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

**New Expedited Protocols**

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

**Is the UVA Study Tracking # on Coversheet the same as the # on the Investigator Agreement Signature page? [ ] Yes/NA**

**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**

**[ ]  Database Protocol [ ]  Database Plus Protocol [ ]  Non- Database Protocol**

**If study involves identifiable health information is at least one member of personnel employed by UVA HIPAA Covered Entity or has completed HIPAA training to be a “covered person” as designated by the SOM?**

**[ ]  NA [ ]  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.*

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

**Funded by Grant from DoD or FDA?**  **[ ] No [ ] Yes GIRB #** \_\_\_*List Sponsor in database*

**DoD Regulated Research? [ ]  Yes [ ]  No Department of Justice Regulated Research? [ ]  Yes [ ]  No**

**Advertisement(s) Submitted? [ ]  No [ ]  Yes,** **Located: [ ]  With New Protocol** **[ ] Under Subject Recruitment – To Be Reviewed**

**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\*\**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Q#** | **Note** | **Q#** | **Note** | **Q#** | **Note** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IND Exempt (drug/biologic)?** | [ ] NA\* | [ ] Yes | [ ] No | *If No, send to Full Board review NAME:*      *Is FDA Letter granting exemption on file?* [ ] NA[ ] Yes [ ] NoIf IND Exempt, click FDA Regulated on Reg page  |
| **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 exemption on file?* [ ] NA[ ] Yes [ ] NoIf IND Exempt, click FDA Regulated on Reg page |
| **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*If yes, is FDA Letter granting exemption on file?* [ ] NA[ ] Yes [ ] No*If IDE exempt click FDA Regulated on the Reg Page*  |
| **RUO Device** | [ ] NA\* | [ ] Yes | [ ] No |  |
| **IVD** | [ ] 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/2019-10/Expedited%20Review.doc) for additional info |

|  |
| --- |
| **ADDITIONAL APPROVALS/REVIEWS** [ ]  NONE**If any of the items below are applicable- they should be checked below and on regulatory page of IRB Online.** |
| Cancer Center Protocol Review Committee **(PRC)** | [ ]  NA [ ]  PRC Exempt [ ]  Pending Approval [ ]  On fil |
| Institutional Biosafety Committee **(IBC)** | [ ]  NA [ ]  Pending Approval [ ]  On file |
| **SOM CTO-PI of Multi-site** | [ ]  NA [ ]  Pending Approval [ ]  On file |
| **SOM CTO** **Need for IND/- SR vs NSR status** *(IRB-HSR may determine IDE Exempt status without review by SOM CTO )*  | [ ]  NA [ ]  Pending Review [ ]  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 |
| **Information Security (InfoSec)** | [ ]  NA [ ]  Pending Approval [ ]  On file |
| **SOM Issues:** **If PI is in SOM and *FDA approval section, 3 or more questions NO-refer*** | [ ]  NA [ ]  Referred to School of Medicine: David Driscoll *No response required* |
| 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 Emeritus Professor/retired faculty member?** | [ ]  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)  |
| **Outside IRB approval**\* 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 [ ]  NA IF YES, the IRB does not require a copy of the outside IRB approval to approve the study.  |
| **Certificate of Confidentiality Approval**  | [ ]  NA [ ]  Yes [ ]  NoIf study is not funded by the NIH 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 NIH.*  *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>  |
| **Scientific Review by Department**  | [ ]  NA [ ]  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. ? |
| 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.  |
| **Transfer IRB of Record from Non-UVA IRB to UVA IRB for an Active Study** | [ ]  Yes [ ]  No If YES –1. Verify new templates created via Protocol Builder and application uses Option A or B for DSMP2. 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  |

|  |  |
| --- | --- |
| **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 is 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 PI of Multi-Site Study (for sites within the U.S.)** Is there a Single IRB of Record for all U.S. domestic sites in the study?  | [ ]  Yes [ ]  NoIf NO, are all of the reviewing IRB for each site accredited? [ ]  Yes [ ]  NoIf NO, does each IRB have policies and procedures in place to address items listed in Appendix B? *(reference from section 25.2.1.2 of the UVA HRPP SOP*)[ ]  Yes [ ]  No *Answer must be YES*  |
| **International Sites**Are any of the sites outside of the U. S.? | [ ]  Yes [ ]  NoIf YES, is the local IRB/Ethics Committee for each site accredited? [ ]  Yes [ ]  NoIf NO, does each IRB have policies and procedures in place to address items listed in Appendix B? *(referenced from section 25.2.1.2 of the UVA HRPP SOP*)[ ]  Yes [ ]  No *Answer must be YES* |
| **UVA Medical Students as Subjects- GRIME**If this study will enroll UVA Medical Students as subjects, 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 as subjects, 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, include this citation on the assurance form and submit Privacy Certificate (See HRPP SOP) |
| **Export Control**Sanctioned Countries | [ ]  NA [ ]  Pending Approval [ ]  On file |
| **Native American Topics** | [ ]  Yes [ ]  NoIf YES, is approval on file from the tribe?  |

|  |
| --- |
| **REGULATORY ITEMS** [ ]  NONE**If any of the items below are applicable- they should be checked below and on the 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 the NIH *and collects identifiable information* or has an IND/IDE)*OR if CoC 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* |
| [ ]  Gene Transfer Study  |
| [ ]  HDE |
| [ ]  HIPAA- De-identified and / or no health information, no consent |
| [ ]  HIPAA- Identifiable-External Disclosure-Tracking Required, no consentAdd 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. 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 |
| [ ]  Investigational Drug or Biologic |
| [ ]  PI of Multi-site Study |
| [ ]  PRC Audit ( see AG 5-12) |
| [ ]  PRC Review of Mod’s Required |
| [ ]  PRC Exempt (see AG 5-20) |
| [ ]  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 |

***Insert a short description of the protocol in the receipt event.***

The IRB determined the protocol met the criteria for approval per the federal regulations and was approved.

It is open to enrollment. **OR**

The IRB determined the protocol met the criteria of approval with conditions. It is not yet open to enrollment.

The purpose of this study is to…..

The study will involve…..

***-If applicable,***

This Assurance provides approval to collect data or specimens, as outlined in the protocol, into a repository.

An additional protocol with IRB approval is required to remove any data or specimen for analysis.

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

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

N: Ages:

***-If applicable,*** The following documents were submitted with this protocol: (e.g. survey, manual of operations etc.)

*DO NOT INCLUDE ADVERTISMENT HERE (e.g. any materials used to recruit subject )*

**For all protocols add the following under the Regulatory Information heading of the comment section.**

***If the study is NOT regulated by the FDA add:***

This study is not regulated by the FDA as it does not involve research on a drug, biologic or device.

***If the study is regulated by the FDA and Device determined to be exempt from an IDE add:***

This study is regulated by the FDA as it involves research on a device.

The device (INSERT NAME) was determined by the IRB to be exempt from IDE requirements according to 21CFR812.2(c ) (3).

***Use the following option if it is noted in the letter from SOM-CTO as the study involves a supplement/isotope in which the intent of the study does not include evaluating the supplement’s/isotope’s ability to diagnose, cure, mitigate, treat or prevent disease.***

This study is not regulated by the FDA because it has been determined that the product as used in this study does not meet the criteria of a drug.

***-If applicable,*** *add (****CHOOSE ONE:***IND/IDE Exemption letter from FDA on file.

No vulnerable subjects to be enrolled ***OR-If applicable,*** *add regulatory wording for any additional vulnerable populations to be enrolled.*

***-If applicable,*** Outside IRB Approval on file from *Insert name of outside IRB*.

This study has been reviewed and approved by the PRC/IBC ***ENTER #*****OR**  No additional committee approvals are required

***-If applicable,*** A certificate of confidentiality application is on file. **OR** As this study is funded by the Federal Government and involves the use of sensitive information this study is automatically granted a Certificate of Confidentiality.

***-If applicable****,* SOM notified for additional review of use of FDA approved products.

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.

The IRB determined this protocol met the criteria of minimal risk.

***Add regulatory criteria (expedited criteria/ waiver criteria****) This is done by clicking on the regulatory button and this information will automatically insert.*

PLEASE REMEMBER (*this feeds in automatically when you click regulatory)*

* If an outside sponsor is providing funding or supplies, you must contact the SOM Grants and Contracts Office/ OSP regarding the need for a contract and letter of indemnification. If it is determined that either of these documents is required, participants cannot be enrolled until these documents are complete.
* You must notify the IRB of any new personnel working on the protocol PRIOR to them beginning work.
* You must obtain IRB approval prior to implementing any changes to the approved protocol or consent form except in an emergency, if necessary to safeguard the well-being of currently enrolled subjects.
* ***If prisoners will not be enrolled and consent for the main study (verbal or written) will be obtained add:*** -No prisoners are allowed to be enrolled in this study. If one of your subjects becomes a prisoner after they are enrolled in the protocol you must notify the IRB immediately.
* You must notify the IRB-HSR office within 30 days of the closure of this study.
* You are required to submit either an IRB Status Report or an IRB Update Form to the IRB-HSR at least once a year.

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol**  | **[ ]** N/A | **OR** | Version Date:  |
| **IRB Application** | **[ ]** N/A | **OR** | Version Date:  |
| **Data Security Plan** | **[ ]** N/A  | **OR** | Version Date:  |
| **HIPAA Authorization (stand alone)** *Verify Information Sheet is included with form*  | **[ ]** N/A | **OR** | Version Date:  |
| **Adult:**  | **[ ]** N/A  | **OR** | Version Date:  |
| **Parental Permission*****# of parent signatures*** | **[ ]** N/A | **OR** | Version Date: [ ]  1 [ ]  2 |
| **Adult/Minor:*****# of parent signatures*** | **[ ]** N/A | **OR** | Version Date: [ ]  1 [ ]  2 |
| **Assent:** *Verbal* **[ ]** No **[ ]** Yes | **[ ]** N/A  | **OR** | Version Date:  |
| **Age of Majority Consent Addendum and Cover Letter**  | **[ ]** N/A  | **OR** | Version Date:  |
| **English/Non English short form** | **[ ]** N/A | **OR** | Version Date:  |
| **Translated Consent (***Insert language*) | **[ ]** N/A | **OR** | Version Date:  |
| **English Version of Translated Consent**  | **[ ]** N/A | **OR** | Version Date:  |
|  **OTHER** | **[ ]** N/A | **OR** | Version Date:  |

**Check the appropriate box or boxes below**

|  |  |
| --- | --- |
| **EXPEDITED CATEGORIES**: | **TIPS** |
| [ ]  | Cat # 1 | 1. Clinical studies of drugs and medical devices only when conditions (a) or (b) is met:
2. Research on drugs for which an investigational new drug application is not required.
3. Research on medical devices for which
	1. an investigational device exemption (IDE) application is not required; or
	2. the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
 | * Choose EITHER a or b- do not include both in comment field.
* a. Research on marketed drugs that significantly increases the risks associated with the use of the drug is not eligible for expedited review.
* B. Choose EITHER i or ii- do not enter BOTH in the comment field.
* Used for a study involving a drug or device study where an IND/IDE is not required.
* If research is NOT being done to to determine safety and efficacy of a drug/device Do NOT use this criteria
 |
| [ ] [ ]  | Cat #2aCat #2b | 1. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:
	1. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period, and collection may not occur more frequently than two times per week; or
	2. From other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than two times per week.
 | * Only list a/b in comment field if they are applicable to current study.
 |
| [ ]  | Cat # 3 | Prospective collection of biological specimens for research purposes by noninvasive means. | * ***TIP****- see* [*review category*](https://research.virginia.edu/sites/vpr/files/2019-10/Expedited%20Review.doc) *for examples.*
 |
| [ ]  | Cat # 4 | Collection of data through non-invasive procedures (not involving general anesthesia or sedation) employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.  | * Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.
* DO NOT use this category if evaluating a device for safety and efficacy ( refer to expedited category # 1)
* ***TIP****: see* [*review category*](https://research.virginia.edu/sites/vpr/files/2019-10/Expedited%20Review.doc) *for examples*
 |
| [ ]  | Cat # 5 | Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment and/or diagnosis).  | * ***TIP:*** *According to* [*OHRP Request for Comment*](http://www.hhs.gov/ohrp/requests/com102607.html)  *this category may include “research involving materials that were previously collected for either the non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research. Also see* [*Admin question*](https://research.virginia.edu/irb-hsr/when-can-expedited-category-5-be-used) *for further information*
* *Note to staff- if study involves an IND or IDE- consult with IRB Director regarding use of this expedited category for the study*
 |
| [ ]  | Cat # 6 | Collection of data from voice, video, digital, or image recordings made for research purposes |  |
| [ ]  | Cat # 7 | Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.  | * ***TIP****: see* [*review category*](https://research.virginia.edu/sites/vpr/files/2019-10/Expedited%20Review.doc) *for additional explanation*
 |

**REGULATORY PAGE- WAIVER CRITERIA**

**IDENTIFYING**

**[ ]  1.** Identifying- Waiver of Consent

2018 Common Rule

*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

2018 Common Rule

*Recruitment 2 a or b is checked. If the study involves more than one group of subjects (controls vs. non- controls, patients vs. health care providers) make it clear in the wording below- which group you are referring to if not applicable for all subjects.*

[ ] **Funded by a non-Common Rule Agency besides the FDA (e.g. Dept of Justice)? *If yes,*** ***add***

This protocol has been granted a Waiver of Consent to contact potential subjects via INSERT APPLICABLE REG.

*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

2018 Common Rule

*Recruitment 2 a or b is checked. If the study involves more than one group of subjects (controls vs. non- controls, patients vs. health care providers) make it clear in the wording below- which group you are referring to if not applicable for all subjects.*

[ ] **Funded by a non-Common Rule Agency besides the FDA (e.g. Dept of Justice)? *If yes,*** ***add***

This protocol has been granted a Waiver of Consent to contact potential subjects by direct contact by a person who is their health care provider via INSERT APPLICABLE REG.

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.*

2018 Common Rule

[ ] **Funded by a non-Common Rule Agency besides the FDA (e.g. Dept of Justice)? *If yes,*** ***add***

This protocol has been granted a Waiver of Consent to use a screening log via INSERT APPLICABLE REG.

*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.*

*2018 Common Rule*

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 22).*

2018 Common Rule

[ ]  **If funded by DoD add:**

This protocol has been granted a waiver of documentation of consent for pre-screening questions under 32CFR219.117(c)

[ ] **Funded by a non-Common Rule Agency besides the FDA (e.g. Dept of Justice)? *If yes,*** ***add***

This protocol has been granted a Waiver of Documentation of Consent for pre-screening questions via INSERT APPLICABLE REG.

*NOTE: FDA does not require waiver of consent for screening, recruiting or determining eligibility. Consent must be obtained before any clinical procedures that are performed solely to determine eligibility or for drug washout.*

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

*For additional guidance see Waiver of Documentation of Consent section (page 22) .Per the FDA Information Sheet on Screening Test Prior to Study Enrollment this includes asking subjects to consent to a drug “wash out” period.*

*2018 Common Rule*

This protocol has been granted a waiver of documentation of consent for minimal risk pre-screening procedures under 45CFR46.117(c). [ ]  ***If funded by DOD add*** and 32CFR219.117(c).

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

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

*2018 Common Rule*

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 the application .*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 22).*

*2018 Common Rule*

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.*

*2018 Common Rule*

Written consent will be obtained for this study.

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

*2018 Common Rule*

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.*

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

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

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

*If yes, add page 14: Other Approvals*

* **Is this protocol funded by a grant held by a non- UVA institution?** [ ]  Yes [ ]  No

*If yes, add page 14: Grant*

* **Does the study include Populations Requiring Additional Protections/use of LAR with a written consent? [ ]** Yes **[ ]** No

 *If yes, add page 15/16: Populations Requiring Additional Protections/Use of LAR*

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

*If yes, add page 17: Recruitment*

* **Does the study include sharing data/ specimens outside of the UVA HIPAA covered entity**

**without the written consent of the subject?** *Nutrition services employees are part of UVA HIPAA covered entity* **[ ]** Yes **[ ]** No

*If sending names to Center for Survey Research for health related research- answer YES*

*If yes, see* [*Sending or Receiving Data and/ or Specimens*](https://research.virginia.edu/irb-hsr/sending-or-receiving-specimensdata) *to determine required steps & documentation*

* **Does this study involve banking at UVA of specimens, 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 17: Banking*

* **Is this study approvable with conditions? [ ]** Yes **[ ]** No

*If yes, add page 17: Closed to Enrollment*

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

 *If yes, add page 18: 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 20: Device Use*

*If study team is not testing for safety/ efficacy, but doing research on a device- consult with IRB Director*

* **Does this study include the use of an Investigational Drug/Biologic or research of an Approved**

 **Drug/Biologic? [ ]** Yes **[ ]** No

 *If yes, add page 20: Investigational Drug/Biologic*

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

 *If yes, add page 20: Waiver of Consent*

* **Does this study include Waiver of HIPAA Authorization for the main study and involve [ ]** Yes **[ ]** No

 **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?**

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

**Administrative Staff Completing Form:       Date**

**ADDITIONAL COMMENTS FOR ASSURANCE FORM:**

DO NOT WRITE TIPS OR NOTES TO STAFF IN COMMENT FIELD OF ASSURANCE FORM

|  |
| --- |
| **OTHER APPROVALS** |
| [ ]  | SOM-CTOPI of Multi-site Trial | *If required- add the following to the approval comment field* SOM CTO approval on file for PI of multisite trial.  |
| [ ]  | SOM-CTOReview regarding need for IND/Device- SR vs NSR status | *If required- add the following to the approval comment field* SOM CTO review on file regarding need for ***PICK ONE*** IND /IDE- SR vs NSR status.*IRB may consult with SOM CTO regarding IDE exempt status, but this is not required.* |
| [ ]  | SOM-CTOReview regarding IND/IDE held by outside PI | *If required- add the following to the approval comment field* SOM CTO review on file regarding IND/IDE held by outside PI |
| [ ]  | SOM CTO-Outside academic investigator serving as Sponsor | *If required- add the following to the approval comment field* SOM CTO review of sponsors’ protocol on file as outside academic investigator is serving as sponsor. |
| [ ]  | PRC | *If PRC approval is required- add the following to the approval comment field*PRC approval on file.*If there is a PRC approval, the version date listed on the PRC approval for the IRB protocol may not match the final version date. If the version date changes following the pre-review, add the following statement to the approval: Note: the version date of the protocol approved by the PRC is X. Additional changes resulted from the IRB’s administrative review. The final version date of the protocol is X.* *Check PRC approval form to verify if the PRC will review modifications. If yes, document on regulatory page.*  |
| [ ]  | IBC | *If an IBC# is required- add the following to the approval comment field*IBC# (INSERT NUMBER) on file.  |
| [ ]  | Departmental Scientific Review Committee | *If required- add the following to the approval comment field* Departmental Scientific Review Committee approval on file. |
| [ ]  | Is identifiable data being stored on a HIPAA compliant server? see List of Compliant Servers under U/IRB/IRB-HSR/Admin FAQ/Security/ Secure Drives  | [ ]  Yes [ ]  NoIf no- refer protocol to InfoSec for review as the data must be stored on a HIPAA compliant location.  |
| [ ]  | GRIME | *If required- add the following to the approval comment field* GRIME approval on file for enrolling UVA medical students as subjects.  |
| [ ]  | GMEC | *If required- add the following to the approval comment field* GMEC approval on file for enrolling UVA medical residents or fellows as subjects. |
| [ ]  | Export Control | *If required add the following to the approval comment field:*Export Control approval on file |

|  |
| --- |
| [ ]  **Grant**  |
| *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 PROTECTIONS:** If no, skip to next sectionIf yes, complete appropriate section(s) and add relevant language to assurance form |
| **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.*Children are approved to enroll in this protocol per 45CFR46.404/**[ ]** Yes **[ ]** No 21CFR50.51This protocol requires the [ ] signature of one parent per 45CFR46.408(b)/ **[ ]** Yes **[ ]** No 21CFR50.55/(e)(1)[ ]  signature of no parent per 45CFR46.408(c)/ **[ ]** Yes **[ ]** No 21CFR50.55/(e)**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 21CFR50.55a**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 main comment field of 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. **Wards of State***Note to staff: no additional requirements are needed for children who are wards of the state to enroll in a minimal risk expedited /exempt study.*  |
| **Pregnant Women or Fetuses?** **[ ]** Yes **[ ]** No  | **Add:** Enrollment of pregnant women/ fetuses approved under 45CFR46.204 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.***  |
| 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: [ ]** DoD Directive 3216.02 *( TIP-if funded by DoD and study involves Fetal Tissue Research*)  |

|  |  |
| --- | --- |
| **Prisoners?** **[ ]** Yes **[ ]** No  | **Add** Enrollment of prisoners approved under 45CFR46Subpart C ***If DHHS funded add***: and by 46.306(a)(2) Category (Circle One: i, ii, iii, or iv)DHHS Secretarial Approval on file. See AG 3-34 for instructions. **If study will be carried out inside the Bureau of Prisons add:** 28CFR812.512***Add to main page comment field:*** *PRISONERS MAY BE ENROLLED. PRISONER REP REQUIRED FOR REVIEW OF ALL EVENTS.* **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. He/she 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:**** If the study involves an interaction or intervention with subjects (e.g. Not a chart review with waiver of consent) the Prisoner Representative must complete the [Research Involving Prisoners Checklist](http://www.virginia.edu/vpr/irb/HSR_docs/Checklists/vulnerable_pop_prisoner_checklist.doc) .
* *Review information in HRPP SOP Section 12.6 regarding additional requirements if the research will be conducted within the Bureau of Prisons.*
* *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 an LAR is not needed as subjects have only mild cognitive impairment |
| **Employees/Students?** **[ ]** Yes **[ ]** No  | **If YES, complete the vulnerable populations checklist for Employees/Students** |

**[ ]  RECRUITMENT**

*If you need additional assistance reviewing the recruitment material refer to the* [Advertising Approval Checklist](https://research.virginia.edu/sites/vpr/files/2019-08/Advertising_Approval_Checklist.docx). *Stamp recruitment material with approval date stamp. If stamp has expiration date, complete as NA because ad approvals do not expire. Enter type of recruitment in IRB Online under Adverts*

|  |
| --- |
| *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. 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*

**[ ]  APPROVABLE WITH CONDITIONS?**

*If YES, complete section below.*

**The protocol is processed in the following manner:**

* Enter event as “Approvable with Conditions” *Enter the following at the top of the comment field*: This approval 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*>”
* On the Main page, enter approval and expiration dates.
* Post event on the agenda
* Enter the status of the protocol as APPROVABLE WITH CONDITIONS
* Add a statement in IRB Online 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> “
* Print Assurance

**REMINDERS:**

* The pending items must include ONLY outside IRB approval/ documentation from outside study site. All other items must be approved by the IRB Director.
* NO ADDITIONAL DOCUMENTATION SUCH AS SEPARATE COVER LETTERS IS ALLOWED.

**[ ] 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 device is exempt from IDE regulations, do all the following apply?[ ]** Yes **[ ]** No

* All other procedures in study fall under an expedited category
* Study is minimal risk
* If the study involves an in-vitro diagnostic device the results will not be given back to the subject.
	+ Additional guidance for an in vitro diagnostic device study may be found in “Regulating In Vitro Diagnostic Device (IVD) Studies.” <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071230.pdf>
	+ *See additional information under Administrative FAQ’s-Review Process- May the IRB review a protocol involving an in-vitro diagnostic device which has an IDE# via expedited review”*

***IF YES***

* Identify expedited category # 1 on the Regulatory page of IRB Online.
* ***If this is research on a non-approved device 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***) was determined by the IRB to be exempt from IDE requirements according to 21CFR812.2(c)(3).
* ***If this is research on an approved device being used in an approved manner check Approved Drug, Device or Biologic, Investigational Device & IDE Exempt in IRB Online/ Regulatory page and write the following comment on the assurance form:***Device has FDA approval and is being used according to FDA labeling. Device 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, Approved, Investigational Device and IDE Exempt will be checked, telling you it is an approved device which is being investigated.*

**IF NO:**

* ***The protocol must be sent to SOM CTO for opinion on need for IDE and to Full Board to determine SR vs NSR device status.***
* ***See AG 3-13 for steps to be taken.***
* ***If the device is determined by the Full Board to be NSR, the protocol may be reviewed in an expedited manner. Enter the following statement in the Protocol Approval 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).

**[ ] Device Use:**

***If yes, complete section below, add language to assurance form and note status 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 RUO* ***)* 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,** *answer the following questions:*

**[ ]** Yes **[ ]** No All other procedures fit under an expedited category.

**[ ]** Yes **[ ]** No The study is minimal risk. *Minimal Risk: probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45CFR46.102*

***If both questions above are answered YES:***

***On Regulatory page note:*** *Expedited Category # 4*

***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 a Research Use Only Device. It is not being evaluated for safety and efficacy but is being used in an unapproved manner. This study is not regulated by the FDA, therefore the FDA device regulation 21CFR812 do not apply to this protocol.

***If both questions above are NOT answered YES: send to FULL BOARD. NOTE; Full Board does NOT determine NSR/SR status.***

*YOU ARE NOW DONE WITH THIS PAGE*

**►IF NO, (** *is NOT an RUO***) will the device be used as a medical device in this study (e.g. intended for use in the dx of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease)? [ ]** Yes **[ ]** No

**►IF NO,** *( is NOT being used as a medical device)*answer the following questions.

**[ ]** Yes **[ ]** No All other procedures fit under an expedited category.

**[ ]** Yes **[ ]**  No The study is minimal risk.

***If both items above are NOT answered YES, send to FULL BOARD.***

***If all items above are answered YES:***

***On Regulatory page note:*** *Expedited Category # 4*

**If device being used as approved write the following in the assurance comment field:**

The device (***insert name of device***) being used in this study has FDA approval/ clearance and will be used according to labeling. The study is regulated by the FDA, but the FDA device regulation 21CFR812 does not apply to this protocol.

***If device is being used in an unapproved manner check the following on the Regulatory page check:***

**[ ]**  *Device: Unapproved USE only or no evaluation*

***Also, 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. The study is regulated by the FDA, however,the FDA device regulation 21CFR812 does not apply to this protocol.

**►IF YES*,*** *( is being used as a medical device)*

**Does the device have FDA approval for ANY indication? [ ]** Yes **[ ]** No

**►IF YES** answer the following questions.

**[ ]** Yes **[ ]** No All other procedures fit under an expedited category.

**[ ]** Yes **[ ]**  No The study is minimal risk.

***If both items above are NOT answered YES, send to FULL BOARD.***

***If both items above are answered YES:***

***On Regulatory page note:*** *Expedited Category # 4*

***On Regulatory page check either:***

**[ ]** *Approved Drug, Device or Biologic*

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

The device (***insert name of device***) being used in this study has FDA approval/ clearance. The device is regulated by the FDA, however, the FDA device regulation 21CFR812 does not apply to this protocol.

**[ ]**  *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 device is regulated by the FDA, however, the FDA device regulation 21CFR812 does not apply to this protocol.

 **►IF NO,**

* To FULL BOARD for Review. As expedited criteria # 4 not applicable.
* DO NOT use Expedited Criteria # 1 as the device is not being evaluated therefore FDA regulations do not apply.

 NOTE: FB does NOT determine SR/NSR status but may determine if protocol is minimal risk, therefore allowing future continuations to be expedited via Category # 9 *Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (7) do not apply but the IRB has determined and documented at a convened full IRB meeting that the research involves no greater than minimal risk and no additional risks have been identified.*

[ ]  **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*

|  |
| --- |
| DO NOT WRITE TIPS OR NOTES TO STAFF IN COMMENT FIELD OF ASSURANCE FORM***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 or biologic* ***already approved*** *by the FDA for the indication, dose and route to be used in this protocol?**In IRB Online/ Regulatory Page 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 by the IRB to be exempt from IND requirements according to 21CFR312.2(b).  **FULL BOARD REVIEW ONLY:** **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 by the IRB to NOT be exempt from IND requirements according to 21CFR312.2(b). IND# required ***OR (enter #)*** on file.  |

|  |
| --- |
| **WAIVER OF CONSENT- OPTIONAL*****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.**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,** * 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.

**\* An inadvertent release of the information would not stigmatize a subject (e.g. research does not include a sensitive topic such as HIV, spousal abuse, mental illness, etc.) and would not affect their employment/ insurance options (e.g. breast cancer, heart disease etc.)** **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 only if:**1. Research involves the study of public programs (45 CFR 46.116(e)), OR
2. Research meets all of the following four criteria from 45 CFR 46.116(f):
	1. No more than minimal risk to participants
	2. Waiver/alteration will not adversely affect the rights and welfare of participants
	3. Research could not practicably be carried out without the waiver/alteration
	4. Participants will be provided with pertinent information after participation

**IF YES, *Insert the following:*** The protocol grants waiver of consent for deception per: (45 CFR 46.116(e)), OR 45 CFR 46.116 (f)*If any of the following are checked add:* Also granted waiver of consent under1) [ ] Funded by DoD? *If yes,* *add* and 32CFR219.117(c) (waiver for use of deception is rarely OK under DOD)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-* (*very rare- consult with IRB Director*) |

**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.*

|  |
| --- |
| **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.* * + *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/2019-11/Consent%20Tips.doc) *for additional Information.*

*On Regulatory Page mark the following:**HIPAA- de-identified and/ or no health information ( no consent)* [ ]  ***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. **[ ]**  **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)* [ ]  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- COMPLETE BELOW** |
| **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 [ ] No1. *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[ ]  for the continued use of data/specimens collected under parental/guardian permission. [ ]  *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 shared outside of the UVA HIPAA covered entity.
 |

**WAIVER OF DOCUMENTATION OF CONSENT- OPTIONAL**

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

*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.*

**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 BELOW**

**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/2019-11/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 [eg: Data at UVA Identifiable, Data going outside of UVA is a LDS”. ]*

**IF IDENTIFIABLE- SEE BELOW**

**ALTERATION OF HIPAA AUTHORIZATION FOR VERBAL AUTTHORIZATION -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 [ ]

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, 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:***

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

[ ]  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)

**Appendix A: Recruitment**

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

**APPENDIX B: OPTIONAL** **CHART REVIEW ONLY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **N/A**  | **Comment**  |
| Does the title match between the cover sheet, IRB Protocol/IRB Application, consent and database? | [ ]  | [ ]  | [ ]  |       |
| Are all required template sections of the Protocol/IRB Application present? | [ ]  | [ ]  | [ ]  |       |
| Version date present and consistent across all documents? | [ ]  | [ ]  | [ ]  |       |
| Are all pages numbered sequentially? | [ ]  | [ ]  | [ ]  |       |
| Is the hypothesis clearly stated? Does it focus on the questions the study will answer? | [ ]  | [ ]  | [ ]  |       |
| If the study involves waiver of consent and use of the CDR does information in the CDR table match the information found in the HIPAA section Question E? | [ ]  | [ ]  | [ ]  |       |
| Is there an appropriate DSMP in place? | [ ]  | [ ]  | [ ]  |       |
| If waiver of consent is requested – does the protocol meet the criteria for a Waiver? ( see AG 3-7) | [ ]  | [ ]  | [ ]  |       |
| Are answers to Protocol Builder questions consistent with the type of study being submitted? (If sponsor protocol is present, responses must be consistent) ***this is just an overview*** | [ ]  | [ ]  | [ ]  |       |
| If stated that study only includes collection of previously collected specimens and/or data ( retrospective research) -is there a stop date listed which is prior to day this protocol is approved? | [ ]  | [ ]  | [ ]  |       |

**NON- CHART REVIEW**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IRB-HSR COVER SHEET**  | **Yes** | **No** | **N/A**  | **Comment**  |
| If answered yes to **Database** are there any interactions with subject such as blood draw/ questionnaire etc.? *If yes- this cannot be a database only study.*  | [ ]  | [ ]  | [ ]  |       |
| Does the **title** match between the cover sheet, Protocol/IRB Application consent and database? | [ ]  | [ ]  | [ ]  |       |
| Is there a **sponsor?** If yes, is it listed? ( if protocol is being done under a subcontract from a grant- need to list both groups under sponsor ( who is grant from/ who is subcontract from) | [ ]  | [ ]  | [ ]  |       |
| If sponsor is a foundation will there be a grant or contract in place? *Must be answered yes.* | [ ]  | [ ]  | [ ]  |       |
| Is there a **Sponsor's Protocol?** If yes :Sponsor's Protocol #      Date      | [ ]  | [ ]  | [ ]  |       |
| If there is an outside supply source sending free drug, supplement, device etc. to UVA did they answer yes to the contract question? ( need an MTA) | [ ]  | [ ]  | [ ]  |       |
| If **DoD funded** and study involves DoD personnel, data or specimens, do we have approval from DoD IRB/ other federal IRB? ( is outside IRB approval documented on Regulatory page?) | [ ]  | [ ]  | [ ]  |       |
| **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? (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 company?  | [ ]  | [ ]  | [ ]  |       |
| Will the study require a DUA or Tracking of disclosures?*If YES, enter info into IRB Online* | [ ]  | [ ]  | [ ]  |       |
| Has this protocol been reviewed by the **PRC** and is the documentation of approval present with the submission? | [ ]  | [ ]  | [ ]  |       |
| If no, is the **device exempt** from IDE requirements? *May consult with SOM CTO office for their opinion.* | [ ]  | [ ]  | [ ]  |       |
| If no, is the **device NSR?***May consult with SOM CTO office for their opinion.* | [ ]  | [ ]  | [ ]  |       |
| If they are getting free drug/ devices- did they answer YES to the contract question?*If no- notify PI to consult with Grants and Contracts*  | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application** | **Yes** | **No** | **N/A** | **Comment** |
| In the FDA Approval section: are 3 or more questions answered NO?  If yes, refer protocol to IRB Chair and Steve 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? | [ ]  | [ ]  | [ ]  |       |
| **RECRUITMENT PROCEDURES** | **Yes** | **No** | **N/A** | **Comment** |
| If subjects will be contacted is this process 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 AND METHODS** | **Yes** | **No** | **N/A**  | **Comment**  |
| 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) | [ ]  | [ ]  | [ ]  |       |
| If the study involves waiver of consent and use of the CDR does information in the CDR table match the information found in the HIPAA section Question E? | [ ]  | [ ]  | [ ]  |       |
| If randomized, is the method and probability of receiving each treatment described? Does info in protocol match that in consent? | [ ]  | [ ]  | [ ]  |       |
| **RISKS/ BENEFIT ANALYSIS/DSMP** | **Yes** | **No** | **N/A**  | **Comment**  |
| Is there an appropriate description of the risk-benefit ratio? | [ ]  | [ ]  | [ ]  |       |
| Are the potential benefits to the subject (if any) accurate and clearly described? | [ ]  | [ ]  | [ ]  |       |
| Are all the risks (including known incidence) clearly described? Including study procedures, screening. | [ ]  | [ ]  | [ ]  |       |
| Have adequate safeguards (safety tests) been adopted to reduce risk exposure as much as possible? | [ ]  | [ ]  | [ ]  |       |
| **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**       **NA** | **Yes** | **No** | **N/A** | **Comment** |
| Is the payment amount free of undue influence? | [ ]  | [ ]  | [ ]  |       |
| If payment is not pro-rated is this coercive?  | [ ]  | [ ]  | [ ]  |       |
| Is payment information consistent across protocol and consent? | [ ]  | [ ]  | [ ]  |       |
| Is the difference between compensation (payment) vs reimbursement for travel or other expenses clear? | [ ]  | [ ]  | [ ]  |       |
| Has study team requested a method of payment other than a check via oracle?  If yes, is this needed/appropriate for this protocol?  | [ ]  | [ ]  | [ ]  |       |
| Has study team stated they cannot obtain SS# for compensation?  If yes, is this appropriate for this protocol? | [ ]  | [ ]  | [ ]  |       |
| **BIOMEDICAL**       **NA** | **Yes** | **No** | **N/A**  | **Comment**  |
| Does the protocol involve an approved drug/ device? *If yes, is approval verification from FDA provided?*  | [ ]  | [ ]  | [ ]  |       |
| Is an MRI with contrast being used? If yes, study is not expeditable. | [ ]  | [ ]  | [ ]  |       |
| **BIBLIOGRAPHY/ REFERENCES** | **Yes** | **No** | **N/A**  | **Comment**  |
| Was a reference list provided? | [ ]  | [ ]  | [ ]  |       |
| **Genomic Data study funded by NIH?**       **NA** | **Yes** | **No** | **N/A**  | **Comment**  |
|  *NOTE: Waiver of consent not allowed if data/specimens collected after 1/25/15* | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Specimen Banking**      **NA *(remember specimen banking refers to LONG TERM STORATE for UNSPECIFIED research and does not include specimens that are stored after 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? | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Waiver of Consent \_**      **NA** | **Yes** | **No** | **N/A**  | **Comment**  | **PI/SC to address** |
| If waiver of consent is requested – does the protocol meet the criteria for a Waiver? *See AG 3-7 and* [*Consent Tips*](https://research.virginia.edu/sites/vpr/files/2020-04/Consent%20Tips.doc) | [ ]  | [ ]  | [ ]  |       | [ ]  |
| If stated that study only includes collection of previously collected specimens and/or data ( retrospective research) -is there a stop date listed which is prior to day this protocol is approved?  | [ ]  | [ ]  | [ ]  |       | [ ]  |
| If applicable , does protocol specify that data is also being collected for such things as : QI, clinical care, national registries, certification or licensure*? IF NO, and study is prospective and coded or identifiable IRB may not approve Waiver.*  | [ ]  | [ ]  | [ ]  |       | [ ]  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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) | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IRB-HSR CONSENT**       **NA** | **Yes** | **No** | **N/A**  | **Comment**  |
| **AGREEMENT BETWEEN PROTOCOL AND CONSENT** |  |  |  |  |
| Are procedures outlined in the protocol consistent with information in the consent? | [ ]  | [ ]  | [ ]  |       |
| Does the # of subjects to be enrolled match between the protocol and consent?  | [ ]  | [ ]  | [ ]  |       |
| **GENERAL INFORMATION** |  |  |  |  |
| Is clear, concise, non-technical language used throughout? | [ ]  | [ ]  | [ ]  |       |
| Are appropriate subheadings and sequence used throughout? | [ ]  | [ ]  | [ ]  |       |
| Is the use of person consistent throughout?  | [ ]  | [ ]  | [ ]  |       |
| Are any references to future studies, not yet approved by the IRB removed?  | [ ]  | [ ]  | [ ]  |       |
| If surrogate consent is requested have they answered “YES” to the question: “ "Will participants with impaired decision making capacity be allowed to enroll in this study?” | [ ]  | [ ]  | [ ]  |       |
| Are subjects who are Wards of State to be enrolled?*If yes, and study meets minimal risk criteria an Advocate for the Wards is not required.*  | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SOURCE OF SUPPORT** | **Yes** | **No** | **N/A** | **Comment** |
| Is the source of financial support for the study listed and consistent with the cover sheet? | [ ]  | [ ]  | [ ]  |       |
| **STUDY DESCRIPTION** | **Yes** | **No** | **N/A** | **Comment** |
| Is there a clear statement of the purpose of the study? | [ ]  | [ ]  | [ ]  |       |
| Is there some background information given regarding the topic under study (ie.) what is non-small cell lung cancer? | [ ]  | [ ]  | [ ]  |       |
| Is there a clear explanation of the reason a particular subject was invited to participate? | [ ]  | [ ]  | [ ]  |       |
| Is the duration and length of each subject’s participation included?  | [ ]  | [ ]  | [ ]  |       |
| Are all procedures described clearly defined as either research related or completed as part of the subject’s clinical care (regardless of study participation)?  | [ ]  | [ ]  | [ ]  |       |
| Are the dose, route, and frequency of drug(s) to be given noted? | [ ]  | [ ]  | [ ]  |       |
| If the study involves the use of questionnaires, is there a description of the general content and time required to complete them? | [ ]  | [ ]  | [ ]  |       |
| Is the total volume of blood to be drawn (if any) described in tablespoons or teaspoons? | [ ]  | [ ]  | [ ]  |       |
| If randomization is involved, is probability of receiving each treatment listed? | [ ]  | [ ]  | [ ]  |       |
| If subjects will be reimbursed, is template wording regarding need for receipts/mileage and money being withheld from state in the consent form? | [ ]  | [ ]  | [ ]  |       |
| **RISKS AND BENEFITS SECTION** | **Yes** | **No** | **N/A** | **Comment** |
| Is there a complete and clear description of the potential risks of the study procedures (i.e., is quantitative information on the expected frequency of the listed side effects provided)? | [ ]  | [ ]  | [ ]  |       |
| Are reproductive risks adequately described? | [ ]  | [ ]  | [ ]  |       |
| Is there a clear description of the precautions taken to minimize risks? | [ ]  | [ ]  | [ ]  |       |
| Are the potential benefits to the subjects (if any) clearly described? If there are no benefits is this clearly stated? | [ ]  | [ ]  | [ ]  |       |
| If frequency of risks are specified are they free of percentages or fractions?  | [ ]  | [ ]  | [ ]  |       |
| **ALTERNATIVE TREATMENTS** | **Yes** | **No** | **N/A** | **Comment** |
| If applicable, have all alternative treatments been satisfactorily described? | [ ]  | [ ]  | [ ]  |       |
|  |  |  |  |  |
| **COSTS AND PAYMENTS** | **Yes** | **No** | **N/A**  | **Comment**  |
| Is the language included in this section consistent with that included in the protocol? | [ ]  | [ ]  | [ ]  |       |
| If study includes reimbursement is it clearly stated if subject needs to save receipts?  | [ ]  | [ ]  | [ ]  |       |
| If payment is not prorated, is this coercive?  | [ ]  | [ ]  | [ ]  |       |
| **CONFIDENTIALITY/HIPAA** | **Yes** | **No** | **N/A**  | **Comment**  |
| Have adequate measures been taken to protect subjects from breaches of confidentiality and/or invasion of privacy? | [ ]  | [ ]  | [ ]  |       |
| Has a certificate of confidentiality been requested and/or issued? If yes, does the use of the C of C allow the study to be determined to meet the “minimal risk” criteria? *If no, the protocol must go to the full board. .*  | [ ]  | [ ]  | [ ]  |       |
| If protocol includes Certificate of Confidentiality- add comment 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 (if identifiable health information involved)?  | [ ]  | [ ]  | [ ]  |       |
| **RIGHT TO WITHDRAW**  | **Yes** | **No** | **N/A** | **Comment** |
| Is this section clearly worded and non-coercive? | [ ]  | [ ]  | [ ]  |       |
| Are the risks of subject withdrawal stated (if applicable)? | [ ]  | [ ]  | [ ]  |       |
| Are reasons why a subject might be withdrawn from the study by investigators clearly defined? | [ ]  | [ ]  | [ ]  |       |
| Are procedures for ensuring continued care of the withdrawn subject adequately addressed? | [ ]  | [ ]  | [ ]  |       |
| **COMPENSATION FOR INJURY** | **Yes** | **No** | **N/A**  | **Comment**  |
| Is the standard statement or other satisfactory wording included? If sponsors language was added is it consistent with UVA required language?  | [ ]  | [ ]  | [ ]  |       |
| **SIGNATURE** | **Yes** | **No** | **N/A**  | **Comment**  |
| Are the appropriate signature lines included based on type of study? (e.g.) parental permission/ obtaining assent/ use of LAR? | [ ]  | [ ]  | [ ]  |       |
| In the event the participant is unable to give informed consent for participation in this study, does the consent contain signature section for use of LAR? | [ ]  | [ ]  | [ ]  |       |
| If there is minimal risk OR therapeutic benefit to the participant does the consent form contain ONE parent/guardian signature? | [ ]  | [ ]  | [ ]  |       |
| If there is more than minimal risk but no benefit to the participant?*Cannot be approved by expedited review.*  | [ ]  | [ ]  | [ ]  |       |
| The following statements are not to be listed in the consent form:1. This protocol was reviewed by IRB
2. The investigational drug/device in study has been found to be safe in previous studies if purpose of this study is to determine safety.
3. Any part of the protocol was approved by the Office of the General Counsel
4. Subject will be paid for lost wages etc.
 | [ ]  | [ ]  | [ ]  |       |
| If optional procedures are listed, there are Optional boxes for subjects to indicate whether or not they agree/consent to those optional procedures | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |
| --- | --- | --- | --- |
| **SPECIMEN BANKING       N/A** | **Yes** | **No** | **Comment** |
| Are the procedures for collecting the specimen outlined clearly in the consent? | **[ ]**  | **[ ]**  |       |
| Are the risks of donating the specimen clearly defined? | **[ ]**  | **[ ]**  |       |
| Is the party responsible for storing the specimen and protecting the subject’s privacy been noted?  | **[ ]**  | **[ ]**  |       |
| Are the appropriate signature lines included? | **[ ]**  | **[ ]**  |       |
| **GENETIC RESEARCH** **N/A** | **Yes** | **No** | **Comment** |
| Does the Genetic Research being done meet the minimal risk standard? *If no- send to Full Board* | **[ ]**  | **[ ]**  |       |
| Is the information that is being sought through this testing clearly explained? | **[ ]**  | **[ ]**  |       |
| Are the procedures for collecting the specimen outlined clearly in the consent? | **[ ]**  | **[ ]**  |       |
| Are the tests that will be done on the specimen clearly explained? | **[ ]**  | **[ ]**  |       |
| Are the risks of donating the specimen clearly defined? Either blood draw or removal of additional tissue. | **[ ]**  | **[ ]**  |       |
| Will the subject or the subject’s family be provided with the test results? Are the associated risks of being given this information provided? | **[ ]**  | **[ ]**  |       |
| Is the party responsible for storing the specimen and protecting the subject’s privacy been noted? | **[ ]**  | **[ ]**  |       |
| Is there a description of how the confidentiality of the subject will be protected? | **[ ]**  | **[ ]**  |       |
| Are the appropriate signature lines included? | **[ ]**  | **[ ]**  |       |

**Administrative Staff Completing Form:       Date**

**Submission Checklist**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IRB-HSR PROTOCOL** | **Yes** | **No** | **N/A**  | **Comment** |
| Is the submission signed and dated by PI? | [ ]  | [ ]  | [ ]  |       |
| Have the study personnel completed the mandatory IRB-HSR online training? | [ ]  | [ ]  | [ ]  |       |
| If studies affiliated with the PRC, is the committee approval on file or part of the submission? *( NA for 5 year update)* | [ ]  | [ ]  | [ ]  |       |
| Are all documents listed on the protocol cover sheet submitted with the submission?  | [ ]  | [ ]  | [ ]  |       |
| If protocol is funded by a grant- has the grant been approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| Do the version dates match those from pre-review?  | [ ]  | [ ]  | [ ]  |       |
| Has a receipt event been entered for such items as PRC approval, SOM CTO approval, outside IRB approval, New Medical Device application form?  | [ ]  | [ ]  | [ ]  |       |
| Have all applicable vulnerable population checklists been completed?  | [ ]  | [ ]  | [ ]  |       |
| Is the person who signed as the Department Chair listed on the protocol as personnel? (*answer must be no*)  | [ ]  | [ ]  | [ ]  |       |

**Administrative Staff Completing Form:       Date**