potential for Benefit:  Not otherwise approvable but offers the opportunity to alleviate the following serious problem:  *TIP\_ Need DHHS approval and review by UVA General Council office* |

**Prisoners**

|  |  |
| --- | --- |
| **In order to allow enrollment of Prisoners certain criteria must be met.** | **PROVIDE STUDY SPECIFIC JUSTIFICATION BELOW** |
| This study meets the criteria for approval under one of the criteria for research enrolling prisoners because: |  |
| This study meets the criteria for approval criteria for epidemiologic studies enrolling prisoners because:  NA |  |

**Pregnant Women, Fetuses**

|  |  |
| --- | --- |
| **In order to allow enrollment of Pregnant Women/ Fetuses certain criteria must be met.** | **Comments** |
| *Review Populations checklist for Pregnant Women/ Fetuses to verify all applicable justifications have been documented.* |  |

**Neonates**

|  |  |
| --- | --- |
| **In order to allow enrollment of Neonates certain criteria must be met.** | **Comments** |
| *Review Populations checklist for Neonates to verify all applicable justifications have been documented.* |  |

|  |
| --- |
| **ADDITIONAL PAGES** |

* **Did this submission include an update to current Protocol Builder templates?**  Yes  No

*If yes, see page 9 for updates to make to IRB Online*

* **Does the protocol require the approval of any other UVA committee/office?**  Yes  No

*If yes, add page 15: Other Approvals*

* **Is this protocol funded by an external grant?**  Yes  No

*If yes, add page 15: Grant*

* **Does the study include Populations requiring additional protections/use of LAR with a written consent?** Yes No

*If yes, add page 16/17: Population requiring additional protections/Use of LAR*

* **Did the IRB review the protocol to determine if it meets the minimal risk criteria?** Yes No

*If yes, add page 18:*

* **Does the submission include a method to recruit subjects (letter, phone script, website) ?**  Yes  No

*If yes, add page 18: Recruitment (If being handled separately, answer NO)*

* **Does this study involve banking at UVA of specimen, or data, including name/contact info of subjects**

**for future research?** Answer NO if this is a database or if specimens are only being kept after the study for a specified

verification process and then destroyed  Yes  No

*If yes, add page 18: Banking*

* **Does the study include sharing data/ specimens outside of the UVA HIPAA covered entity** Yes No

**without the written consent of the subject***?*

*Answer this question No if sharing data with any of the following areas as agreements are already in place to share PHI with them. No tracking required.*

* *VP Office of Research*
* *Nutrition Services (Morrison’s)*
* *UVA Center for Survey Research*

*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*

* **Is this study being approved but not being opened to enrollment?** Yes No

*If yes, add page 18: Closed to Enrollment*

* **Does this study include an Investigational Drug/Biologic or an Approved**

**Drug/Biologic being used in an unapproved manner?** Yes No

*If yes, add page 19: Investigational Drug/Biologic*

* **Does the study involve the evaluation of a device for safety and efficacy?** Yes No

*If yes, add page 20: Device Evaluation*

* **Does the study involve the USE (and not evaluation) of a device in an unapproved manner**

**or the use of a Research Use Only (RUO) device ?** Yes No

*If yes, add page 22: Device Use*

* **Does the study involve deception?** Yes No

*If yes, add page 22: Waiver of Consent*

* **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 who will receive identifiable health information?** Yes No

*If yes, add page 27: Unaffiliated Investigator, Access to PHI, Waiver of Consent/HIPAA Authorization*

* **Does the study involve Planned Emergency Research and Exception of Informed Consent (EFIC)** Yes No

*If yes, add page 27: EFIC criteria*

* **Does the study involve Waiver of Consent for Age of Majority ?** Yes No

*If yes, add page 25 Waiver of Consent*

|  |
| --- |
| **PROTOCOL STATUS:** |
| Open to Enrollment |
| Approvable with Conditions |

**Administrative Staff Completing Form Following Full Board Review:       Date**

**POST FULL BOARD REVIEW: COMMENTS FOR ASSURANCE FORM:**

|  |  |  |
| --- | --- | --- |
| **OTHER APPROVALS** | | **If required- add the following to the approval comment field** |
|  | HIRE | HIRE Committee approval on file. |
|  | RDRC | RDRC approval on file |
|  | MR Physicist | MR Physicist approval on file for justification for use of gadolinium. |
|  | SOM-CTO  PI held IND or IDE | SOM CTO approval on file for PI held ***PICK ONE*** IND /IDE. |
|  | SOM-CTO  PI of Multi-site Trial | SOM CTO approval on file for PI of multisite trial. |
|  | SOM-CTO  Review regarding SR/NSR status | 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 regarding need for IND | SOM CTO determined an IND is ***PICK ONE*** required/ not required. |
|  | SOM-CTO  Review regarding IND/IDE held by outside PI | *For studies involving investigational device enter:*  SOM CTO review on file regarding need for an IDE. Their opinion is (INSERT). Full IRB to determine if device is SR or NSR. If SR, an IDE will be required.  *For studies involving an investigational drug enter:*  SOM CTO determined an IND is ***PICK ONE*** required/ not required. |
|  | SOM CTO-Outside academic investigator serving as Sponsor | SOM CTO review of sponsors’ protocol on file as outside academic investigator is serving as sponsor. |
|  | PRC | PRC approval on file |
|  | IBC# | IBC# (INSERT NUMBER) on file. |
|  | IDS | IDS email notification on file |
|  | Scientific Review Committee | Scientific Review Committee approval on file. |
|  | InfoSec | Information Security approval on file. |
|  | GRIME | *GRIME approval on file for enrolling UVA medical students as subjects.* |
|  | GMEC | *GMEC approval on file for enrolling UVA medical residents or fellows as subjects.* |
|  | Laser | *Laser Safety Officer approval on file.* |
|  | Export Control | *Export Control Office approval on file* |

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| **Grant** |
| *For grant held by a NON UVA faculty member with funding to UVA via sub contract add the language below into the assurance form : Add the following statement to the comment field on the main page*: UVA funding for study coming via sub-contract from (INSERT NAME OF INSTITUTION) which holds the grant with (INSERT NAME OF SOURCE OF FUNDING) |

|  |  |
| --- | --- |
| **POPULATIONS REQUIRING ADDITIONAL PROJECTIONS:**  *If yes, complete appropriate section(s) and add relevant language to assurance form and enter criteria in IRB Online* | |
| **Children?**  Yes No | * *Check NO to 21 CFR references below if protocol does not determine safety and/or efficacy of a drug/ device or biologic.* * *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.*   **Children are approved to enroll in this protocol per:**  45CFR46.**404**/Yes No 21CFR50.51  *Specify arm if applicable:*  45CFR46.**405**/Yes No 21CFR50.52 *Specify arm if applicable:*  45CFR46.**406**/Yes No 21CFR50.53 *Specify arm if applicable:*  45CFR46.**407**/Yes No 21CFR50.54 *Specify arm if applicable:*  **This protocol requires the signature of :**  **one** parent per 45CFR46.408(b)/Yes No 21CFR50.55/(e)(1)  **both** parents per 45CFR46.408(b)/ Yes No 21CFR50.55/(e)(2)  **no** parent per 45CFR46.408(c)/Yes No 21CFR50.55/(e)  *Staff: Verify consent/ assent forms have the correct # of signature lines and verify correct # of signature lines are noted on Regulatory page in IRB Online*  **Is Assent Required?** Yes No  **If yes, add the following statement:**  This protocol requires the (PICK ONE:verbal/written) assent of the child per 45CFR46.408(a)/  Yes No 21CFR50.55  **If no, add the following statement:**  No assent required per 45CFR46.408(a)/Yes No 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 and unable to provide assent.  **Also- if no , add the following applicable statements to the comment field on the main page of the protocol in IRB Online**  No assent required- therapeutic-Tx not available outside of protocol  No assent required- Children not capable of giving assent  No assent form required- no subjects age 7 to <15  No assent form required- obtaining verbal assent.  **If study approved under 406 or 407choose one of the following to add to approval comment field:**  Children who are Wards of the State have been excluded from this protocol.  *Staff: Verify Wards of State are listed as an exclusion criteria in the protocol.*  Children who are Wards of the State will be included in this protocol per 45CFR46.409/21CFR50.56. Study team will contact the IRB and the UVA advocate for children who are wards of the state (INSERT NAME), if a potential subject is a ward of state or if an enrolled subject becomes a ward of the state. |
| **Pregnant Women or Fetuses?**  Yes No | ***Add:*** Enrollment of pregnant women/ fetuses approved under 45CFR46.204  ***Note to staff- there is no FDA equivalent for this regulation***  NOTE:45CFR46. Subpart B: If DoD regulated may replace the phrase “biomedical knowledge with generalizable knowledge. |
| **Neonates?**  Yes No | ***Add:*** Enrollment of neonates approved under 45CFR46.205  ***Also complete Children section above.***  ***Note to staff- there is no FDA equivalent for this regulation*** |
| Research involving after delivery, the placenta, the dead fetus or fetal material? Yes  No | ***Add:*** 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*) |

|  |  |
| --- | --- |
| **Prisoners?** Yes No | ***Add:*** Enrollment of prisoners approved under 45CFR46 Subpart C .  ***If DHHS funded add:*** and by 46.306(a)(2) Category (Circle One: i, ii, iii, or iv).  DHHS Secretarial Approval on file.  **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 and voted. 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.  ***Add to main page comment field:***  *PRISONERS MAY BE ENROLLED. PRISONER REP REQUIRED FOR REVIEW OF ALL EVENTS.*  ***Notes to staff:***   * Either the Prisoner Representative or primary reviewer must complete the [Research Involving Prisoners Checklist](http://www.virginia.edu/vpr/irb/HSR_docs/Checklists/vulnerable_pop_prisoner_checklist.doc) . If the study will be done within the Bureau of Prisons, the checklist must be completed by the Prisoner Representative. * Prisoner Representative MUST be **“\*\**present***” at meeting.   ***\*\*Present:*** *The prisoner representative may attend the meeting by phone, video-conference or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting. The prisoner representative must present his / her review either orally or in writing at the convened full board meeting when the research involving prisoners is reviewed.*   * *If study funded by DHHS must obtain approval from DHHS Secretary prior to approval. See AG 3-34 for instructions.* * *If funded by DoD, involvement of prisoners of war is prohibited per DoD Directive 3216.2.* * *If funded by DoD, epidemiologic research is also allowed when:*    + *The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.*   + *The research presents no more than minimal risk*   + *The research presents no more than an inconvenience to the participant.* * *There is no FDA equivalent for this regulation* |
| **Impaired Decision Making Capacity?**  Yes No | ***If applicable add:*** Use of a Legally Authorized Representative approved under 45CFR46.116  ***/if applicable*** 21CFR56.111  ***If use of an LAR is not needed insert the following sentence in the comment field on the main page of the protocol in IRB Online*:** Use of LAR not needed as subjects have only mild cognitive impairment. |
| **Employees/Students?**  Yes No | **If YES, complete the populations checklist for Employees/Students** |

|  |
| --- |
| **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. | |

**RECRUITMENT**

*If you need additional assistance reviewing the recruitment material refer to* [Advertising Approval Checklist](https://research.virginia.edu/sites/vpr/files/2019-08/Advertising_Approval_Checklist.docx)*.*

*Stamp recruitment material with approval date stamp. Enter type of recruitment in IRB Online under Adverts*

|  |  |
| --- | --- |
| *IF STUDY NOT OPENED TO ENROLLMENT : add the following comment to the comment field on the main page of the protocol*  *When study is opened to enrollment send ads to IRB Compliance coordinator in charge of Ads for approval.*  *IF STUDY OPENED TO ENROLLMENT: add the following comment to comment field of assurance form:*  Approved with this protocol is/are the following recruitment material(s):      .*Insert item as checked below:* | |
| **Advertising**  Public Cable Service Announcement  Poster/Flyers/Brochure-  Newspaper/Journal Ads-  Internet (non-UVA)  Television  Radio  Social Networking- Facebook/Twitter  UVA Health System Subject Recruitment Website  Other indirect contact (describe): | **Direct Contact by a UVA researcher**  Recruitment letters/emails  Telephone Contact Script  Other direct contact (describe): |

**BANKING**

*If YES, complete section below and add language to assurance form and note status on regulatory page of IRB Online*

***Add the following statement to IRB Online Protocol Main Page- Comment Field***

This protocol includes banking at UVA of INSERT AS APPLICABLE: specimens, data, names and contact information of subjects for future research.

Verify a database # is included with the closure form before closing this study.

*If specimens will be kept check Specimen Banking at UVA on Regulatory Page*

**CLOSED TO ENROLLMENT?**

*If YES, complete section below*

***Insert the following comment in the Comment Field of the Assurance Form:***

This protocol was found to be approvable with conditions which does not grant authorization to recruit or enroll subjects, or collect subject data. The conditions required by the IRB must be incorporated and approved by the IRB-HSR prior to enrolling subjects. *<INSERT ITEMS REQUIRED*>”

***Note to Staff:***

* *Set the status of the protocol as CLOSED TO ENROLLMENT/ NO SUBJECT ENROLLED*
* *Consent forms will NOT be stamped or given to the study team until the protocol is opened to enrollment.*
* *Add a statement to the Comment Field on the Main Page of the protocol:* Do not open this study to enrollment until the following items are received <*insert name of pending items*>
* *NO ADDITIONAL DOCUMENTATION SUCH AS SEPARATE COVER LETTERS ARE ALLOWED.*

|  |
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| **INVESTIGATIONAL DRUG/BIOLOGIC or APPROVED DRUG/BIOLOGIC USED IN UNAPPROVED MANNER:**  *If yes, complete section below , add language to assurance form and note status on regulatory page of IRB Online* |
| ***Note: If the drug is FDA approved, Protocol Builder will automatically check the box for “Approved Drug, Device or Biologic” if the study team answered YES to the following question in PB:***  *Does this protocol involve research of a drug, device or biologic* ***already approved*** *by the FDA for the indication, dose and route to be used in this protocol?*  *Also check FDA Regulated and Investigational Drug, telling you it is an approved drug which is being investigated.*  **Is the drug/biologic exempt from an IND per 21CFR312.2(b)?** Yes No  **If yes,** *check “IND Exempt” in IRB Online/ Regulatory page and write the following comment on the assurance form:* This study is regulated by the FDA. Drug/biologic (***insert name***) determined to be exempt from IND requirements according to 21CFR312.2(b).  **If no,** *enter the IND# and info into IRB online and write the following comment on the assurance form.*  This study is regulated by the FDA. Drug/biologic (***insert name***) determined to NOT be exempt from IND requirements according to 21CFR312.2(b). IND# required ***OR (enter #)*** on file. |

**Device Evaluation:**

***If yes, complete section below, add language to assurance form and check FDA Regulated and other applicable boxes on the regulatory page of IRB Online.***

**For additional information see the Device Review Decision Tree found at U/IRB/IRBHSR/Administrative FAQ’s/Algorithms/Device Decision Tree.**

**Is the device exempt from 21CFR812.2 (c)(3)?**  Yes  No  *Answer YES if an in-vitro diagnostic device*

**Exempt Criteria**

1. a legally marketed device when used in accordance with its labeling
2. 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

*Additional criteria noted in AG 3-13*

**►IF YES,**

**Check ‘Investigational Device’ and ‘ Investigational Device: Exempt’ in IRB Online/ Regulatory and write the following comment on the assurance form:** This study is regulated by the FDA. The device (***insert name***) determined by the IRB to be exempt from IDE requirements according to 21CFR812.2(c)(3).

***NOTE:*** *The FDA classifies an approved device being used in an approved manner as an ‘Investigational Device’ as it is the device under investigation.*  ***If the device is FDA approved, protocol builder will automatically check the box for “Approved Drug, Device or Biologic” if the study team answered YES to the following question in PB:***

*Does this protocol involve research of a drug, device or biologic* ***already approved*** *by the FDA for the indication, dose and route to be used in this protocol?*

*Therefore, both approved and investigational Device will be checked, telling you it is an approved device which is being investigated.*

***If this is research on an approved device being used in an approved manner write the following comment on the assurance form:***Device has FDA approval and is being used according to FDA labeling.

**►IF NO,**

**NSR**: *If the device is determined by the Full Board to be NSR, check ‘Investigational Device’ and ‘Investigational Device: NSR’ in IRB Online/ Regulatory and enter the following statement in the Assurance Comment Field:* 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).

**SR:** *If the device is determined by the Full Board to be SR check ‘Investigational Device’ and ‘Investigational Device: SR’ in IRB Online/ Regulatory and* *enter the following statement in the Assurance Comment Field*: 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).

**Device Use:**

***If yes, complete section below, add language to assurance form, check FDA Regulated and other applicable boxes on regulatory page of IRB Online.***

**For additional information see the Device Review Decision Tree found at U/IRB/IRBHSR/Administrative FAQ’s/Algorithms/Device Decision Tree.**

**Is the device a “Research Use Only” device?** Yes No

**►IF YES, (is a research use only device)will the results be used to diagnose or treat a subject?** Yes No

**►IF YES, the device falls under FDA regulations- see Device Evaluation page**

**►IF NO (not a research use only device) , does the device have FDA approval for ANY indication?** Yes No

**►IF YES,**

***1. On Regulatory page check****: Device: Unapproved USE only; no evaluation*

***Write the following in the assurance comment field:***

The device (***insert name of device***) being used in this protocol 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. *Verify if the study is FDA Regulated per the* [*FDA Regulated Guidance Document*](https://research.virginia.edu/sites/vpr/files/2019-08/fda_regulated_studies.docx)*. If FDA regulated add the following statement.*

However, as this study involves the use of a device in an unapproved manner, this study is regulated by the FDA.

***2. Did the Full Board determine the study is minimal risk?*** Yes No

►IF YES, *on the regulatory page check Expedited Category # 9 and change “Type” to Expedited.*

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| **WAIVER OF CONSENT*- OPTIONAL (Includes Waiver of Consent for Age of Majority Consent)***  *Regulatory Page- Waiver Criteria- # 4 or 5 checked.*  *If yes, complete section below and add appropriate language to assurance form*  ***On IRB ONLINE/Regulatory page check #4-****Waiver of Consent-Screening Log* ***and/or # 5****- Waiver of Consent- Main Study as noted below and add comment to event.*  *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.* |
| **Does the protocol or part of the protocol meet the criteria below for Waiver of Consent?** Yes No,   1. The research involves no more than minimal risk to the subjects. 2. The research could not practicably be carried out without the waiver or alteration, 3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. 4. The waiver or alternations will not adversely affect the rights and welfare of the subjects. 5. When appropriate, subjects or their legally authorized representative will be provided with additional pertinent information after participation.   **IF YES, *insert the following wording in the comment field of the assurance form.***  **This protocol has been granted a waiver of consent under 45CFR46.116 for**  a screening log ***Check #4-Waiver of Consent-Screening Log***  the main study **Check *#5-Waiver of Consent- Main Study***  **for the continued use of data/specimens collected under parental/guardian permission. Check #11- Waiver of Consent/HIPAA Authorization – Age of Majority**  *other- insert*:  ***Add additional regulations as applicable-e.g. DoD, FDA***  1) **Funded by DoD?**, ***If yes,*** ***add*** and 32CFR219.117(c)  2) ***Involve testing of an in-vitro device*?** ***add*** and "FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using leftover Human Specimens that are Not Individually Identifiable. "  3)  and 21CFR50.23: *(Tip: Includes drugs or devices- emergency use)*  4)  and 21CFR50.24: *(Emergency Research*)  **Protocol involves Deception:**  Yes No, ***(describe deception)*** *- insert*:  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:   1. Research involves the study of public programs (45 CFR 46.116(c)), **OR** 2. 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 biospecimens, the research could not practicably be carried out without using such information or biospecimens 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)  ***If any of the following are checked add:* Also granted waiver of consent under**  1) **Funded by DoD?**, ***If yes,*** ***add*** and 32CFR219.117(c)  2) ***Involve testing of an in-vitro device*?** ***add*** and "FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using leftover Human Specimens that are Not Individually Identifiable. "  3)  and 21CFR50.23: *(Tip: Includes drugs or devices- emergency use )*  4)  and 21CFR50.24: *(Tip* *Includes drugs or devices-* (*see AG: EFIC* ) |

**Does data collected include "health information"?** Yes  No

*FOR SCREENING LOGS: If the screening log itself does not contain health information but it 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 YES, COMPLETE NEXT PAGE –**

*For additional information on these topics please see U/IRB/IRB-HSR/Administrative FAQ's****/*** *Sources for regulations and guidance regarding when waiver of consent and when waiver of HIPAA authorization are required.*

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| **HEALTH INFORMATION- *OPTIONAL***  *IF YES, check all applicable items below (De-identified, Limited Data Set, or Identifiable Data)*  *More than 1 category may apply: example- data being kept at UVA is identifiable, while data going to central registry is a LDS*  *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.*  **De-identified-** *HIPAA not applicable.*   * + *Coded samples used for In-vitro diagnostic device studies MAY be considered de-identified.*   + *See* [*Consent Tips on Waiver of Consent*](https://research.virginia.edu/sites/vpr/files/2020-04/Consent%20Tips.doc) *for additional 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.   *On Regulatory Page mark the following:*  *HIPAA- de-identified and/ or no health information ( no consent)*  **Limited Data Set**  *Note :* For subjects over the age of 89, their date of birth and age may be recorded.  *If data at UVA is a LDS* s*end PI-* [*Data Use Agreement.*](https://research.virginia.edu/sites/vpr/files/2019-08/Data_Use_Agreement_Memo_PI_Instructions.doc) *and add comment to assurance form:* DUA sent to PI  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 get DUA with outside recipient in contract.*  *On Regulatory Page mark the following:*  *HIPAA- Limited Data Set.*  *Under Data Use Agreement section mark the following:*  *Data Use Agreement: Protocol Specific*  *Data Use Agreement Type- Recipient Outside of UVA*  *Add comment to assurance form:*  *HIPAA DUA will be obtained by Grants and Contracts office.*  No Recipient Outside UVA. LDS identifiers will be kept at UVA but not shared outside of UVA.  *On Regulatory Page mark the following:*  *HIPAA- Limited Data Set.*  *Under Data Use Agreement section mark the following:*  *Data Use Agreement: Protocol Specific*  *Data Use Agreement Type- PI*  **Identifiable Data**  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)*  *NOTE: 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*   External *give PI Tracking Instructions*  *On Regulatory Page mark the following:*  *HIPAA- Identifiable-External Disclosure- Tracking Required ( no consent)*  **Was more than one category (de-identified, limited data set, identifiable) above chosen? Yes No,**  *IF YES, (e.g. identifiable at UVA and limited data set sent outside of UVA) add a comment to the comment field on the main page of the protocol in IRB Online and in the Assurance Form comment field describing the situation [eg: “Data at UVA identifiable, data going outside of UVA as a LDS” ”]*  **IF IDENTIFIABLE- SEE THE NEXT PAGE.** |

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| **WAIVER OF HIPAA AUTHORIZATION- *OPTIONAL***  *If yes, complete section below and add appropriate language to assurance form.*  *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 IDENTIFIABLE, does the protocol or part of the protocol 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 Assurance Form.**   * This protocol has been granted a waiver of HIPAA authorization under 45CFR 164.512(i)(2) for   a screening log  the main study  *other- insert*:   * + The following HIPAA identifiers will be collected*.* (      )   + The PHI, deemed to be the minimum necessary for this protocol, includes (***insert protected health information from privacy plan section of protocol***):   + ***If waiver of HIPAA authorization 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 without additional IRB-HSR approval.   + No identifiable health information will be taken outside of the UVA HIPAA covered entity. |

**WAIVER OF DOCUMENTATION OF CONSENT- *OPTIONAL***

*Regulatory Page: Waiver Criteria 6, 7, 8 and or 9 checked.*

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

*On IRB ONLINE/Regulatory page check Waiver of Documentation of Consent/HIPAA Authorization for category as noted below. (e.g. pre-screening questions, minimal risk –pre-screening procedures, questionnaires and or the main study).*

*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.*

**Does this study meet the criteria listed below for Waiver of Documentation of Consent?** Yes No

1. *That the only record linking the subjects and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality OR*
2. *That 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.*
3. *If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.*

**IF YES, add the following items to the comment field of the assurance form:**

Waiver of **Documentation** of Consent granted under 45CFR46.117(c )

Funded by DoD? Yes No  ***If yes, add:*** and 32CFR219.117(c)

Regulated by FDA? Yes No  ***If yes, add:*** and 21CFR56.109(c) (See [FDA Regulated Studies](https://research.virginia.edu/sites/vpr/files/2019-08/fda_regulated_studies.docx) or additional information.

for pre-screening questions- ***Check item # 6****- Waiver of Documentation of Consent- Pre-screening questions*

for minimal risk pre-screening procedures-***Check item # 7-*** *Waiver of Documentation of Consent- Minimal risk Pre-Screening Procedures*

for questionnaires-***Check item # 8****- Waiver of Documentation of Consent/HIPAA Authorization- Questionnaires*

for the main study-***Check item # 9****- Waiver of Documentation of Consent/HIPAA Authorization-Main Study*

**Does data collected include health information for questionnaires or the main study?** Yes  No

***If only pre-screening questions and/or minimal risk pre-screening procedures checked above answer this question NO. These are covered under Health Care Operations.* IF YES, COMPLETE:**

**HEALTH INFORMATION- OPTIONAL**

*Check all applicable items below (De-identified, Limited Data Set, or Identifiable Data)*

*More than one category may apply: example- data being kept at UVA is identifiable, while data going to central registry is a Limited Data set.*

*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.*

**De-identified-** *HIPAA not applicable. No additional documentation required*

* + *Coded samples used for In-vitro diagnostic device studies MAY be considered de-identified.*
  + *See* [*Consent Tips on Waiver of Consent*](https://research.virginia.edu/sites/vpr/files/2020-04/Consent%20Tips.doc) *for additional Information.*

*On Regulatory Page mark the following:*

*HIPAA- de-identified and/ or no health information (no consent)*

**Limited Data Set-** S*end PI-* [*Data Use Agreement.*](https://research.virginia.edu/sites/vpr/files/2019-08/Data_Use_Agreement_Memo_PI_Instructions.doc) ***Add comment to assurance form:*** DUA sent to PI

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 get DUA with outside recipient in contract.*

*On Regulatory Page mark the following:*

*HIPAA- Limited Data Set.*

*Under Data Use Agreement section mark the following:*

*Data Use Agreement: Protocol Specific*

*Data Use Agreement Type- Recipient Outside of UVA*

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.*

*Under Data Use Agreement section mark the following:*

*Data Use Agreement: Protocol Specific*

*Data Use Agreement Type- PI*

**Identifiable Data**

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)*

**Was more than one category (de-identified, limited data set, identifiable) above chosen?  Yes  No,**

*IF YES, (e.g. identifiable at UVA and limited data set sent outside of UVA) add a comment to the comment field on the main page of the protocol in IRB Online and in the Assurance Form comment field describing the situation [e.g: Data at UVA Identifiable, Data going outside of UVA is a LDS”. ]*

**IF IDENTIFIABLE- SEE THE NEXT PAGE.**

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**ALTERATION OF HIPAA AUTHORIZATION FOR VERBAL AUTHORIZATION – *OPTIONAL***

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

*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 YES, does the study qualify, per criteria listed below, for alteration of the HIPAA authorization to allow for verbal/oral authorization?** Yes  No

*A. 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:*

*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 there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and*

*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.*

*B. The research could not practicably be conducted without the waiver or alteration and*

1. *The research could not practicably be conducted without access to and use of the protected health information*

***IF NO, add the following statement to the comment field of the assurance form:***

Study team will obtain a signature from each subject on the HIPAA Authorization Form.

***IF YES, add the following statements to the comment field of the assurance form:***

Alteration of HIPAA Authorization granted under 45CFR164.512(i)(2) to obtain an oral HIPAA authorization.

for:

questionnaires.

the study.

The IRB determined that obtaining written HIPAA authorization would be impracticable because:

***Choose from the following options:***

the study will be conducted over the phone or via email- making obtaining written HIPAA authorization impracticable.

the study will be conducted in a public area with oral consent under DHHS regulations. Requiring a written HIPAA authorization would seriously limit recruitment.

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***

**Unaffiliated Investigator, Access to PHI, Waiver of Consent/HIPAA Authorization**

*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 Assurance Form.**

* 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)

**Planned Emergency Research and Exception from Informed Consent (EFIC) Requirements**

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

Does the study involve planned emergency research with waiver of consent (EFIC)?

Yes No

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

The IRB determined, with concurrence of a licensed physician member or consultant unaffiliated with the investigation, that the requirements for an exception to informed consent process for research in emergency circumstances were met in relation to the protocol(s) (21 CFR 50.24(a),(b)) and approved the waiver of informed consent process requirements at 45 CFR 46.116(a), (b) and 46.408.

*Note- The investigator will be required to summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.*

**IF NO, do not complete any additional information.**

***TIP: If EFIC is approved, a waiver of HIPAA authorization may also be required- See Waiver of consent/ HIPPA authorization section.***

**Appendix A: Recruitment**

If conducting pre-review and need additional guidance, please refer to the [Advertising Approval Checklist](https://research.virginia.edu/sites/vpr/files/2019-08/Advertising_Approval_Checklist.docx)

**Appendix B: Optional**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IRB-HSR COVERSHEET** | **Yes** | **No** | **N/A** | **Comments/Issues** |
| If the IDE/IND is held by a non-UVA investigator (not commercial sponsor), has SOM CTO review letter been obtained and on file? |  |  |  |  |
| If the IDE/IND is held by the UVA investigator is this information in the database and is SOM CTO approval on file? |  |  |  |  |
| If they are getting free drug/devices did they say YES to contract?  *If no-notify PI to consult with SOM Office of Grants and Contracts* |  |  |  |  |
| Are any populations requiring additional protections being recruited?  *If yes, attach applicable checklist to scientific reviewers form* |  |  |  |  |
| Does the title match between the coversheet, IRB Protocol, IRB Application and consent? |  |  |  |  |
| If Grant from DoD or FDA is funding study, is the sponsor of the grant listed under sponsors? |  |  |  |  |
| If there is an outside supply source sending free drug, supplement, device etc. to UVA did they answer yes to the contract question? ( need a non- funded agreement) |  |  |  |  |
| If DoD funded and study involves DoD personnel, data or specimens, do we have approval from DoD IRB/ other federal IRB? |  |  |  |  |
| If location of study is OTHER than UVA, and UVA is going to that location to do research, do we have a letter of permission/outside IRB approval from the outside institution giving permission for UVA to do this research? |  |  |  |  |
| If location of study is something other than UVA, are Unaffiliated Investigator Agreements present for each non-UVA employee that are not covered by site IRB approval? (note PI must be a UVA employee) |  |  |  |  |
| If applicable, is an IRB Authorization Agreement in place for a protocol for which IRB-HSR is the IRB of record for an outside institution? |  |  |  |  |
| Will the study require a DUA or Tracking of disclosures?  *If YES, enter info into IRB Online* |  |  |  |  |
| If any of personnel are non-UVA employees and they are not covered by local site IRB protocol, is there a non- affiliated investigator agreement in place for each of them? Is the non-UVA section of the protocol in place? Is there a contract in place to cover the responsibilities of the non- UVA employees if they will have access to subjects or identifiable data? *( NA for update to current templates unless new non- UVA personnel added)* |  |  |  |  |
| If data collection or work with identifiable data or tissues is done at another institution outside of UVA, IRB/Ethics committee approval from other institution is required and is Outside IRB checked under Regulatory OR if there is no IRB for the outside site- is there documentation on file from the administration of the outside institution noting their knowledge and approval of the work being done?  *( NA for update to current templates)* |  |  |  |  |

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| **IRB-HSR PROTOCOL** | **Yes** | **No** | **N/A** | **Comment/Issues** |
| In FDA Approval section: are 3 or more questions answered NO? If yes, refer protocol to IRB Chair and David Driscoll for review. |  |  |  |  |
| **HYPOTHESIS/OBJECTIVES** | **Yes** | **No** | **N/A** | **Comment** |
| Is the hypothesis clearly stated?  Does it focus on the questions the study will answer? |  |  |  |  |
| **Human Participants** | **Yes** | **No** | **N/A** | **Comment/Issues** |
| If protocol will include children: Under PARTICIPATION OF CHILDREN if neither question 4a or 4b is answered yes are Wards of State listed under exclusion criteria? |  |  |  |  |
| Are subjects who are Wards of State to be enrolled?  If yes, and study requires two parent signatures an Advocate for the Wards is required. (see Scientific Reviewers checklist). |  |  |  |  |
| If requesting use of LAR is there therapeutic benefit to subjects?  If No, is there no more than a minor increase over minimal risk?  If No- use of LAR not approvable |  |  |  |  |
| **Recruitment Procedures** | **Yes** | **No** | **N/A** | **Comment/Issues** |
| If subjects will be contacted is this explained in detail? |  |  |  |  |
| Is the consenting process explained and appropriate? |  |  |  |  |
| If study involves a screening log that includes HIPAA identifiers are processes in place for DUA or Tracking? |  |  |  |  |
| Is a stand-alone HIPAA authorization required? ( see protocol recruitment section) If YES, has it been submitted? |  |  |  |  |
| **Research Design/Methods** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| If randomized, is the method and probability of receiving each treatment described?  If randomized, does information in protocol match the consent? |  |  |  |  |
|  |  |  |  |
| Are the study procedures and study visits clearly outlined and described? |  |  |  |  |
| Are all procedures clearly defined as either research related or completed as part of the subject’s clinical care (regardless of study participation) |  |  |  |  |
| Has justification been provided for use of a placebo? |  |  |  |  |
| **Risk/Benefit Analysis** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Are the potential benefits to the subject (if any) accurate and clearly described? |  |  |  |  |
| Is there an appropriate description of the risk-benefit ratio? |  |  |  |  |

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| **Data and Safety Monitoring Plan** | **Yes** | **No** | **N/A** | **Comment/Issues** |
| Are all the risks (including known incidence/frequency) clearly described (including study procedures, screening). |  |  |  |  |
| Have appropriate statements regarding reproductive risks and birth control been included? |  |  |  |  |
| Have adequate safeguards (safety tests) been adopted to reduce risk exposure as much as possible? |  |  |  |  |
| If study is funded by Department of Defense is a Research Monitor listed?  (required for FB only) *See SOP section 25.11 for additional information* |  |  |  |  |

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| **COSTS** | **Yes** | | **No** | | **N/A** | | **Comment** | |
| Are the financial obligations of the subject, the sponsor and the institution clearly described? |  | |  | |  | |  | |
| Is there a clear description distinguishing between the costs related to research procedures versus clinical care procedures (done regardless of study participation)? |  | |  | |  | |  | |
| **Compensation/ Reimbursement** | | **Yes** | | **No** | **N/A** | **Comment /Issues** | |
| Is the payment amount free of undue influence? | |  | |  |  |  | |
| If payment is not pro-rated- is this coercive? | |  | |  |  |  | |
| If there is no payment, is it okay that there is no payment? | |  | |  |  |  | |
| Is payment information consistent across protocol and consent? | |  | |  |  |  | |
| Is the difference between compensation (payment) versus reimbursement for travel or other expenses clear? | |  | |  |  |  | |
| If compensation will be done via gift card/ petty cash- is justification acceptable? | |  | |  |  |  | |
| If SS# not be obtained- is it appropriate for the study? NOTE: only allowed if total payment per subject /calendar year is <=$50. | |  | |  |  |  | |

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| **BIOMEDICAL**       **NA** | **Yes** | **No** | **N/A** | **Comment** |
| Does the protocol involve an approved drug/ device?  *If yes, is approval verification from FDA provided?* |  |  |  |  |
| **BIBLIOGRAPHY/ REFERENCES** | **Yes** | **No** | **N/A** | **Comment** |
| Was a reference list provided? |  |  |  |  |

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| **Specimen Banking**      **NA**  ***(Specimen banking refers to LONG TERM STORATE for UNSPECIFIED research and does not include specimens that are stored during the study for verification purposes ONLY and then destroyed).*** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Is loss of confidentiality listed as a risk in the DSMP? |  |  |  |  |
| If the data being generated is a direct assay of or direct inference of a hereditary genetic trait, does the DSMP adequately describe any additional risk? |  |  |  |  |
| Under who will be responsible for storing the specimen, are roles or titles used as opposed to individual names? |  |  |  |  |
| If someone outside of UVA will have control over the specimens is the question (Do you plan to ship specimens outside of UVA) answered YES in the Specimens section of the protocol (Section 25) and in the Specimen Banking section. |  |  |  |  |
| If participants can withdraw their specimens or request that they be destroyed, is the appropriate language present in the “Changing your mind later” section of the consent? |  |  |  |  |
| Is this information in this section consistent with the consent? |  |  |  |  |

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| **Waiver of Consent**      **NA** | **Yes** | **No** | **N/A** | **Comment/Issues** |
| If waiver of consent is requested, does the protocol meet the criteria for a Waiver? (see AG 3-7) |  |  |  |  |
| **Waiver of Documentation of Consent**      **NA** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| If waiver of documentation is requested- are the criteria met? ( see AG 3-14) |  |  |  |  |

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| **IRB-HSR CONSENT**      **NA** |  |  |  |  |
| **Agreement between protocol and consent** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Does the # of subjects to be enrolled match between the protocol and the consent form? |  |  |  |  |
| Are procedures outlined in the protocol consistent with information in the consent? |  |  |  |  |
| Is the risk/benefit ratio consistent with the information in the DSMP and the consent? |  |  |  |  |
| **GENERAL INFORMATION** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Is clear, concise, non-technical language used throughout? |  |  |  |  |
| Are appropriate subheadings and sequence used throughout? Note: Make sure any procedures listed in visits called “follow-up” are truly follow-up visits and are not part of study treatment. |  |  |  |  |
| Is the use of person consistent throughout? |  |  |  |  |
| Are all pages numbered sequentially? |  |  |  |  |
| Are any references to future studies, not yet approved by the IRB removed? |  |  |  |  |
| If use of an LAR is requested have they answered “YES” to the question: “Will participants with impaired decision making capacity be allowed to enroll in this study?” |  |  |  |  |
| **Why is this research being done?** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| If necessary, is there some background information given regarding the topic under study (i.e.) what is non-small cell lung cancer? |  |  |  |  |
| Is the purpose of the study accurately and clearly stated? |  |  |  |  |
| Is there an accurate and clear explanation of the reason a particular subject was invited to participate? |  |  |  |  |
| Is the FDA approval status of the drug/device stated? |  |  |  |  |
| **How long will this study take?** | **Yes** | **No** | **N/A** | **Comment/Issues** |
| Is the duration and length of each subject’s participation included? |  |  |  |  |

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| **What will happen…** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Are all procedures described clearly defined as either research related or completed as part of the subject’s clinical care (regardless of study participation)? |  |  |  |  |
| Is lay language used throughout? |  |  |  |  |
| Are procedures listed in chronological order using headings? |  |  |  |  |
| If randomizing, is all information from the template instructions included? |  |  |  |  |
| Are the dose, route, and frequency of drug(s) to be given noted (if applicable)? |  |  |  |  |
| If placebo is used, it the term defined according to template instructions? |  |  |  |  |
| If questionnaires are being used, are they described and is the length of time to complete them indicated? |  |  |  |  |
| If the study contains a follow-up period, is a follow-up heading included w/ a clear description of procedures & time required? |  |  |  |  |
| Is a table included if there are 3 or more visits/study procedures? |  |  |  |  |
| If subjects will be reimbursed, is template wording regarding need for receipts/mileage and money being withheld from stated in the consent form? |  |  |  |  |
| **If we take blood/specimen samples** | **Yes** | **No** | **N/A** | **Comment /Issues t** |
| Is the volume of blood/specimen to be taken clear for each visit? |  |  |  |  |
| Is the total amount of blood/specimen to be taken listed? |  |  |  |  |

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| **Risks** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Are risks bulleted using proper headings (i.e. is it formatted to promote readability for the subject) |  |  |  |  |
| Is frequency of risks noted as likely, less likely, rare, but serious (or similar format). |  |  |  |  |
| If frequency is specified, is it free of percentages and fractions? |  |  |  |  |
| If radiation is being used, are risks of radiation clear and is standard radiation template wording or radiation safety approved language included |  |  |  |  |
| If numerous radiological exams are being used, verify if Radiation Safety has assessed cumulative risk |  |  |  |  |
| Are reproductive risks for men and women adequately described (if necessary)? |  |  |  |  |
| If there are risks from sudden termination of study drug, is this risk clearly stated? |  |  |  |  |
| **Benefits– Could you be helped** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Are any potential benefits accurately and clearly described? If no benefits, it this clearly and accurately stated? |  |  |  |  |
| **Alternative Treatments** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Have alternative treatments been clearly described (if applicable?) |  |  |  |  |
| **Will you be paid?** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| If the study includes reimbursement for travel or other expenses, is it clearly defined? If the subject needs to save receipts, is this specifically addressed? |  |  |  |  |
| Is the difference between compensation (payment) vs reimbursement for travel or other expenses clear? |  |  |  |  |
| If subjects will be paid by gift card/ petty cash- delete statement that State may withhold their payment |  |  |  |  |
| **Cost** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Is it clear who is paying for study drug/device? |  |  |  |  |
| Is it clear what specific procedures are paid for by the sponsor and which charges will be billed to the subject/subject’s insurance? |  |  |  |  |

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| **Withdrawal** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| If this is a device study, has the wording in this section been modified appropriately? |  |  |  |  |
| Are reasons why the subject might be withdrawn from the study by PI or sponsor present in this section? |  |  |  |  |
| Are procedures to provide continued follow-up for withdrawing addressed? |  |  |  |  |

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| **Confidentiality/HIPAA** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Has a Certificate of Confidentiality been requested and/or issued, is application with submission or on file, is it checked under regulatory? |  |  |  |  |
| If protocol includes Certificate of Confidentiality and study not funded by NIH- add to comment field on main page- “ Need C of C approval with continuation (*enter YEAR*) |  |  |  |  |
| If a Waiver of Documentation of Consent is to be granted- does the protocol also meet the criteria for Waiver of HIPAA Authorization under HIPAA regulations?  Both are required if identifiable health information included) |  |  |  |  |
| **Specimen Banking**       **NA** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Is the risk of loss of confidentiality present? |  |  |  |  |
| Are the appropriate signature lines present? |  |  |  |  |
| Have all the appropriate template sections been included and answered? |  |  |  |  |
| **Genetic Research**       **NA** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Is the risk of loss of confidentiality present? |  |  |  |  |
| Are the appropriate signature lines present? |  |  |  |  |
| Have all the appropriate template sections been included and answered? |  |  |  |  |

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| **Signature** | **Yes** | **No** | **N/A** | **Comment /Issues** |
| Are the appropriate signatures lines included based on type of study? |  |  |  |  |
| If there is minimal risk or therapeutic potential for participants, does the consent form contain one parent/guardian signature line? |  |  |  |  |
| Is there is more than minimal risk, but no benefit to the participant, does the consent contain a second parent/guardian signature line? |  |  |  |  |
| LAR Signature: If the signature line for the Attending Physician has been deleted, does the protocol involve therapeutic research or no more than a minor increase over minimal risk? |  |  |  |  |
| The following statements are NOT listed in the consent form:  1. This protocol was reviewed by the IRB. 2. This investigational drug/device has been found to be safe in previous studies. 3. Any part of the project was approved by the office of General Counsel. 4. Subject will be paid for lost wages etc. |  |  |  |  |
| If verbal assent required- is the signature section present for the person obtaining assent? |  |  |  |  |
| If optional procedures are listed, there are Optional check boxes for subjects to indicate whether or not they agree/consent to those optional procedures |  |  |  |  |

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| **Electronic Document Final Copies** | **Yes** | **No** |
| Has the study been downloaded and the IRB-HSR # or UVA Study Tracking number in the header? |  |  |
| Has the receipt new protocol event been assigned a date on the meeting agenda? |  |  |
| Has the pending version date(s) of the IRB protocol and consent been added to the database? |  |  |
| Has the receipt new protocol event and information for the agenda been entered into the database? |  |  |
| Have all appropriate fields in the database been filled in? |  |  |
| Have the appropriate Reviewer Checklists been added to IRB PRO? |  |  |
| Have the items still pending been entered into the protocol receipt event? |  |  |