**TRANSFER OF IRB OVERSIGHT**

|  |
| --- |
| **INSTRUCTIONS AND INFORMATION**  This form should be completed to document the transfer of IRB oversight for the following scenarios:   1. Previously approved ongoing study at UVA is transferred ***FROM*** the UVA IRB ***TO*** a non-UVA IRB 2. UVA study team has previously relied on a non-UVA IRB(A) and the IRB oversight for continued UVA participation is transferred ***FROM*** the non-UVA IRB(A) ***TO*** another non-UVA IRB (B).   Submit the following completed documents to [SIRB@virginia.edu](mailto:SIRB@virginia.edu) **NOTE:** DO NOT ACCESS CRCONNECT   * ***Transfer of IRB Oversight* Document with UVA PI Signature** * Documentation from Reviewing/Receiving IRB/Sponsor/DCC requesting transfer * Current Version of Protocol Document * Original approval notice for the Reviewing/Receiving IRB * If applicable, most recent Continuation approval notice from the Reviewing/Receiving IRB * ***Appendix A: IRB-HSR Consent/Assent Local Wording Template*** * ***Appendix B: Common Questions and Reponses for UVA Study teams completing Local Site Questionnaires*** * ***Appendix C: Local Context Stand-Alone Addendum*** |

**Submitted Date:**  **Submitted By:       IRB-HSR#/UVA Tracking #**

**UVA PI:**    **Sponsor Name:**

**Study Title:**

**Effective Date of Transfer**: **Current Expiration Date @ UVA:**

**(**Allow enough time for all communications and agreements to occur)

**1. TRANSFER DIRECTION (indicate below)**

1. From the **UVA IRB** to a Non-UVA IRB: N**ame of non-UVA IRB:**
2. From a non-UVA IRB (A) to another non-UVA IRB (B)

**Name of IRB A**: **Name of IRB B:**

1. **Rational for Transfer:**
2. **Will the Non-UVA IRB be operating under the** [**Revised Common Rule 2018**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html)**?**  YES  NO

***(Confirm response with the Non-UVA Reviewing IRB)***

**2. Non-UVA IRB/REVIEWING/RECEIVNG IRB CONTACT INFORMATION**

|  |  |
| --- | --- |
| Name of IRB ***AFTER*** transfer of oversight is complete. |  |
| FWA# |  |
| Study Funding Entity |  |
| Non-UVA IRB Contact  Address/Phone #/Email | Name:  Address:  Telephone:       Email: |
| Is the Non-UVA IRB, which is responsible for IRB oversight AFTER transfer, a member of SMART IRB and will the SMART IRB Reliance Agreement and SOP’s be used? See SMART Participating Institutions [HERE](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=2ahUKEwiImPit6tvdAhVHqlkKHV48CkEQjBAwAXoECAYQCQ&url=https%3A%2F%2Fsmartirb.org%2Fparticipating-institutions%2F&usg=AOvVaw00In5OPEiqw2B3hTR3jbph) | YES  NO--UVA IRB-HSR will need to initiate a NEW Reliance Agreement  NO--Reliance Agreement with: NeuroNext, NCI CIRB, CITN  OTHER: |

**3. ADDITONAL INFORMATION**

|  |  |
| --- | --- |
| Will subjects be enrolled /continue to be enrolled at UVA? | YES If yes, **N=**  NO |
| Explain the roles & responsibilities of UVA researchers. |  |
| Will the Non-UVA IRB serve as the HIPAA Privacy Board? | YES  NO |
| Are other institutions relying on the UVA IRB for review of their engagement in this research study? | NO  YES, If Yes, list relying sites where UVA IRB is currently serving as the IRB of Record\*:  *\*Additional Reliance Agreements may be necessary* |
| Which entity will maintain IRB records once the IRB oversight has been transferred?  **Note:** The entity that assumes responsibility for the records is responsible for ensuring that they are retained in accordance with [21 CFR 56.115(b).](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.115) | Original Reviewing IRB:  Receiving IRB:  Institution for Original IRB:  CRO:  Data Coordinating Center |
| Is the study federally funded **or** regulated by FDA? | YES  NO (**Note: If YES, do not answer remaining questions in this box**)  ***If NO,*** *does the Reviewing IRB apply the federal regulations to all research regardless of funding source (have unchecked the FWA box)*  **Yes  No**  ***If YES,*** *will the Reviewing IRB report Ups, serious or continuing non-compliance to federal agencies, regardless of funding source?*  **Yes  No**  *If No****,*** UVA will report UP’s et al to Federal agencies)  Note: UVA study team will need to verify responses with the Reviewing IRB. |
| Do you confirm that the UVA study team will take responsibility for ensuring that all local consent language, provided by the UVA IRB-HSR, is included in all versions of the consent(s)? | YES |
| Do you confirm that the UVA site has the adequate resources (including space, equipment and personnel) for conducting the study? | YES |
| Do you confirm the UVA Study Team will carry out their responsibilities: [Reviewing and Relying Site Responsibilities.](https://research.virginia.edu/sites/vpr/files/2019-08/Reviewing_and_Relying_Site_Responsibilities.docx)? | YES |
| Will subjects be recruited or receive study interventions in a UVA patient care setting? | YES  NO  *If YES, all study team members must review the* [*Guideline for Research in Patient Care Settings*](https://research.virginia.edu/sites/vpr/files/2019-08/Guideline_Research_in_Patient_Care_Settings.pdf) *prior to the start of the study.* |

3. Legal/Regulatory

**NOTE:** All UVA study team members must have complete and current human subjects training certifications before IRB oversight can be ceded to a non-UVA IRB.

**Recruitment**

The following procedures will be followed:

* Finders fees will not be paid to an individual as they are not allowed by UVA Policy.
* Only those individuals listed as personnel on this protocol will recruit and or conduct the consenting process with potential subjects.

**Clinical Privileges**

The following procedures will be followed:

* Investigators who are members of the clinical staff at the University of Virginia Medical Center must have the appropriate credentials and been granted clinical privileges to perform specific clinical procedures whether those procedures are experimental or standard.
* The IRB cannot grant clinical privileges.
* Performing procedures which are outside the scope of the clinical privileges that have been granted may result in denial of insurance coverage should claims of negligence or malpractice arise.
* Personnel on this protocol will have the appropriate credentials and clinical privileges in place before performing any procedures required by this protocol.
* Contact the Clinical Staff Office- 924-9055 or 924-8778 for further information.

**Sharing of Data/Specimens**

Data and specimens collected under an IRB approved protocol are the property of the University of Virginia. You must have “permission” to share data/ specimens outside of UVA other than for a grant application and or publication. This “permission” may come in the form of a contract with the sponsor or a material transfer agreement (MTA) with others. A contract/ MTA is needed to share the data outside of UVA even if the data includes no HIPAA identifiers and no code that could link the data back to a HIPAA identifier.

* No data will be shared outside of UVA, beyond using data for a grant application and or publication, without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.
* No specimens will be shared outside of UVA without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.

**Compensation in Case of Injury**

If a subject requests compensation for an injury, the study team should notify the IRB-HSR (924-9634/243-9847) the UVA Health System Patient Relations Department (924-8315). As a proactive courtesy, the study team may also notify UVA Health System Patient Safety and Risk Management (924-5595).

On request, the study team should provide the Risk Management Office with the following information/documents:

* Subject Name and Medical Record Number
* Research medical records
* Research consent form
* Adverse event report to IRB
* Any letter from IRB to OHRP

**Subject Complaints**

During a research study, the study team may receive complaints from a subject. If the study team is uncertain how to respond to a complaint, or is unable to resolve it with the subject, the study team may contact the IRB-HSR (924-9634/243-9847), the UVA Health System Patient Relations Department (924-8315).

**Request for Research Records from Search Warrant or Subpoena**

If the study team receives a request for research records from a search warrant or subpoena, they should notify UVA Health Information Services at 924-5136. It is important to notify them if information from the study is protected by a Certificate of Confidentiality.

**Credentialing/ Clinical Privileges**

The following procedures will be followed:

* Investigators who are members of the clinical staff at the University of Virginia Medical Center must have the appropriate credentials and been granted clinical privileges to perform specific clinical procedures whether those procedures are experimental or standard.
* Performing procedures which are outside the scope of the clinical privileges that have been granted may result in denial of insurance coverage should claims of negligence or malpractice arise.
* Contact the Clinical Staff Office- 924-9055 or 924-8778 for further information.

4.Investigator Agreement for Protocols Overseen by a NON UVA IRB

**BY SIGNING THIS DOCUMENT, THE INVESTIGATOR CONFIRMS THAT:**

* I am not currently debarred by the US FDA from involvement in clinical research studies.
* I am not involved in any regulatory or misconduct litigation or investigation by the FDA.
* if this study involves any funding or resources from an outside source, or if I will be sharing data outside of UVA prior to publication that I will contact the Dean’s office regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
* the proposed research project will be conducted by me or under my close supervision. It will be conducted in accordance with the protocol submitted to and approved by the Non UVA IRB including any modifications, amendments or addendums submitted and approved by the Non UVA IRB.
* no personnel will have access to subjects or their information until they have completed the human subject research protection on-line training through CITI and the Non UVA IRB has been notified.
* all personnel working on this protocol will follow all Policies and Procedures of:
* the IRB of Record
* the UVA Human Research Protection Program (HRPP SOPS)
* the School of Medicine Clinical Trials Office: <http://www.medicalcenter.virginia.edu/intranet/cto/index.html>

|  |  |  |
| --- | --- | --- |
| The UVA Corporate Compliance and Privacy Office, a | As soon as possible and no later than 24 hours from the time the incident is identified. | UVA Corporate Compliance and Privacy Office- Phone 924-2938 |
| UVA ITS: if breach involves electronic data- | As soon as possible and no later than 24 hours from the time the incident is identified. | ITS: Information Security Incident Reporting procedure, <https://security.virginia.edu/reporting-information-security-incident-procedure> |
| UVA Police if breach includes such things as stolen computers stolen off UVA Property.  Contact applicable police department if item stolen from UVA grounds. | IMMEDIATELY. | Phone- (434) 924-7166 |

**I agree to carry out the following responsibilities:**

1. Provide the IRB of Record with:
   1. The list of research personnel engaged in the conduct of research;
   2. Evidence of training for all engaged research personnel, including the investigator; and
   3. Any other information required for IRB review.
2. Assure that all research activities at UVA are not initiated until all IRB and funding-related requirements are completed.
3. Assure that any additional UVA requirements for ancillary human research protection reviews (pharmacy, radiation safety, etc.) are obtained and followed.
4. Conduct protocols and obtain informed consent as approved by the IRB and in compliance with IRB of Record’s policies and procedures and all relevant federal, state and local regulations for human subjects’ research.
5. Report to the IRB of Record, all post-approval events such as proposed modifications, protocol violations,
6. Provide any information requested to the IRB of Record that may be necessary for the continuing review process. This may include information regarding subject recruitment, summary of all enrolled subjects, screen failures, minor violations, and all other information needed for continuing review.
7. Notify the IRB of Record within five days of becoming aware of potential unanticipated problems involving risk to subjects or others or of serious or continuing non-compliance.
8. If at any time IRB approval lapses, cease all human subjects research work related to the expired protocol. Notify the IRB of Record of any subjects who are already enrolled who may be harmed if research ceases.
9. Promptly cooperate with any investigations of serious or continuing non-compliance or unanticipated problems.
10. Promptly cooperate with any post approval monitoring conducted by the UVA. Such cooperation will include, but is not limited to, providing research records and related information and meeting with institutional research representatives upon request.
11. Signed consent forms and other research records will be retained in a confidential manner. Records will be kept according to UVA Records Management policies.
12. Cooperate with the IRB of Record in reporting and resolving any conflicts of interest reported by UVA investigators, including but not limited to entering into management plans, as required by the IRB of Record.
13. If written consent is being obtained insert the approved UVA local consent language into all consent forms used to enroll UVA subjects.

**Signature**

**UVA Principal Investigator**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_

Principal Investigator Principal Investigator Date

Signature Name Printed

5.Privacy Plan

**The following procedures must be followed.**

* The data will be secured per the Data Security Plan of this protocol.
* Only investigators for this study and clinicians caring for the patient will have access to data.
* UVA [University Data Protection Standards](http://security.virginia.edu/university-data-protection-standards) will be followed.
* If identifiable data is transferred to any other location such as a desktop, laptop, memory stick, CD etc. the researcher must follow the University’s [Highly Sensitive Data Protection Standard for Individual-Use Electronic Devices or Media](http://security.virginia.edu/highly-sensitive-data-protection-standard-individual-use-electronic-devices-or-media) Additional requirements may be found in the University's [Security of Network-Connected Devices Standard](http://security.virginia.edu/security-network-connected-devices-standard). If identifiable data is taken away from the UVA Health , Medical Center Policy # 0218 will be followed.
  + - * Data will be securely removed from the server/drive, additional computer(s), and electronic media according to the University's [Electronic Data Removal](http://security.virginia.edu/electronic-data-removal-standard) Standard.
      * Data will be encrypted or removed if the electronic device is sent outside of UVA for repair according to the University's [Electronic Data Removal](http://security.virginia.edu/electronic-data-removal-standard) Standard .
      * If PHI will be faxed, researchers will follow the UVA Health Policy # 0194.
      * If PHI will be emailed, researchers will follow the UVA Health Policy # 0193 and [University Data Protection Standards (UDPS 3.0)](http://security.virginia.edu/university-data-protection-standards).
      * Data may not be analyzed for any other study without additional IRB approval.
      * If you are using patient information you must follow UVA Health Policy # 0021.
      * Both data on paper and stored electronically will follow the [University's Record Management policy](http://uvapolicy.virginia.edu/policy/IRM-017) and the Commonwealth statute regarding the Destruction of Public Records.

***If you have a question or concerns about the required security standards contact InfoSec at***

[***it-security@virginia.edu***](mailto:it-security@virginia.edu)

**Summary of Requirements to Comply with UVA Health, Medical Center and University Policies and Guidance as noted above:**

**Highly Sensitive Data** is:

-personal information that can lead to identity theft if exposed or

-data that reveals an individual’s health condition and/or history of health services use.

**Protected Data (PHI)** a type of Highly Sensitive Data, is data combined with a HIPAA identifier

**Identifiable Data** under HIPAA regulations is considered to be *Highly Sensitive Data at UVA.*

A **Limited Data Set** (LDS) under HIPAA regulations is considered to be *Moderately Sensitive Data* at UVA. The only HIPAA identifiers associated with data: dates and or postal address information limited to town or city, state, and zip code.

|  |  |
| --- | --- |
| **Highly Sensitive Data (Identifiable Health Info per HIPAA )** | **Moderately Sensitive Data**  **(Limited Data Set and De-identified data per HIPAA)** |
| *General Issues* | *General Issues* |
| Discussions in private  Do not share with those not on the study team or those who do not have a need to know. | Do not share with those not on the study team or those who do not have a need to know. |
| Password protect | Password protect |
| Physically secure (lock) hard copies at all times if not directly supervised.  If not supervised hard copies must have double protection (e.g. lock on room OR cabinet AND in building requiring swipe card for entrance). | Physically secure (lock) hard copies at all times if not directly supervised. |
| For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely. | For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely. |
| Encrypt  See [Encryption Solutions Guidance](http://security.virginia.edu/encryption)  *Files on UVA Health Network drives are automatically encrypted. If not stored there it is study teams responsibility to make sure data are encrypted.* |  |
| If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVA Purchase order. | If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVA Purchase order. |
| Store files on a network drive specifically designated for storing this type of data, e.g. high-level security server/drives managed by Information Technology Services or the “F” and “O” managed by UVA Heath Computing Services. You may access it via a shortcut icon on your desktop, but you are not allowed to take it off line to a local drive such as the desktop of your computer (e.g. C drive) or to an individual Use Device\*. May access via VPN |  |
| Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract is in place | Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract is in place. |
| If collected without consent/ HIPAA authorization will NOT be allowed to leave UVA HIPAA covered entity unless disclosure is approved by the IRB and the disclosure is tracked in EPIC | If collected without consent/ HIPAA authorization will NOT be allowed to leave UVA HIPAA covered entity unless disclosure is approved by the IRB and a contract is in place prior to sharing of data. |

|  |  |
| --- | --- |
| **Highly Sensitive Data (Identifiable Health Info per HIPAA )** | **Moderately Sensitive Data**  **(Limited Data Set and De-identified data per HIPAA)** |
| *Electronic Data Collection & Sharing* | *Electronic Data Collection & Sharing* |
| (e.g. smart phone app, electronic consent using tablet etc.)  MUST consult with InfoSec or UVA Health Web Development Office: 434-243-6702   * + - University Side: IT‑Security@virginia.edu     - UVA Health: Web Development Center: |  |
| May use:   * Globus * UVA Health Dropbox within Sookasa * Qualtrics Portal for HSD * Any additional programs identified by Information Security at [ITS Web in the Software Gateway](https://virginia.service-now.com/its?id=software_gateway&sys_id=82089b97dbfcab00cebc550a489619b5).  UVAHealth employees can also review [Online Account Request to find additional options](https://hit.healthsystem.virginia.edu/default/index.cfm/help-desk/).   May NOT use:   * UVA Box * UVA Collab * Question Pro * non-UVA licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc. | May use:   * Globus * UVA Health Dropbox within Sookasa * Qualtrics portal for MSD * UVA Box * UVA Collab * Any additional programs identified by Information Security at [ITS Web in the Software Gateway](https://virginia.service-now.com/its?id=software_gateway&sys_id=82089b97dbfcab00cebc550a489619b5).  UVA Health employees can also review [Online Account Request to find additional options](https://hit.healthsystem.virginia.edu/default/index.cfm/help-desk/).   May NOT use:   * non-UVA licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc. |
| The following vendors for handling communication with subjects are NOT allowed:   * Google Voice * Facebook (including Messenger) * Linked In * Snapchat | The following vendors for handling communication with subjects are NOT allowed:   * Google Voice * Facebook (including Messenger) * Linked In * Snapchat |

|  |  |
| --- | --- |
| *Individual-Use Device* | *Individual‑Use Device* |
| Do not save to individual‑use device\* without written approval of your Department AND VP  or Dean.  If approval obtained, data must be password  protected and encrypted. |  |
| Do not save an email attachment containing HSD to an individual use device \* |  |
| *E Mail* | *E Mail* |
| Do not share via email with Outlook Web/ or forward email using other email vendors like Gmail/ Yahoo |  |
| Do not send via email on smart phone unless phone is set up by UVA Health |  |
| Email may include name, medical record number or Social Security number only if sending email to or from a person with \* HS in their email address.  *NOTE: VPR & IRB staff do not meet this criteria!* | In addition to sharing LDS, may include initials if persons sending and receiving email work within the UVA HIPAA covered entity.\*\* |
| *FAX* | *FAX* |
| Verify FAX number before faxing | Verify FAX number before faxing |
| Use Fax Cover Sheet with Confidentiality Statement | Use Fax Cover Sheet with Confidentiality Statement |
| Verify receiving fax machine is in a restricted access area | Verify receiving fax machine is in a restricted access area |
| Verify intended recipient is clearly indicated | Verify intended recipient is clearly indicated |
| Recipient is alerted to the pending transmission and is available to pick it up immediately | Recipient is alerted to the pending transmission and is available to pick it up immediately |
| *TEXT* | *TEXT* |
| Not acceptable. | Only acceptable if using a University contracted phone or with approval from Information Security. |
| LOST OR STOLEN RESEARCH DATA | LOST OR STOLEN RESEARCH DATA |
| Must report in accordance with the protocol and in accordance with the [Reporting an Information Security Incident Procedure](https://security.virginia.edu/reporting-information-security-incident-procedure)  Any data breach must also be reported to the IRB of Record if the report meets the criteria of an Unanticipated Problem. | Must report in accordance with the protocol and in accordance with the [Reporting an Information Security Incident Procedure](https://security.virginia.edu/reporting-information-security-incident-procedure)  Any data breach must also be reported to the IRB of Record if the report meets the criteria of an Unanticipated Problem. |

*\* Individual Use Device – examples include smart phone, CD, flash (thumb) drive, laptop, C drive of your computer,*

*\*\* At UVA this includes the following areas:, the 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.*

*Identifiable health info may also be shared with the following areas without tracking the disclosure as agreements are in place to protect the information:*

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

***APPENDIX A:***

**IRB-HSR Consent/Assent Local Wording Template**

**(For all Single IRB’s except NCI CIRB)**

**Version: 10-13-20**

Note: This document only contains the language requirements for this institution. It is not a complete template. No additional local wording may be added without the written approval of the IRB-HSR.

*NOTE: As updates are made to the local wording template by the UVA IRB, you are permitted to make applicable revisions to your currently approved consent/assent documents.*

1. ***For All consents/assents****, add a space for Participants Name at the top of the first page. Insert place the patient’s sticky label containing name/ medical record number onto the 1st page of the consent form.*

**Participant’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. **In footer include: (**UVA Tracking #**)**

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. *If the study might affect the clinical care of a patient (regardless of whether the study has a certificate of confidentiality) the consent must go to medical records. Add the Bar code on EVERY page of the consent form and the* ***MRN# on page 1 only****.*

 **Medical Record #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. *If there is a* ***Conflict of Interest,*** *add the following section, after the Sponsoring Section, in the* ***consent form.***

# Conflict of Interest

When a person or an organization has a financial or other interest large enough to seem as if it could affect their judgment, it is called a conflict of interest. Members of this study team have a conflict of interest with this study which is explained below. *(Enter any information regarding potential conflict of interest here)*

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. *Under* ***“Who to contact if I have questions about my rights”*** *or similar section, where requested, insert in the* ***consent form****:*

UVA Research Compliance Monitor

P.O. Box 801011 Charlottesville, VA 22908 Telephone: 434-924-8660

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. *Under “Will you be paid for being in this study?” inert the following in the consent form when applicable*

*NEW SECTION REQUIREMENT if UVA Subjects will be compensated*

**INSTRUCTIONS:** If subjects will be compensated with money insert the following section. Do not insert this section for reimbursement of travel expenses.

You will be paid $ for finishing this study by ***indicate the type of compensation-check, gift certificate etc.***

You should get your payment about***insert time frame*** after finishing the study ***or*** about***insert time frame***after each visit. The income may be reported to the IRS as income.

**INSTRUCTIONS:** If the payment will be prorated for incomplete participation, please make this clear by inserting the following paragraph:

If you do not finish the study,you will be paid $ ***insert amount*** for ***insert specifics: e.g. each visit/each procedure. –or-***You will not be paid at all if **you** decide not to finish this study. If the study leader says you cannot continue, you will be paid the full amount for the study.

**INSTRUCTIONS:** If subjects will be reimbursed for travel expenses insert the following section.

You will be reimbursed up to ***enter amount*** for your travel expenses***. Insert specifics such as mileage will be reimbursed at state rate or what other expenses you will reimburse. Also insert any upper limits for things like lodging as appropriate.***

You should get your reimbursement about***insert time frame***after you submit your receipts/ mileage.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. **Risks of Genetic Research**

*If study involves genetic research and similar language is not already in the consent, the UVA site is permitted to enter additional info regarding genetic risks as noted below in the* ***consent form****:*

A Federal law, called the Genetic Information Non-discrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Virginia also has state laws that prohibit employers and health insurers from discriminating on the basis of genetic test results and other genetic information.  Like GINA, these state laws would not protect you from genetic discrimination by other types of insurance providers, such as life insurance or long-term disability insurance.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. **Risks of Gadolinium**

*Enter the following statement in the Risks section of the* ***consent form*** *for those studies that call for an MRI/MRA with gadolinium for research*

**Risk of using gadolinium:**

You will receive or are scheduled to receive a contrast called Gadolinium for your MRI/MRA. This substance will help the tissues show up better.

The following risks are associated with gadolinium contrast:

* Allergic reaction. Some people experience temporary itching after receiving MRI contrast. Less than one person in 300,000 will experience severe allergic reaction, which, requires treatment. Severe allergic reaction may include s difficulty breathing or wheezing, tightness in the throat, swelling of lips, tongue or throat, fast heartbeat.
* Contrast infiltration. Contrast that is injected outside the vein into other tissues can cause local pain and swelling at the injection site. Treatment generally consists of hot or cold packs and elevation of the affected arm. Infiltrations most often get better over time.
* Temporary metallic taste in the mouth, tingling in the arm, nausea, or headache occurs in less than 1 in 100 people.
* The FDA has received information about an extremely rare disease called Nephrogenic Systemic Fibrosis (NSF) is a rare disease that is linked with the use of Gadolinium in people with severe kidney disease.

NSF causes hardening and thickening (fibrosis) of the skin, connective tissues like muscles, tendons, ligaments, and blood vessels throughout the body. In addition, those who develop NSF may have scarring of their body organs. The signs of NSF also include:

* burning, itching, swelling, hardening and tightening of skin;
* red or dark patches on the skin;
* yellow spots on the whites of the eyes;
* stiffness in joints with trouble moving or straightening the arms, hands, legs or feet;
* pain deep in the hip bones or ribs;
* Muscle weakness.

In most of the cases reported to the FDA, symptoms of NSF started between 2 days to 18 months after a person received the Gadolinium-based contrast agent. NSF may get worse and may lead to death. There is no known treatment for NSF.

If you have any of the symptoms listed above after receiving Gadolinium-based contrast for a study MRI/MRA, please contact the study team immediately. The study team will review your symptoms and perhaps recommend a skin biopsy, which is the only way to determine if you actually have NSF.

The FDA has received information indicating that gadolinium may deposit in the brain and other organs of some people who have had four or more gadolinium contrast-enhanced MRI scans and it may remain for a long time. Although no signs or symptoms of negative health effects or changes to organs have been seen with these deposits to date, it is not known if these deposits may lead to negative health effects in the future.

Before you receive gadolinium/additional gadolinium for research:

* You will be screened by UVA Department of Radiology staff prior to getting gadolinium. If radiology screening shows that it might be unsafe for you to receive this contrast, then you will not be able to receive the contrast.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. **Compensation in Case of Injury-*CONSENT FORM ONLY***

**FULL BOARD - FOR INDUSTRY SPONSORED TRIALS OPTION #1 MUST BE USED AND WORDING MUST BE IDENTICAL**

**What if you are hurt in this study?**

**Use one of the options below. The option you choose may not conflict with the language used in the contract.**

Option # 1: Commercial sponsor pays for injuries regardless of insurance type. **This option is required if the study has a commercial sponsor unless you have pre-approval from OSP/SOM Grants and Contracts office to not use this option.**

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability, or discomfort. The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study.  Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

Option # 2: Commercial sponsor pays for those with Medicare/Medicaid, those who are uninsured and those with commercial insurance if the commercial insurer does not pay.

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability or discomfort.  The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study if you are (a) uninsured, (b) insured by Medicare/Medicaid, or (c) insured by commercial (non-government) insurance but your injury or illness is not covered by your commercial insurance.   Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

Option # 3- There is no sponsor, or the sponsor is a government agency such as the NIH or there is a commercial sponsor who has not agreed to pay for injuries.

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

**EXPEDITED - FOR INDUSTRY SPONSORED TRIALS OPTION #1 MUST BE USED AND WORDING MUST BE IDENTICAL**

**What if you are hurt in this study?**

**Use one of the options below. The option you choose may not conflict with the language used in the contract.**

Option # 1: Commercial sponsor pays for injuries regardless of insurance type. **This option is required if the study has a commercial sponsor unless you have pre-approval from OSP/SOM Grants and Contracts office to not use this option**.

If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability, or discomfort. The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study.  Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

Option # 2: Commercial sponsor pays for those with Medicare/Medicaid, those who are uninsured and those with commercial insurance if the commercial insurer does not pay.

If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability or discomfort.  The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study if you are (a) uninsured, (b) insured by Medicare/Medicaid, or (c) insured by commercial (non-government) insurance but your injury or illness is not covered by your commercial insurance.   Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

Option # 3- There is no sponsor or the sponsor is a government agency such as the NIH or there is a commercial sponsor who has not agreed to pay for injuries.

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. **Pregnancy and Drug testing in Minors –*Consent and Assent form for girls if age appropriate add if applicable:***

If you are pregnant or think you might be pregnant please tell us so we may talk about this with you.

***(If applicable*)** If you are female and of child-bearing potential, your blood sample will be tested to find out if you are pregnant. This test must be negative in order to continue study participation. The results of the pregnancy test will be provided to you.  Also, Virginia law requires release of the test results to your parent(s)/legal guardian if they request the results or request a copy of your medical records.

If the results of the drug screen are positive, we will share the results with both you and your parent/guardian and, if necessary, the study doctor will make referrals for treatment. The result must be negative for you to continue participation in this study.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. **IF REVIEWING IRB IS SERVING AS THE HIPAA PRIVACY BOARD INCLUDE THE STATEMENT BELOW- *Consent and Assent form when enrolling minors***

The doctor will talk about you and the research study with your parent/guardian, however, will not talk about it with anyone else except the people working here. If the doctor needs to talk to anyone else about you, they will ask you and your parent/guardian if it is OK.

If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. **SIGNATURE SECTION:**

**Replace with the UVA Signature Section templates as applicable. You are able to use the Model Consent Signature section so long as all relevant sections are accounted for. Verify with the Reviewing IRB.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **NOTE: \*** **SIGNATURE FROM IMPARTIAL WITNESS\* (REQUIRED for ALL CONSENT DOCUMENTS)**  **ADD THE FOLLOWING TEMPLATE SECTION ONLY ONCE AFTER ALL PERTINENT SIGNATURE SECTIONS ARE INCLUDED IN THE CONSENT DOCUMENT**  **Signature from Impartial Witness**  **If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.**  I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions they had about the study.   I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.  **Please indicate with check box the identified individual(s):**  Subject  Parent(s)/Guardian of the subject  Subject’s surrogate  {include only the check boxes pertinent to your study}   |  |  |  |  |  | | --- | --- | --- | --- | --- | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ IMPARTIAL WITNESS (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ IMPARTIAL WITNESS (PRINT) |  | \_\_\_\_\_\_\_\_ DATE | |

**ENROLLMENT OF ADULTS**

**Consent from Adult**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (PRINT) |  | \_\_\_\_\_\_\_  DATE |  |  |

**To be completed by participant if 18 years of age or older.**

**Person Obtaining Consent**

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT(PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

**INSTRUCTIONS:** If verbal assent (and not written assent) will be obtained from the child, DELETE the section

“Assent from Child” below and only include the “Person Obtaining Assent of the Child” section in the consent document:

**ENROLLMENT OF MINORS**

**Assent from Child**

**Consent from the parent/guardian MUST be obtained before approaching the child for their assent.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARTICIPANT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (PRINT) |  | \_\_\_\_\_\_\_  DATE |  |  |
|  | | | | | | |

**Person Obtaining Assent of the Child (less than 18 years of age)**

**Consent from the parent/guardian MUST be obtained before approaching the child for their assent.**

By signing below, you confirm that the study has been explained to the child (less than 18 years of age), all questions have been answered and the child has voluntarily agreed to participate.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING ASSENT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PERSON OBTAINING ASSENT (PRINT) |  | \_\_\_\_\_\_\_  DATE |

**Parental/ Guardian Permission**

By signing below, you confirm you have the legal authority to sign for this child.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (PRINT NAME) |  | \_\_\_\_\_\_ DATE |  |  |
| **INSTRUCTIONS:** Second parent/guardian signature section to be added if there is risk but no benefit to the participant. | | | | | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (PRINT NAME) |  | \_\_\_\_\_\_ DATE |  |  |

**If you are unable to obtain parental permission from both parents/guardians, explain why not:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Person Obtaining Parental/Guardian Permission**

By signing below you confirm that you have fully explained this study to the parent/guardian, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME) |  | \_\_\_\_\_\_\_\_ DATE |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Surrogate Consent for Adult Participant**

In the event the adult participant is unable to give informed consent for participation in this study:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PERSON GIVING CONSENT FOR PARTICIPANT DATE

(Signature/ Printed)

RELATIONSHIP TO PARTICIPANT: *Check one of the options below*

\_\_\_\_\_Agent under an Advance Directive that authorizes participation in research

\_\_\_\_\_Court-appointed Guardian

\_\_\_\_\_Spouse (unless divorce action has been filed)

\_\_\_\_\_Next of kin

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Person Obtaining Consent of the Surrogate**

By signing below you confirm that you have fully explained this study to the potential subject’s surrogate, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Person Obtaining Assent of the Adult Subject**

The subject is unable to give assent due to the following reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**OR**

By signing below, you confirm that the study has been explained to the adult subject, all questions have been answered and the adult subject has not demonstrated resistance or dissent by word or gesture to enroll in the study. You also confirm that if the subject demonstrates resistance or dissent at any point in the study that they will not be subjected to any additional study interventions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING ASSENT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PERSON OBTAINING ASSENT (PRINT) |  | \_\_\_\_\_\_\_  DATE |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Consent of the Subject to Continue to Be in the Study**

Your legal representative gave his/her permission for you to be in this research study. This is because you were not able to make your own decision due to your illness. Your condition is now better. You are being asked to decide whether to continue to be in this study. The decision is up to you. Before you sign this form, please ask questions about any part of this study that is not clear to you. When you sign below, you are saying you understand the information we gave you about the study and in this form.

**If you sign this form it means that you agree to continue being in the study.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

PARTICIPANT (SIGNATURE) PARTICIPANT (PRINT) DATE

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Person Obtaining Consent of the Subject to Continue to Be in the Study**

By signing below you confirm that you have fully explained this study to the subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

PERSON OBTAINING PERSON OBTAINING CONSENT DATE

CONSENT (SIGNATURE) (PRINT)

**INTERPRETER SECTION**

*If the study is explained to a potential subject in a language other than English, the signature of the interpreter is required, and signatures are required on separate forms depending on the language spoken by EACH individual. See table below for additional information.*

|  |  |
| --- | --- |
| ***INDIVIDUAL*** | ***SIGN*** |
| *Subject/Surrogate* | *Translated Short Form OR translated Full Consent* |
| *Interpreter* | *EITHER*   * *Translated Short Form AND English Version of Full Consent* * *Translated Full Consent* |
| *Person Obtaining Consent* | *English Version of Full Consent* |
| *Parent/Guardian* | *Applicable form in language they understand (sign one of the following)*   * *English Version of Full Consent,* * *Translated Full Consent* * *Translated Short Form* |

**The study was explained to the following individuals in a language other than English.**

*Check all that apply.*

Subject

Parent(s)/Guardian of the subject

Adult subject’s surrogate

**Interpreter**

By signing below, you confirm that the study has been fully explained in a language the person understood and that all questions have been answered.

***APPENDIX B:***

**Common Questions and Responses for Completion of Local Site Questionnaires for sIRB**

**(For all Single IRB’s except NCI CIRB)**

**Version: 01-08-20**

**(Information for UVA study team completing Local Site Questionnaire for Reviewing sIRB)**

**Note: If signature required by IRB-HSR, email completed Questionnaire to** [**sirb@virginia.edu**](mailto:sirb@virginia.edu)

**SITE INFORMATION – Section I**

**Site Legal Name**: University of Virginia Health System; University of Virginia Medical Center

**Type of Entity:**

Hospital

Academic Institution

**Site Address:**  1215 Lee St, Charlottesville, VA 22903

**Federal Wide Assurance (FWA) number:** 00006183

**Local IRB Registration Number:** 0000264

**HRPP accredited**-Yes, through AAHRPP

**Date of last Accreditation:** June 2018

**Have there been any government inquires/ investigations in the past 3 years?**  NO

**Describe your entity’s human subject protection training and education requirements for researchers and study staff. Please include initial as well as continuing education.**

<https://research.virginia.edu/sites/vpr/files/2019-08/03-00-Education.pdf>

**Does your organization have a quality assurance/ auditing/post approval monitoring group responsible for overseeing ongoing research?** Yes, see Section 2: <https://research.virginia.edu/human-research-protection-program/hrpp-standard-operating-procedures>

**Are there any other oversight mechanisms?** NO

**Are you affiliated with any separate legal entities where human subjects research might occur?**   NO

**SITE PERSONNEL – Section II**

**Site Administer:** Contact Information for individual who will serve as the Site Administrator/IRB Contact

**Institutional Official (IO)**: Contact information for the Institutional Official

**Signer of Reliance Agreements**: Contact information for person with authority for signing agreements for UVA

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name** | **Email** | **Phone** | **Mailing Address** | **IRB Contact** | **Site Administrator** | **IO** | **Signer of Reliance Agreements** |
| Eileen Sembrowich  Associate Director,  IRB-HSR | ecs3b@virginia.edu | 434-243-6542 | UVA IRB-HSR  One Morton Drive  Suite 400, Box 5  Charlottesville, VA 22903 |  |  |  |  |
| Melur K. “Ram” Ramasubramanian, PhD | mkr5a@virginia.edu | 434-924-3606 | VP for Research University of Virginia PO Box 400301 136 Hospital Drive  Charlottesville, Virginia 22904 |  |  |  |  |

**LOCAL LAWS/REGULATIONS/POLICIES – Section III**

1. **Describe the state law or institutional requirement regarding the use of legally authorized representatives for research. If applicable, please include the priority order in which individuals may sign (i.e. spouse, adult child, parent).**

<https://research.virginia.edu/irb-hsr/surrogate-consent-use-legally-authorized-representative-lar>

1. **What is the age of majority in your state?** Eighteen (18)
2. **Describe any state law or institutional requirement regarding emancipated minors.**

<https://research.virginia.edu/sites/vpr/files/2019-08/Vulnerable_Population_checklist_CHILDREN.doc>

1. **Describe any state laws or institutional requirements applicable to obtaining consent/assent from minors.**

<https://research.virginia.edu/sites/vpr/files/2019-08/Vulnerable_Population_checklist_CHILDREN.doc>

1. **Will reconsent of minors be required once they reach the age of majority?**

<https://research.virginia.edu/human-research-protection-program/hrpp-standard-operating-procedures>

***11.7.5 Consent when a Minor becomes an Adult***

*Individuals enrolled as children with parental or guardian consent must be re-consented when they become adults (e.g. reach the legal Age of Majority in the state where the research is being conducted) unless an IRB determines that a waiver of consent can be granted.*

1. **What are your state reporting requirements for positive HIV, hepatitis, or other infectious disease testing?**

*Any investigator engaged in research in which sensitive information is gathered from human subjects (or any person who intends to engage in such research) may apply for a CoC. Research can be considered "sensitive" if it involves the collection of:1.Research on HIV, AIDS, and STDs; 2.Information about sexual attitudes, preferences, practices; 3.Information about personal use of alcohol, drugs, or other addictive products; 4.Information about illegal conduct; 5.Information that could damage an individual's financial standing, employability, or reputation within the community; 6.Information in a subject's medical record that could lead to social stigmatization or discrimination; or 7.Information about a subject's psychological well-being or mental health. 8.Genetic studies, including those that collect and store biological samples for future use; 9. Research on behavioral interventions and epidemiologic studies. This list is not exhaustive. Investigators contemplating research on a topic that might qualify as sensitive should contact the IRB Office for help in applying for a CoC.*

1. **Describe any laws or institutional polices regarding drug testing, including drug testing of minors.**

*If the results of the drug screen are positive, the researchers will share the results with both the minor and your parent/guardian and, if necessary, the study doctor will make referrals for treatment.*

**Describe any laws or institutional polices regarding genetic testing?**

*Section 25.9*: https://www2.virginia.edu/vpr/hrpp/sop/UVA-HRPP-SOP-FULL-VERSION.pdf

1. **Describe any laws or intuitional policies regarding the return of research results to subjects including genetic testing results.**

<https://research.virginia.edu/irb-hsr/genetic-research>

1. **Does your site prohibit the use of a short form consent process?**  NO
2. **Is any part of the site a covered entity under HIPAA?**  YES

If Yes, is research a considered a covered function?  YES

1. **Does your IRB require that the PI submit an application with your IRB even though IRB oversight will be deferred to an outside IRB?**  YES

<https://research.virginia.edu/irb-hsr/reliance-non-uva-irb-serve-single-irb-sirb-record>

1. **Does your site have a process for the review and management of research related conflict of interest?**  YES

<https://med.virginia.edu/office-for-research/policies-governing-research/conflict-of-interest-committee/>

1. **Does the institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects**?  YES

*A partial HIPAA waiver if required from a Privacy Board for review of medical records to identify eligible subjects.*

1. **Does the institution require HIPAA authorizations to be separate or can they be included in the consent form?** *Include in the consent form*
2. **Local HRPP contact information if subjects wish to speak to someone locally about rights:**

*UVA Research Compliance Monitor*

*PO Box 801011 Charlottesville, VA 22908 Telephone: 434-924-8660*

1. **Please indicated which of the following ancillary committee approvals must be obtained (as appropriate to protocol) before a project can be activated at your site?**

|  |
| --- |
| Cancer Center Protocol Review Committee **(PRC)** |
| **HIRE** (Radiation Committee) Review |
| Institutional Biosafety Committee **(IBC)** |
| **RDRC** |
| **Gadolinium Use for Research** (MR Physicist approval of justification) |
| SOM CTO-**PI of Multi-site/IND-IDE Determination/Outside Academic** |
| **Biomedical Engineering-New Medical Device** |
| **Laser Safety** |
| **Information Security (InfoSec)** |
| **Investigational Drug Services (IDS)-Pharmacy** |
| **ESCRO committee:** viable embryos/embryonic stem cells |
| **Use of Student Data**: GRIME/GMEC |

**REQUIRED CONSENT LANGUAGE – Section IV**

**Provide required consent language pertaining to compensation in the event of research related injury:**

**What if you are hurt in this study?**

Option # 1: Commercial sponsor pays for injuries regardless of insurance type. This option is required if the study has a commercial sponsor unless you have pre-approval from OSP/SOM Grants and Contracts office to not use this option.

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability, or discomfort. The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study.  Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

Option # 2: Commercial sponsor pays for those with Medicare/Medicaid, those who are uninsured and those with commercial insurance if the commercial insurer does not pay.

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability or discomfort.  The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study if you are (a) uninsured, (b) insured by Medicare/Medicaid, or (c) insured by commercial (non-government) insurance but your injury or illness is not covered by your commercial insurance.   Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

Option # 3- There is no sponsor, or the sponsor is a government agency such as the NIH or there is a commercial sponsor who has not agreed to pay for injuries.

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

**Provide required HIPAA/ Privacy language:**

**IF sIRB IS SERVING AS THE HIPAA PRIVACY BOARD INCLUDE THE STATEMENT(S) BELOW-**

The doctor will talk about you and the research study with your parent/guardian but will not talk about it with anyone else except the people working here. If the doctor needs to talk to anyone else about you, they will ask you and your parent/guardian if it is OK. {WHEN ENROLLING MINORS}

If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others. {WHEN ENROLLING ADULTS AND MINORS}

**Provide any additional consent language that is required by the institution:**

*(Attach copy of APPENDIX A -Reliance Agreement Request form when relying on Non-UVA IRB)*

***APPENDIX C:***

**Addendum to the Informed Consent Document to Participate in a Research Study**

**(For all Single IRB’s except NCI CIRB)**

**Version: 01-08-20**

***NOTE: Only submit this addendum to the UVA IRB if the non-UVA IRB does NOT permit any local context additions to the main/core consent***

**UVA Tracking #\_\_\_\_Title: [add to header]**

**What is the purpose of this addendum?**

In addition to the information provided in the main consent for this study, the following is additional information specific to the University of Virginia. Please read this form which describes the additional information in some detail. A member of the research team will describe this additional information to you and answer all your questions. You should consider the following information before agreeing to participate in this research study.

|  |  |
| --- | --- |
| **Principal Investigator University of Virginia:** | <Insert name, address, and phone # of PI> |
| **Sponsor:** | <Insert name of sponsor. If no external sponsor, delete row. > |

**1. Who do you contact if you have questions about your rights as a participant in this study?**  
 UVA Research Compliance Monitor

P.O Box 801011

Charlottesville, VA 22908 Telephone: 434-924-8660

**2. What if you are injured because of your participation in this study?**

**[Choose appropriate option from the list below and delete redundant options]**

Option # 1: Commercial sponsor pays for injuries regardless of insurance type. **This option is required if the study has a commercial sponsor unless you have pre-approval from OSP/SOM Grants and Contracts office to not use this option.**

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability, or discomfort. The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study.  Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

Option # 2: Commercial sponsor pays for those with Medicare/Medicaid, those who are uninsured and those with commercial insurance if the commercial insurer does not pay.

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability or discomfort.  The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study if you are (a) uninsured, (b) insured by Medicare/Medicaid, or (c) insured by commercial (non-government) insurance but your injury or illness is not covered by your commercial insurance.   Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

Option # 3- There is no sponsor, or the sponsor is a government agency such as the NIH or there is a commercial sponsor who has not agreed to pay for injuries.

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

**FOR UVA Study Team ONLY:**

**SUBJECT STUDY ID#**      

**Date Reviewed with Subject:**

**Name of Study Personnel who reviewed with Subject:**