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| --- | --- | --- | --- |
| **IRB Number:** | | |  |
| **Study Title:** | | |  |
| **Principal Investigator:** | | |  |
| **Version Date:** | | |  |
|  | | | |
| **A Research Repository** – often referred to as “banking” - collects, stores, and distributes human data/specimens for research purposes. Repository activities involve three components: (i) the collection of data/specimens; (ii) storing and managing the data/specimens; and (iii) distributing the data/specimens to recipient investigators.  If the research study is creating a repository of data/specimens that will be made available to other investigators outside of this research study (including other investigators at CHLA), information must be provided outlining the nature of this process.  Operation and management of the repository is subject to **oversight by the CHLA Institutional Review Board (CHLA IRB)**. The IRB will review and approve a protocol specifying the conditions under which data/specimens may be stored and shared and ensuring adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. The IRB will also review and approve a data/specimen collection protocol and informed consent document (if applicable) that would be used to collect data/specimens. Once this form is completed, it should be uploaded to the iStar application for IRB review.  It may be recommended that a **Certificate of Confidentiality** be obtained to protect the confidentiality of repository data/specimens (when appropriate). | | | |
| **Glossary** | | | |
| **Anonymous:** | | | Identifiers were not collected at any point in the research and cannot be retrieved by the investigator. Example: There are no identifiers (direct or linked via a code) on the data collection form or associated with the specimens. |
| **Coded:** | | | Data/specimens are labeled with a unique ID number or code. A separate link (key) is kept which connects this ID number to a patient identifier (e.g. name, medical record number, etc.). Generally, this is done if you anticipate that you might need to gather or verify subject data at more than one point over the life of the study. Example: The data collection form or specimen has a unique identifying number, and a separate link is kept which correlates this number to the subject’s identity. |
| **De-identified or Anonymized:** | | | Data/specimens from which all identifiers have been removed and cannot be retrieved by the investigator. For a data set/specimen to be considered de-identified/anonymized, a key code must not exist and/or the data/specimen must be stripped of any indirect identifiers (study ID) or direct identifiers. Examples: (1) The data collection form includes identifiers. The data are then transferred, without the identifiers, to another document, and the initial data collection form is destroyed.  (2) The specimens are initially labeled with identifiers. The identifiers are stripped from the specimens before they are provided to the recipient investigator. |
| **Identified:** | | | Data/specimens are directly labeled with subject identifying information (e.g. name, social security number, medical record number, etc.) so that the data/specimens can readily be connected with a specific subject. Example: Rose Smith, MR#007 |
| **Repository Manager/Gatekeeper:** | | | The individual or group of individuals responsible for the security and disposition of the data/specimens stored in the repository. |
| **Section I – Collection of Data/Specimens** | | | |
| 1. Please identify the repository manager(s) under item 2.1 of the iStar application. | | | |
| 2. Please specify below the types of material that will be stored in the repository (check all that apply below): | | | |
|  | Specimens (e.g., surgically obtained specimens, biopsy, specimens obtained through a blood draw, specimens obtained by catheter [urine], other [nail, hair, saliva, breast milk, pus, buccal cells]) | | |
|  | Data (information) | | |
| **Section II – Repository Storage and Data Management** | | | |
| 3. Please specify the exact location of the repository at CHLA: | | | |
| 4. Please indicate below how the specimens/data are labeled at the repository (check all that apply below): | | | |
|  | Coded - If this is checked, please indicate who will hold the key (check all that apply below): | | |
|  |  | Only the institution(s) providing the data/specimens to the repository | |
|  | CHLA | |
|  | Other (please describe): | |
|  | De-identified/Anonymized | | |
|  | Anonymous | | |
|  | Other (please describe): | | |
| 5. Please describe the specific types of research to be conducted with the data/specimens (check all that apply below): | | | |
|  | Specific diagnosis/condition | | |
|  | Related diagnosis/condition | | |
|  | Unrelated to the diagnosis/condition | | |
|  | Other (please describe): | | |
| 6. If the subject wishes to withdraw from the repository,  please describe how this will occur. (Or indicate “not applicable” if the data/specimens are anonymous or are not linked or if waivers of consent/permission/assent have been requested for the entire study): | | | |
| **Section III – Recipient Investigators** | | | |
| 7. Please identify the gatekeeper(s) responsible for reviewing the adequacy of the investigator requests for use of the data/specimens under item 2.1 of the iStar application. | | | |
| 8. What type of subject identification information will be provided to recipient investigators with the data/specimens? (check all that apply below, if more than one applies describe the circumstances for each here): | | | |
|  | Coded (i.e. subject codes or “links” that usually numerically link the data/specimen to identifiable information). | | |
|  | Direct identifiers (i.e. name, medical record number) If this is selected, please specify which identifiers will be provided and justify why the identifiers need to be provided: | | |
|  | No information will be provided (anonymous specimens/data only) | | |
| 9. Will results of research conducted with the subject’s data/specimens be shared with the subjects? | | | |
|  | Yes, because the information could have an impact on the clinical care of the subject. If this is checked, please describe the plan to inform the subjects of the outcome of the research: | | |
|  | No, because the information will have no impact on clinical care and/or there is uncertainty regarding the utility of the information. | | |
|  | No, because the identity of the subject will not be known. (Note: this option only applies to anonymous or de-identified/anonymized data/specimens.) | | |
| 10. Please provide the following assurance by checking the box below: | | | |
|  | Data/specimens will not be released to any investigators who do not have IRB oversight. | | |
| **NOTE: If the PI is leaving the institution, the project must be amended to clarify what will happen to the repository.** | | | |