

Standard Operating Procedures for Data Banks

Please outline the Standard Operating Procedures (SOPs) for storing and sharing data collected for the research. Please include the following information:

1. Please explain how you will protect subjects' confidentiality by responding to the following questions:
 - a. Please outline in detail the nature of information directly or indirectly¹ linked to the subject that is:
 - (1) stored with data; and
 - (2) provided with data to other investigators.
 - b. Will data be coded?¹ If so, please:
 - (1) describe how the data are coded,
 - (2) explain where the link is stored, and
 - (3) identify the person(s) who have access to the link.
 - c. Will data be anonymized?² If so, please:
 - (1) describe the process of anonymization, and
 - (2) explain whether anonymization occurs before storing or before sharing.
2. Please describe the process by which an investigator requests data.
 - a. Please submit a copy of the request form that will be used.
 - b. Please identify the person(s) responsible for determining the adequacy of the request for data.
 - c. Please describe the criteria used to determine the adequacy of requests to obtain data (e.g., the type of researchers that will be eligible to receive data).

¹ A "coded" or "indirect" identifier would include data that is identified through codes that may be used to directly or indirectly identify the subject(s). Also called "linked" or "identifiable" data, include those data from identified materials with a code rather than a name or any other personal identifier such as a patient or student number, where the repository retains information linking the code to particular human subjects or where the extent of the demographic information provided with the data is sufficient that the investigator, the repository, or a third party could link the data derived from the research with material from a particular person or a very small group of identifiable persons. See National Bioethics Advisory Commission, Research Involving Human Biological Materials: Ethical Issues and Policy Guidance, Volume 1, Rockville, 1999: 17.

² Anonymized or deidentified data either were created without any links to the subject or supplied by the repository without any direct or indirect identifiers linked to the data, such that the ability to identify a particular individual via direct or demographic information supplied with the information derived from the repository would be impossible for the investigator, the repository, or a third party. National Bioethics Advisory Commission.

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- d. Please describe how you will document the review process for each request to obtain data.
- e. UCLA investigators requesting access to data must provide you with UCLA IRB approval or Certification of Exemption from IRB Review³ for their proposed access to the data.

Please identify the procedures that will be used to document the IRB approval/certification of exemption for each study for which data are requested.

- f. Non-UCLA researchers requesting access to data that has not been anonymized must provide you with IRB approval for their use of the data. Please identify the procedures that will be used to document the IRB approval for non-UCLA investigators' access of data.
 - g. Please provide written assurance that data will only be shared with investigators who provide you with appropriate IRB approval/certification of exemption.
- 3. Please describe how the bank will be maintained if you or any of the co-investigators leave UCLA.
 - 4. Please explain whether any information learned from the collected data will be available to the subject.
 - a. Please also ensure that the research consent form for the collection of the data explains whether or not any information learned from the collected data will be available to the subject.

³Investigators may provide Certification of Exemption for use of the data only if the data they receive has been anonymized.