LINCOLN MEMORIAL UNIVERSITY
INSTITUTIONAL REVIEW BOARD
DATA REPOSITORY APPLICATION

Instructions:

- Use this form if you are engaged specifically in creating a database intended to be used for research purposes. This may include creation of a repository in order to have a pool of potential subjects to contact for future research or to store identifiable data for undetermined future research.
- An individual may sign a consent form and HIPAA authorization allowing his/her information to be kept in a database for future research, however, any future use of information from that database for research purposes will require a new application to be submitted for approval.

Section A: General Information	
Principal Investigator/Credentials:	Institution/Department:
PI Mailing Address:	LMU IRB #:
E-mail address:	Phone/Fax/Pager:
Title or Name of Repository:	
1. This protocol involves (check all that apply):	☐ Data to be collected and banked to use for subject recruitment ☐ Data to be collected and banked for future unspecified research ☐ Data banking and or repository administration for already existing datasets
2. Approximately how many datasets (subjects about whom data is collected) do you expect to collect and bank each year (best estimate)?	☐ 1- 50 ☐ 50 - 100 ☐ 100 – 500 ☐ 500 or more
3. Provide a description of the data to be collected and/or banked for use for future research.	☐ Data Collection sheet is attached to submission OR ☐ Specific data points to be collected are:

Reminders

- Obtaining identifiable private information (data) for research purposes constitutes human subject research.
- Private information that is not individually identifiable is considered not to be human subject research.
- The determination of what constitutes human subject research should be made by the **IRB**, not the investigator. This can be managed by an email to IRB@lmunet.edu
- Data may not be collected, received, used, or distributed for research purposes without IRB approval. It is the data repository administrator's responsibility to assure that approval has been granted prior to releasing data for research purposes.
- Data use must be consistent with what is described in the protocol and consent form (if applicable)

Section B: Data Collection and Informed Consent Process: This section applies to the actual data collection process from potential research subjects.	
1. Data are (check all that apply):	☐ Existing data sets previously obtained *(archived)*

	☐ Data to be collected for future contact of subjects (*research purposes)* ☐ Data to be collected but not used for contact of subjects ☐ Other (explain briefly):
2. How will consent be obtained?	☐ Data banking consent form ☐ Separate data banking section within a research study consent form ☐ Requesting waiver (Complete *Attachment B*) ☐ Other (explain briefly):
3. Where will the data sets be stored (check all that apply)?	☐ LMU repository ☐ Other (please describe):

Section C: Data Repository Administration: Repository administration applies to the entities involved in data storage, security management, and distribution to investigators.

Confidentiality

- The primary risk to subjects whose individually identifiable information is banked for future research is the risk of loss of confidentiality and/or privacy. Some banks will need to maintain a link between the identities of individuals and their coded data in order to contact individuals for possible participation in future research or to update data sets.
- Sometimes individual identity is not necessary for the researcher to have in order to conduct the research. In this case the researcher may use information that is not individually identifiable and the link to any individual's identity is not available to the researcher using the data. This is accomplished through the role of an "honest broker". If data sets are stripped of any identifiers (other terms used for this are de-identifying and anonymizing), there is no way to trace who the data sets came from and therefore no follow-up information can be obtained.

1. Who will collect the data and perform data entry? (*If an honest broker will be managing the data, clearly describe the process that will be used to collect, manage, access, and release data.*)

2. If data will not be anonymized, explain the process by which subjects may have their data removed from the bank and destroyed if they choose to do so later. (**Please note that instructions should also be in the consent form**).

3. How long will the data be stored?
How will data be destroyed when it is no longer needed?

4. Data Security:

a) Where will the data bank be physically located (address and room number)?
b) Explain how data will be identified (i.e. name, initials, code number):
c) Please indicate how repository data will be kept secure:

- ☐ No code/link to data
- ☐ Data are coded; data key is kept separately and securely (check all that apply below):
  - ☐ Paper based records (data) will be kept in locked file cabinet
  - ☐ Password protected computer-based files (i.e. excel spreadsheet)
  - ☐ Paper based records (data) will be kept in a locked office or suite
  - ☐ Computer based files (data) will be stored on a secure network (i.e. O drive – intranet)

d) Provide a brief explanation **and** include who will have access to the data/records:
e) What will happen to the data bank if the PI leaves the institution:

5. Data Distribution: (Provide documentation of procedures to be used for distributing data to recipient investigators)

a. Data banked at LMU will be available to (check all that apply):	☐ LMU researchers (requires separate IRB approval for use) ☐ Non-LMU researchers (requires LMU-IRB and local IRB approval)

b. Data banks may not release records to any investigators until the researcher has received IRB approval for the specific data use. Please describe how IRB approval will be verified prior to release of the data:

☐ N/A PI will be managing the databank and will apply for IRB approval to use the data when research proposal is ready.

Attach the following for submission

☐ **1 copy of this application***

☐ **1 copy of the Standard Operating Procedure for distribution of data 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 you are requesting a waiver of consent/HIPAA)**

☐ **1 copy of the instrument to be used for data collection if applicable**

☐ **1 copy of the informed consent form if applicable**

☐ **1 copy of the protocol (address oversight, monitoring of use of data – i.e. how many times a particular subject could be offered studies to participate in)***

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

As the PI of this study, I agree:

- To accept responsibility for the scientific and ethical conduct of this project
- To submit for approval any additions, corrections, or modifications to the protocol or consent form to the LMU IRB for approval prior to the implementation of any changes
- This project will not be started until final approval has been granted from the LMU IRB.

_____ _____

PI Signature Date

The above submission has been reviewed and is supported by this department.

_____ _____ _____

Department Chair/ Supervisor Department Date

_____ _____ _____

IRB Chair Date of Review Date

If you have any questions in filling out this application, please consult or call 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.