Rev 07/19/15 kbk

BIOLOGICAL SPECIMENS COLLECTION AND STORAGE FORM

Please complete this form and add it to your list of documents on the IRQ.

1. Types of biological samples being collected (check all that apply):

- ☐ Blood
- ☐ Sputum
- ☐ Urine
- ☐ Saliva
- ☐ Buccal swab
- ☐ Tissue: specify: _____
- ☐ Other: specify: _____

2. Biological samples will be (check all that apply):

- ☐ Pre-existing
- ☐ Collected de novo (newly collected)
- ☐ Collected for use in this research protocol only
- ☐ Collected for storage in a tissue bank or repository. Storage is defined as any retention other than a temporary retention to permit reanalysis of a degraded sample or a questionable result.
- ☐ Collected as part of a diagnostic or therapeutic procedure (e.g. tumors being biopsied).

3. Biological samples will be (check all that apply (a – d)):

a. ☐ Collected from an NUNM site[1] and
   - ☐ Fully identifiable'
   - ☐ Coded with a unique identifier[2]
   - ☐ Unlinked (anonymized)[3]
   - ☐ Unidentified (anonymous)[4]

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[1] **NUNM site including: Ross Island Bridge Campus and NUNM Clinic**

[2] **Identified samples**: Samples collected and supplied to investigators with personal identifiers sufficient to allow identification of the person who provided the material.

[3] **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 person. Using this information, the investigator, the repository, or a third party could determine which particular person or small group of identifiable individuals provided the biological specimen. Depending on the nature of the identifiers that are associated with a 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 disclosures, or business associate agreement.

[4] **Unlinked Samples (Anonymized):** Samples that may have been acquired from identified human subjects, 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 sample.

b. ☐ Received from non-NUNM site. Complete "Non-NUNM DATA COLLECTION Form".
- ☐ Fully identifiable'
- ☐ Coded with a unique identifier[3]
- ☐ Unlinked (anonymized)[4]
- ☐ Unidentified (anonymous)[5]

c. ☐ Transmitted outside NUNM[6]
- ☐ Fully identifiable'
- ☐ Coded with a unique identifier[3]
- ☐ Unlinked (anonymized)[4]
- ☐ Unidentified (anonymous)[5]

d. ☐ Research test results will be released to participants
- ☐ No lab results will be given to study participants
- ☐ All lab reports will be released to study participants.
- ☐ Some lab reports will be given to participants: please list.
- ☐ Lab performing the test is CLIA approved for that test. **Include a copy of the CLIA certification with this submission** (Any person or facility that performs laboratory tests on human specimens for the purpose of diagnosis and/or treatment is required by federal law to have a CLIA certificate).

[5] **Unidentified samples (anonymous):** Samples that are/were obtained and stored without any identification that may link the specimen to a specific subject.
[6] Include this site on the HIPAA Research Authorization Form