Washington University
Weihl Laboratory
Standard Operating Procedure
Tissue Banking GRASP-LGMD

Effective Date 26 August 2019

I. SCOPE

1. The purpose of the SOP is to guarantee safe and efficient operations and to describe the principles that guide the approach to physicians and researchers regarding the use of banked blood/tissue samples.

II. DEFINITONS

1. None

III. PROCEDURES

1. Informed Consent
   Prior to the collection of human tissue, informed consent must be obtained with the following requirements.
   a) Consent for the collection of tissues samples will be done by way of informed consent document, parental permission form and assent form (as appropriate).
   b) The site study coordinator, PI or Sub-I will review the consent form, including risks and benefits, before consent is signed.
   c) No sample collection will occur prior to signing consent.
   d) Sample collection log form will be prepared to document samples collected and signature of reporter collecting/shipping samples

2. Protection Privacy and Confidentiality
   a) Samples will be de-identified by the study coordinator and upon collection of the samples, or receipt of the samples and sample form documentation if they are shipped to the site.
   b) Each participant will be assigned a unique study number (a unique kindred and DNA identifier number may also be assigned).
   c) A link between the study number and participant's protected health information will be maintained in the REDCap data capture system, only accessible by PI.
   d) REDCap resides in a HIPAA compliant protected space within Washington University. The principal investigator and the approved research staff will have access to the REDCap project. All information is kept on password protected computers and in locked filing cabinets.

3. Request Process for Specimen and Data Use in Future Research
   a) If another investigator wishes to use specimens or data for use in their own research they will provide a request via email to the principal investigator. The request will include justification for sample need and intended use.
   b) Requests can be made either directly to the PI or through a study coordinator.
   c) After the PI reviews the request, a data use agreement or material transfer agreement will be drafted including acceptable use of the specimens/data, restrictions on use, human subject protection, sharing of specimens with third parties or commercial use.
   d) IRB approval or waiver of approval will be necessary for each request by the requesting site.
   e) All specimens and data will be de-identified before they are shared.
   f) The samples will be prepared in the PI's research lab.

g) All specimens that are sent out will be logged in the lab's sample log with the study ID, date, amount and individual the sample is being shared to.
h) When shipping samples, all shipments will be tracked with a tracking number through FedEx.

4. Procedures for returning research results to participants
   a) In general, results from future research with tissue samples will not be returned to participants.

5. Governance and Oversight
   a) Specimen collection will be conducted according to the current and IRB approved protocol.

6. Destruction
   a} The PI and study coordinators will be responsible for the destruction of the specimens and data if the repository closes.

7. Custodianship
   a) If the PI leaves the institution he will appoint an individual to maintain the specimens, or the specimens will be destroyed.