LMU INSTITUTIONAL REVIEW BOARD
HUMAN BIOSPECIMEN REPOSITORY APPLICATION

Instructions:

- Use this form only if you are engaged specifically in collecting and/or retaining specimens for research in a bank or repository. The research may qualify for exempt, expedited, or full committee review depending on what is involved in the study.
- Do not use this form if you are obtaining specimens for analysis or banking that are already described in another application as part of an intervention study and will be destroyed when the study is done or will remain in a currently approved repository.

Note: There are 3 sections on this form

- If this study involves banking of specimens at Lincoln Memorial University or shipping to another institution, only sections A and B apply.
- If this study involves administration of a bank/repository that is not involved in the collection process but only receives specimens from other sources, sections A and C apply.
- If this study involves collection and banking of specimens as well as oversight of the repository, complete sections A, B and C.

Section A: General Information	
Principal Investigator/Credentials:	Institution/Department:
PI Mailing Address:	LMU IRB#:
E-mail address:	Phone/Fax/Pager:
Study Title:	
1. This protocol involves (check all that apply):	☐ Specimen Collection for specified purpose ☐ Specimen Collection and banking for future unspecified use ☐ Specimen banking and/or repository administration of existing specimens
2. Approximately how many specimens do you expect to collect or bank each year (best estimate)?	☐ 1-99 ☐ 100-999 ☐ 1000-9,999 ☐ 10,000 or more
3. What types of specimens will be collected and/or banked for future research? (check all that apply)	☐ Blood ☐ Serum ☐ Plasma ☐ DNA/RNA ☐ Cell cultures ☐ Tissue (describe): ☐ Existing/archival materials (source): ☐ Other (describe):
Reminders ▪ Specimens may not be collected, received or distributed without IRB approval ▪ Generally, personal identifiers may not be released to specimen recipients ▪ Specimen use should be consistent with the uses described in the protocol and specimen donor consent form	

Section B: Specimen Collection and Informed Consent Process: This section applies only to investigators who are engaged in the actual collection process from research subjects.	
1. Specimens are (check all that apply):	☐ Remaining/existing clinical specimens from a diagnostic or therapeutic procedure (*Archived*)

	☐ Specimens collected at the time of clinical care and leftover used for *research purposes* ☐ Specimens collected for *research purposes only* ☐ Other (explain briefly):
2. How will consent be obtained?	☐ Specimen banking consent form ☐ Separate specimen banking section within a research study consent form ☐ Surgical consent form ☐ Requesting waiver (Complete *Attachment B*) ☐ Other (explain briefly): needs explanation
3. Specimen Preparation Methods (check all that apply):	☐ Paraffin embedded (blocks) ☐ Frozen ☐ Other (please specify):
4. Where will the specimens be stored (check all that apply)?	At LMU (complete **Section C** below): ☐ LMU central Human Tissue Repository (HTR) ☐ LMU satellite repository (PI is housing specimen) Transferred from LMU to an external Repository (Check all that apply and specify where): ☐ Cooperative Group Repository: ☐ NIH (name branch): ☐ Other University: ☐ Industry sponsor: ☐ Other (please describe):

Section C: Administration of LMU-Based Repository: This section applies only to entities involved in specimen storage, inventory management, and distribution to investigators.	
☐ N/A PI will not be administering or managing his/her own repository	
1. Where is the bank physically located (address and room number)? (Provide all locations if specimens are housed in multiple locations.)	
2. Confidentiality: The primary risk to subjects who donate specimens to be banked for future research is the risk of loss of confidentiality and/or privacy. Most banks need to maintain a link between the identities of donors and coded specimens to be able to collect valuable clinical follow-up information about the donors; the link is not available to the researcher using the specimens. This is accomplished through the role of an "honest broker". If the specimens are stripped of all identifiers (other terms used for this are de-identifying and anonymizing), there is no way to trace who the specimen came from and therefore no clinical follow-up information can be obtained.	
a. How will the identities of the specimen donors be protected? (check applicable box)	☐ Neither the recipient investigator nor the specimen repository/bank possesses donor identifiers. (*Anonymous*) ☐ Identifiers are maintained at the repository/bank only. There is a firewall between the source and the recipient investigator so that individual identifiers are never given to the recipient investigator (*Coded with an honest broker relationship*) ☐ Identifiers are maintained by recipient investigator and repository. Explain how confidentiality of individual data will be maintained:
b. DHHS/OHRP recommends that specimen repositories obtain a Certificate of Confidentiality to protect donor-subjects from attempts at gaining access to samples to support denial of insurance or employment or for paternity testing. If you are obtaining a Certificate of Confidentiality, list the name of the issuing agency below. If not, please explain why one is not necessary: **For more info see** http://www.hhs.gov/ohrp	

c. If specimens will not be anonymized, explain the process by which subjects may have their specimens removed from the bank and destroyed if they choose to do so later. Please note that instructions should also be in the consent form.	
d. Will clinical follow-up data be linked to the specimens?	☐ Yes ☐ No
e. If yes, for how long will follow-up data be collected?	☐ Indefinitely ☐ Other (please explain above):
f. Who will collect the follow-up data and perform the data entry?	
g. Provide a list of the data points that will be collected:	

3. Data Security: Please indicate how repository data are kept secure. Check all that apply:

☐ No code/link to specimen
☐ Specimens are coded; data key is kept separately and securely
- ☐ Data are kept in locked file cabinet
- ☐ Data are kept in locked office or suite
- ☐ Electronic data are protected with a password
- ☐ Data are stored on a secure network

Give a brief explanation:

4. Specimen Storage: Describe the storage facilities that will be used:

5. Specimen Distribution: (Provide documentation of procedures to be used for distributing bio-specimens to recipient investigators)

a. Specimens banked at LMU may be made available to (check all that apply):	☐ LMU researchers (requires separate HRRC approval for use) ☐ Non-LMU researchers (requires local IRB approval)

b. Banks may not release specimens to any investigators until the researcher has 1) received IRB approval for the specimen use. Please describe how these approvals will be verified prior to release of the samples:

6. Attach the following for submission

- ☐ **1 copy of this application***
- ☐ **1 copy of the Standard Operating Procedure for distribution of bio specimens to recipient investigators if applicable.**
- ☐ **1 copy of Attachment A (if there are any other investigators involved in the administration of the repository)**
- ☐ **1 copy of Attachment B (if requesting a waiver of informed consent/HIPAA)**
- ☐ **1 copy of the collection protocol * (including procedures for obtaining informed consent if applicable)**
- ☐ **1 copy of the informed consent form and HIPAA form if applicable**
- ☐ **1 copy of scientific review verification signed off by committee chair or designee:**

*** These documents are required for all submissions**

_____ _____
PI Signature Date

If you have any questions in filling out this application, please consult the Office of Research, Grants and Sponsored Programs at 423-869-6485 or Dr. Lori McGrew, Chair of the LMU IRB at 423-869-6613.