**NUNM Institutional Review Board**

**Initial Review Questionnaire (IRQ)**

**Cover Sheet**

**Study Title:**

*(Type responses in grey text boxes.)*

**Short Study Name or Acronym:**

*(Limit to 54 characters.)*

**Principal Investigator:**

**Brief Scientific Abstract:**

*(Limit description to this page only. Attachments to this submission to be itemized on next page as indicated.)*

**Attachments to this Submission**

(Itemize all required forms, Consent forms, and supporting documents necessary for this submission in the order attached following number 4 below. Some examples of support documents would include a copy of the proposal, surveys, questionnaires, advertisements, brochures, telephone scripts, recruitment and thank you letters, etc. You must include copies of all data-gathering instruments and any prepared scripts used with participants.)

1. IRQ Cover Sheet
2. Investigator Information
3. IRQ
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**NUNM Institutional Review Board**

**Initial Review Questionnaire (IRQ)**

This questionnaire is based on Federal requirements for the protection of human participants in NUNM studies. All research involving humans (including human organs, tissues, fluids, or potentially confidential information), regardless of funding source, must be reviewed by the Institutional Review Board **prior to study start-up**.

Please allow 4-6 weeks for the review process. For further information call 503-552-1847.

See Glossary of Terms at the end of the document.

1. **General Study Information**

**A. Study Title:**

**B. Short Study Name or Acronym:**

*(Limit to 54 characters.)*

**C. Principal Investigator:**

[ ]  Study is an NUNM Investigator-initiated study.

**D. Funding Source:**

[ ]  Federal, NIH

[ ]  Federal, other:

[ ]  Industry

[ ]  Foundation

[ ]  Internal

[ ]  Other:

[ ]  Unfunded Study

**E. Award Number:**

**F. Funding period** *(if an unfunded study, indicate expected length of study)***:**

**Study start date:**

**Study end date:**

**G. Is this a multi-site study? (If a study is being conducted at NUNM and any other institution, it is a multi-site study.)**

[ ] NO

[ ] YES If YES, please indicate the total number of sites involved:

For multi-site studies, the protocol must clearly differentiate what components of the study are conducted at NUNM and what components are conducted elsewhere. **Please identify the page(s) of the protocol that cover the following:**

1. Research conducted at NUNM:
2. Research conducted elsewhere:

**H. Study Type (check all that apply):**

[ ]  Pilot study

[ ]  Clinical Trial

 [ ]  Phase I

 [ ]  Phase II

 [ ]  Phase III

 [ ]  Phase IV

[ ]  Survey, questionnaires, interview, or non-interventional studies

[ ]  Data only study

[ ]  Retrospective

[ ]  Prospective

[ ]  Secondary data analysis

[ ]  Pre-existing biological specimens

[ ]  Specimen collection only

[ ]  Other:

1. **Study Description**

**A. Scientific Purpose/Rationale:**

1. Briefly explain the scientific purpose of the study and provide page numbers for where a full description of the scientific purpose may be found in the main study documents.
2. Briefly describe the scientific rationale of the study and provide page numbers for where a full description of the scientific rationale may be found in the main study documents.

**B. Study Design Elements:**

What elements of study design are included in this research project? Check all that apply:

[ ]  Questionnaire or Survey

[ ]  Interview

[ ]  Observational

[ ]  Retrospective Chart Review

[ ]  Contributing to/receiving from a data/tissue repository

[ ]  Specimen Analysis

[ ]  Use of Focus Groups

[ ]  Intervention

[ ]  Video or Audio Taping

[ ]  Instruction/Curriculum

[ ]  Other:

**C. Study Hypothesis:**

**D. Specific and Secondary Aims:**

**E. Study Protocol**

Itemize what will happen at each study visit using bulleted lists when possible. Include a study timeline or table of study visits. Include the amount of time participants can expect to spend, for example, on the phone for study purposes, at treatment or other study visits, and filling out questionnaires. Provide enough detail to allow the IRB to clearly understand what the study is about and how it will flow. **In addition, please reference the relevant pages in the main study documents.**

**F. Data Analysis Plan**

Briefly describe the plan for data analysis. State who will conduct the analysis and where the analysis will take place. Please provide page numbers for where the full data analysis plan may be found in the main study documents.

1. **Recruitment Plan and Participant Characteristics**

**NOTE: Recruitment activities must not begin until IRB approval has been awarded.**

**A. General Recruitment Information**

Briefly describe how participants will be recruited (referral, advertisements, etc.). Attach copies of all materials used to recruit participants. If NUNM students or patients of a study investigator will be recruited, describe how coercion will be avoided.

1. If participant family members will be recruited, state how they will be contacted:
2. Number of study participants to be recruited:
3. Number of study participants to be enrolled:
4. Number of participants expected to complete the trial:

**B. Inclusion/Exclusion Criteria**

1. List inclusion and exclusion criteria:
2. How and by whom will eligibility be determined?
3. If only one gender is included in the study, please explain why:
4. If children are included, please explain why:
5. If non-English speaking people are excluded, please explain why (inadequate funding alone is not sufficient reason for exclusion):

**C. Vulnerable Participants**

1. Check the boxes for all participants that you intend to specifically recruit:

[ ]  Fetuses

[ ]  Neonates

[ ]  Mentally ill with impaired decision-making capacity

[ ]  Medically ill with impaired decision-making capacity

[ ]  Pregnant women

[ ]  Prisoners

[ ]  Children (ages 0-18)

[ ]  Elderly

[ ]  Non-English speaking

[ ]  NUNM Students

1. Please justify inclusion of participants from the Vulnerable Participants list:
2. Is this a fertility study during which there is a possibility of participants becoming pregnant?

[ ]  NO [ ]  YES

**D. Participant Identification and Recruitment**

Age range: from       to

NUNM sources of participants/data/specimens (check all that apply):

**Note that NUNM is responsible for the safety of all participants.**

[ ]  NUNM patients

[ ]  Family members of NUNM patients

[ ]  NUNM students

[ ]  NUNM faculty

[ ]  NUNM staff and administration

[ ]  General Public

[ ]  Healthy volunteers

[ ]  Other – Receiving specimens/data from a research repository. If selected, identify title and ID # of repository:

1. Will any identifiable information be accessed prior to informed consent when identifying potential participants?

[ ]  NO If NO, explain how you will identify and recruit participants.

[ ]  YES If YES, please complete *Waiver of Authorization for Consent* below.

1. Are you going to identify and/or recruit patients in the NUNM clinics?

[ ]  NO If NO, explain how you will identify and recruit participants:

[ ]  YES If YES, please specify explicitly how you intend to identify and/or recruit participants in your study.

1. Does this study require contacting individuals to determine if they are willing to participate?

[ ]  NO If NO, explain how you will identify and recruit participants:

[ ]  YES If YES, explain in detail how contact will occur. If phone calls/electronic communications/letters/etc. will be used, attach a copy of the script for each.

**E. Advertisements**

**NOTE: All participant recruitment materials must be approved by the IRB before recruitment begins.**

1. Will advertisements be used to recruit participants?

[ ]  NO [ ]  YES

1. If YES, indicate the type:

[ ]  Posted Advertisements

[ ]  TV or Radio

[ ]  Brochures

[ ]  Internet

[ ]  Newspaper or Magazine

[ ]  Other:

1. Will any other materials be used to recruit participants?

[ ]  NO [ ]  YES, please specify:

**Please attach a copy of all recruitment materials.**

1. **Consent**

**A. General Consent Information**

Describe when, where, and how consent will be obtained and by whom. Describe whether participants will be given time to review the consent prior to signing. If not, explain what steps you have taken to ensure that participants will understand the consent process.

**If vulnerable populations are included, specifically describe how consent will be obtained and any special materials that will be used.**

**Non-English Speaking Participants**

So that the IRB can establish that you have taken steps to minimize the possibility of coercion or undue influence, please describe:

1. In what language you intend to conduct the informed consent session.
2. How you will assure that the language used is understood by the prospective participant or the legally authorized representative.
3. Whether any additional steps will be taken to minimize possible coercion or undue influence. If so, what steps will be taken?

**B. Capacity to Consent**

1. Will participants have the capacity to give informed consent?

[ ]  NO If NO, explain how and by whom capacity to consent will be determined. What procedures will be in place to safeguard the participant from coercion?

[ ]  YES

1. Will a *Waiver of Authorization for Consent* be requested for any part of the study? (As an example, a Waiver of Authorization should always be requested if a review of patient records will take place for recruitment purposes prior to signed consent.)

 [ ]  NO

 [ ]  YES If YES, fill out *Waiver of Authorization for Consent* below.

**C. Waiver of Authorization for Consent**

(Examples that would require a waiver could include but are not limited to a review of medical records for recruitment purposes prior to consent or a study that involves only data collection and analysis and signed consent is not being requested for approval by the IRB.)

1. Explain why a *Waiver of Authorization for Consent* is requested for a specific activity during this study.
2. If a *Waiver of Authorization for Consent* is requested, please describe how it does not violate the rights of study participants. Please also explain how consent will subsequently be obtained.

**D. Clinic Visits**

When research is conducted in a clinical facility where a participant is accustomed to receiving patient care outside of the study, or by an investigator who is also or has been that participant’s clinician, the lines between research and clinical care can become blurred. It is important to prevent such confusion from happening. The questions in this section address the need to differentiate usual care from research.

1. Does this study involve any usual care, such as a “usual care” study arm or particular procedures? (Usual care is medical or other treatment or services that a research participant would receive, even if they did not participate in the research study.)

[ ]  NO

[ ]  YES If YES, answer sections a. and b.

[ ]  N/A

1. Indicate the individual or entity (e.g., the appropriate research personnel vs. the participant’s health care provider) responsible for relevant aspects of the:
* Research:
* Usual care:
1. Indicate how the participant will be able to identify which activity (e.g., treatment or service) is research and which is usual care, and also how the participant will know who (i.e., the researcher or the health care provider) is responsible for the following:
* Explaining potential risks and benefits of the treatment or service to the participant.
* Providing the treatment or service.
* Monitoring the treatment or service.
* Defining whether any adverse events result from usual care or research.
* Alerting the participant if there is a problem with the treatment or service (e.g., a newly discovered risk, a product recall, etc.).
* Documenting the participant’s clinical course while receiving the treatment or service.

**Include page references to where this information is provided in the main study documents.**

**E. Deception**

Will deception be used as part of this study? (*Note: Deception does* ***not*** *include the use of placebo as this is declared in the Consent form.*)

[ ]  NO

[ ]  YES If YES, explain how deception will be used, how it will not compromise participant rights, and how the participant will be debriefed.

**F. Risks to Participants**

Describe any potential risks to participants for each activity that will occur (e.g., blood draws, physical exams, surveys and questionnaires, etc.). Describe how risk will be mitigated as much as possible (e.g., qualified study staff to draw blood, physician to give physical exams, etc.).

**G. Benefits to Participants**

Describe potential benefits to participants. Receiving an incentive is not considered a benefit. Lab tests and free supplements are not necessarily a benefit. However, a chest x-ray as part of the study could be considered a benefit.

**H. Cost to Participants**

Will participants be responsible for any costs associated with participation?

[ ]  NO If NO, state who is responsible for costs.

[ ]  YES If YES, please include the page reference for where costs are explained in the Consent form.

**I. Incentives**

Will participant incentives be used as a part of this study?

[ ]  NO

[ ]  YES If YES, explain what kind or the amount, how it will be distributed, and what will happen if a participant leaves the study early. Also, include the page references for where this information is provided in the Consent form.

If individuals outside of the study team will be paid for referring or enrolling participants in the study, state who will be paid for referring or enrolling, how much, and under what circumstances.

**J. Genetics**

Does this study involve the use of biological specimens used in genetic tests or stored for possible future genetic testing, or will data be obtained that include results from genetic tests? Genetic tests include tests to determine the existence or risk of a disease, disorder, trait, propensity, or syndrome, including nucleic acids (DNA, RNA, mitochondrial DNA), chromosomes, or proteins.

[ ]  NO

[ ]  YES If YES, describe tests to be included as part of this study.

**Will consent be obtained for the genetic portion of this study?**

[ ]  NO, a *Waiver of Authorization for Consent* is being requested (e.g., large data-collection-only study or use of previously-collected specimens).

[ ]  YES

**In Oregon, the public is allowed to opt out of genetic research. If signed consent will not be obtained, procedures must be in place to exclude those who have previously opted out of genetic research. Generally, this means running potential participants through an exclusion database containing the names of individuals who request to be omitted from any genetics research.**

1. **Data**

**A. How Will Research Data Be Obtained?**

Please check all that apply:

[ ]  Medical history and exams/treatment at intervals as specified in the protocol

[ ]  Labs, imaging studies, or other diagnostic procedures at intervals as specified in the protocol

[ ]  Questionnaire(s) – submit copies of each

[ ]  Survey(s) – submit copies of each

[ ]  Medical Record Review

[ ]  Analysis of human biological specimens

[ ]  Collected from an existing research repository/use of data from previous research

[ ]  Indicate name and ID number of research repository:

[ ]  Audio tape recordings, videos, or photographs

[ ]  Other:

**B. Instruments**

Itemize below the data-collection instruments (e.g., questionnaires, surveys, study charts, etc.) to be used for this study and describe their purpose.

**C. Accessing/Using/Disclosing Information (under HIPAA and NUNM regulations)**

**NOTE: Study participants must agree to the sharing of their PHI and the following sentence must be included in the HIPAA section of the Informed Consent: ‘**Your permission to use your identifiable health information (your HIPAA authorization) will expire when the study is complete.’

Select which of the following 18 identifiers will be accessed, collected as data and/or disclosed during the course of this study:

[ ]  Names

[ ]  All geographical subdivisions smaller than a State (i.e., street address, city, county, precinct, zip code, etc.)

[ ]  All elements of dates (except year) for dates directly related to an individual (including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates indicative of such age—note that such ages and elements may be aggregated into a single category of age 90 or older)

[ ]  Telephone numbers

[ ]  Fax numbers

[ ]  Electronic mail addresses\*

[ ]  Social Security numbers

[ ]  Medical record numbers

[ ]  Health plan beneficiary numbers

[ ]  Account numbers

[ ]  Certificate/license numbers

[ ]  Vehicle identifiers/serial numbers, including license plate numbers

[ ]  Device identifiers and serial numbers

[ ]  Web Universal Resource Locators (URLs)

[ ]  Internet Protocol (IP) address numbers

[ ]  Biometric identifiers, including finger and voice prints

[ ]  Full face photographic images and any comparable images

[ ]  Any other unique identifying numbers, characteristics, or codes? Please identify:

[ ]  None of the above/Not applicable

**\*NOTE: E-mails to participants/research team members cannot contain information that would be considered sensitive, such as Protected Health Information (PHI) or references to a health concern, unless the e-mail is encrypted.**

**D. Sources of Protected Health Information (PHI)**

Indicate the source(s) from which you will obtain **protected health information**:

[ ]  Physician/clinic records

[ ]  Lab, pathology and/or radiology results

[ ]  Analysis of biological specimen(s) obtained from the participants in this study or from a repository

[ ]  Interviews/Questionnaires

[ ]  Mental Health records

[ ]  Billing records

[ ]  Other:

Explain why the PHI you will access/use/collect (as indicated in sections C and D above) is the minimum necessary to conduct this research and cannot be reduced further:

**E. External Sharing of PHI**

Indicate to whom PHI may be disclosed during the course of the research study:

[ ]  Clinicians in Private Practice

[ ]  Consultants

[ ]  Statistician(s)

[ ]  Personnel Not Listed as Investigators on this Study

[ ]  Data, Tissue, Specimen Registries

[ ]  Clinicians at NUNM Community Clinics

[ ]  Sponsor

[ ]  Data Monitoring Committee

[ ]  Non-NUNM Researchers (specify):

[ ]  Publications(s)

[ ]  Other Research Laboratory(ies)

[ ]  PHI will not be shared

**NOTE: If PHI is to be disclosed to any of the above individuals/entities, permission must be obtained from the participant in the informed consent/HIPAA authorization document.**

Please explain (*and* be sure to include this information in the consent/HIPAA authorization document):

1. **Which elements** of PHI (health information plus any of the 18 HIPAA identifiers) will be disclosed to the individuals or entities identified above.
2. **When** the sharing of PHI will occur.
3. **Who** will receive the PHI and **why.**

**F. Internal Sharing of PHI**

Indicate to what extent your participants’ health information and/or data will be identifiable at each of the following time points:

At the time the health information/research data is **initially received or accessed** by the research team at NUNM, it is:

[ ]  Directly linked or accessed through identifiers listed above in Section C under Data.

[ ]  Accessed or received with a code that can be linked to identify the participant.

* Who will have access to the key code?
* Where is the key to the code maintained?
* Please describe how the code will be generated/created.

[ ]  Received or accessed with limited identifiers – i.e., only dates (such as date of birth, death, admission, etc.), city, state, or ZIP codes, and/or age). All other identifiers are not included with the data. Note that the entity providing the information may require completion of a *Data Use Agreement*.

[ ]  De-identified (anonymous – without any identification that may link to a specific participant).

At the time the health information/research data is **collected/used by the research team at NUNM**, it is:

[ ]  Directly linked or accessed by any of the identifiers listed above in Section C under Data.

[ ]  Collected or recorded with a code that can be linked to the identity of the participant.

* Who will have access to the key code?
* Where is the key to the code maintained?
* Please describe how the code will be generated/created.

[ ]  De-identified (anonymous – without an identification that may link to a specific participant).

At the time the health information/research data is **disclosed/stored outside of NUNM** (for example, to other researchers at other institutions), it is (select all that apply):

[ ]  N/A – no health information/research data is disclosed outside the research team (i.e., it will never leave NUNM in any form).

[ ]  Disclosed to another clinic or site under this protocol and the transfer of information/data is described in the protocol. The protocol is approved by each institution’s IRB and is active at each site.

[ ]  Disclosed in accordance with the protocol, informed consent form, and HIPAA authorization. Only the identifiers and data noted in those documents are disclosed.

[ ]  Disclosed in accordance with a waiver of informed consent/HIPAA authorization. (Note that the Privacy Act will not permit you to disclose patient/participant name, address, phone number, or social security number under such a waiver.) Appropriate Data Use or Data Transfer Agreements must be completed and submitted to the IRB with this IRQ.

[ ]  Data/information disclosed will be linked only to limited identifiers (age, dates – such as date of birth, death, admission, etc. – and geographic codes – such as city, state, or ZIP codes). All other identifiers are not included with the data.

[ ]  Data/information disclosed will be coded and can ultimately be linked to the identity of the participant.

* Who will have access to the key code?
* Where is the key to the code maintained?
* Please describe how the code will be generated/created:
* Will the recipient of the data outside NUNM have access to the key code?

[ ]  NO

[ ]  YES If YES, is this disclosure covered in the informed consent form and HIPAA authorization?

Will this study require a Data and Safety Monitoring Board?

[ ]  NO

[ ]  YES If YES, who will serve on it?

**G. Data Handling**

Describe plans to protect the privacy of research participants during their involvement in the research (for example, consent, interviews and procedures will occur in a private room).

Unless anonymous at the time of initial receipt and/or access, describe the PI’s plan to protect the confidentiality of data when identifying and recruiting participants, and when collecting data during the course of the study:

**If any of the research data (identifiable or de-identified) will be disclosed outside of NUNM:**

1. Describe the type of health information/research data/forms that are used and stored outside NUNM (for example consent forms, case report forms, lab results, etc.).
2. How are the data/forms transferred from one location to another?

**Electronic Data Transfer:**

[ ]  E-mail with PKI encryption

[ ]  Encrypted CD/DVD

[ ]  NUNM-issued USB flash drive (FIPS compliant)

[ ]  Other:

**Hard Copy Data:**

[ ]  FedEx/UPS (with tracking)

[ ]  Hand-carried by Research Staff (but never taken home)

[ ]  Other:

1. Who will receive the data?
2. How will data be stored at its destination?
3. What plans are in place for returning or destroying data?

**NOTE: Protected Health Information must not be transmitted via e-mail unless data and accompanying passwords or other mechanisms are properly secured. Microsoft Outlook is not a secure form of data transmission, unless information is encrypted.**

**Expiration Date or Event for Retention of Identifiers**

Currently, NUNM regulations require that all research records, including identifiers, code keys with identifiable data, etc., be retained for a *minimum* of three years and then destroyed appropriately.

1. **Investigator and Study Personnel Information**

**A. Principal Investigator**

Is the Principal Investigator licensed, credentialed, insured and privileged at NUNM to perform all interventions (such as physical/mental exams, lab test interpretation, adverse outcome diagnosis, medication prescription/renewal, or invasive procedures) proposed in this research project?

[ ]  NO A licensed, credentialed, and privileged clinician must be identified as the “responsible clinician” for this study. That person must also complete and attach the Clinical Investigator Assurances Form.

[ ]  YES Complete and attach the Principal Investigator Assurances Form.

[ ]  N/A If no interventions.

**B. Clinical Investigators**

**Do the study clinicians have clinical privileges at NUNM clinics?**

[ ]  YES Complete and attach the Investigator Assurance Form.

[ ]  NO If NO, complete information below for the clinician who assumes medical responsibility for the research project. Complete and attach the Clinical Investigator Assurance Form.

Name with Degree:

Malpractice Insurance: [ ]  NO [ ]  YES

Liability Insurance: [ ]  NO [ ]  YES

Clinic Name and Address:

Is this a mentored project for which the PI is acting as a mentor for someone in training (e.g., a MSiMR student)?

[ ]  NO

[ ]  YES Identify the trainee:
If YES, the PI (mentor) must attend the IRB meeting at which the study is initially reviewed.

**C. Study Personnel**

List all personnel involved in the study (both NUNM and non-NUNM personnel) with the Principal Investigator first. All collaborators must be included.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Last Name | Degree | Study Title/Role | Email | Phone |
|       |       |       |       |       |
|       |       |       |       |       |
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|       |       |       |       |       |

Please list any individuals with a potential conflict of interest and describe conflict:

1.
2.
3.
4.

**D. Non-NUNM Personnel**

Only students and other trainees (including residents and fellows) from NUNM may work on research to fulfill educational requirements within an NUNM facility or use data or human biological specimens that have been collected within NUNM for clinical, administrative, or research purposes.

For all non-NUNM personnel included above, indicate below what type of agreement (e.g., Data Use and Business Use agreements) will be in place for this study.

|  |  |  |
| --- | --- | --- |
| Name | Institution | Relationship Between Institutions |
|       |       |       |
|       |       |       |

**E. Required Training for All Study Personnel**

List the dates of Principal Investigator and Co-Investigator(s) (including non-NUNM investigators) Responsible Conduct of Research (RCR) training (***RCR every 5 years)***, Disclosure of Significant Financial Interest (DSFI) compliance ***(DSFI must be current within one year)*** and HIPAA (***HIPAA every 5 years)*** compliance training.

Name RCR Date HIPAA Date DSFI Date

Does the Principal Investigator attest that ALL other study personnel, NUNM and non-NUNM, are current with DSFI ***(DSFI must be current within one year)***, RCR and HIPAA ***(RCR and HIPAA current within 5 years)*** compliance training (if they have access to personal data on the study)? This would include but is not limited to outside clinicians, translators, transcription services, etc.

[ ]  YES

**The PI attests that:**

*Please Initial*

1. Only one person will have access to the study key.
2. Only authorized study staff will have access to study data.
3. Hard copies of study data will be stored in a secure environment (locked cabinets in locked offices).
4. Electronic data will be stored on password-protected computers.
5. Only data necessary to meet the specific aims of the study will be collected and analyzed.
6. No data will be collected or shared until all necessary approvals and forms are signed and in place.
7. The study will remain open during the publication period.
8. Study data will be destroyed (e.g., shredding, burning, or erasing) three years after the Final Review

 Approval.

**Comment Section**

*(Please include any comments you feel would be relevant to the IRB that we have not previously requested in this document.)*

**References**

**Signature**

I attest that the information provided in this document is true and correct.

Principal Investigator Name (Print)

Principal Investigator Signature Date

**Glossary of Terms**

**Business Associate Agreement:** An agreement between two parties, where the ‘business associate’ is either a person or entity that grants either services, representation, or access to Person Health Information, and the covered entity making the request.

**Clinical Procedure:** Any procedure, test, or exam performed by a licensed practitioner (includes blood draws, imaging procedures, genetic tests for clinical purposes run in a CLIA approved lab, and non-invasive exams).

**Coded Samples:** Samples labeled with a code rather than a name or other personal identifier. When such samples are obtained from a tissue repository, the repository usually retains information that links the code to a particular human specimen. Using this information, the investigator, the repository, or a third party could determine which particular person or small group of identifiable individual provided the biological specimen. Depending on the nature of the identifiers that are associated with the specimen, the sample may or may not meet the definition of a “limited data set” as provided by HIPAA. The IRB will make this determination and also determine if the use of the sample, as specified in the protocol, requires a data use agreement, tracking of disclosure, or business associate agreement.

**Coded with a Unique Identifier:** Study participants are assigned an exclusive number or symbol for privacy purposes. A key linking the participant to their identifier is kept separately from patient information to keep files anonymous.

**Data Use Agreement:** This agreement is for a covered entity to acquire a limited data set from an outside source for research, public health, or healthcare operations.

**Fully Identified Data:** Information that has Personal Health Information.

**HIPAA Research Authorization Form:** A Privacy Rule Authorization is an individual’s signed permission to allow a covered entity to use or disclose the individual’s protected health information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization.

**Identifiable Samples:** Samples collected and supplied to investigators with personal identifiers sufficient to allow identification of the person who provided the material.

**Limited Dataset:** A subset of a total body of data.

**Non-limited Dataset:** All access to a set of data.

**Personal Health Information:** Health information that is specific to a person (i.e. name, date of birth, address, phone number, hospital ID#, place of birth, etc.)

**Phase Zero Trial:** Phase 0 studies are exploratory studies that often use only a few small doses of a new drug in a few patients.

**Phase I Clinical Trial:** Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, and begin to identify side effects.

**Phase II Clinical Trial:** The drug or treatment is given to a larger group of people to evaluate its dosing and safety.

**Phase III Clinical Trial:** The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

**Phase IV Clinical Trial:** Studies are done after the drug or treatment has been marketed to gather information on the drug’s effect in various populations and any side effects associated with long-term use. In addition, Phase IV trials evaluate different indications for the drug.

**Pilot Study:** A pilot experiment, also called a pilot study, is a small-scale preliminary study conducted before the main research in order to check the feasibility or to improve the design of the research.

**Tracking of Disclosure Agreement:** Tracking the legal agreements between two or more Parties in which agreement is required before actions in either party’s interest are taken. This agreement or partnership is disclosed to the public.

**Unidentified (Anonymous) Data:** Data that has removed all Personal Health Information.

**Unidentified Samples:** Samples that are/were obtained and stored without any identification that may link the specimen to a specific participant.

**Unlinked (Anonymized) Data:** Data that has removed all Personal Health Information.

**Unlinked Samples:** Samples that may have been acquired from identified human participants, but all identifiers or codes have been removed and destroyed. For unlinked samples, it would be extremely difficult for the investigator, the repository, or a third party to identify the person who provided an individual samples.