**Specimen and Data Sharing**

|  |  |
| --- | --- |
| Yes  No | Specimens will be collected, stored and distributed for research purposes. |
| Yes  No | IRB approval has been obtained for access to either external or internal\* research repositories for which materials have been collected specifically for research purposes and/or are associated with identifiable/coded information. |
| Yes  No | An IRB application has been submitted for establishing a new research repository or converting an existing database, collection of samples, or non-research repository into a research one. |
| Yes  No | The IRB application addresses all the standard operating procedures for the repository outlined below\* |
| Yes  No | A material transfer agreement (MTA) or Data Use Agreement (DUA) has been drafted for data/specimens being sent to another institution  *(MTA information:* [*http://otd.harvard.edu/resources/agreements/materialtransfer/*](http://otd.harvard.edu/resources/agreements/materialtransfer/)*;*  *DUA information:* [*http://vpr.harvard.edu/pages/harvard-research-data-security-policy*](http://vpr.harvard.edu/pages/harvard-research-data-security-policy)*)* |
|  | |
| **Initiating Specimen and Data Repository Research** | |
| Yes  No | An IRB application has been submitted for establishing a new research repository or converting an existing database, collection of samples, or non-research repository into a research one. |
| Yes  No | Determination is made on whether the consent process is consistent with the information provided to participants regarding obtaining/sharing of their data. |
| Yes  No | IRB approval has been obtained for access to either external or internal**\*** research repositories for which materials have been collected specifically for research purposes and/or are associated with identifiable/coded information. |
|  | |
| **IRB Protocol and Consent Form Considerations** | |
| Yes  No | Purpose of repository is fully explained. |
| Yes  No | Location of repository is specified. |
| Yes  No | Indication of whether an advisory committee is required to convene prior to distribution of materials/data. |
| Yes  No | Conditions for releasing data/specimens to a recipient investigator are described. |
| Yes  No | Type of data/specimens is described. |
| Yes  No | Description of the population from which data/specimens were obtained. |
| Yes  No | Explanation of whether the materials will be collected for the proposed research, a clinical procedure, or specifically for the repository. |
| Yes  No | The number of specimens collected per person is explained. |
| Yes  No | Explanation of whether research participants will be asked to give permission to be contacted by the repository in the future, and if so, details regarding the re-contact. |
| Yes  No | Explanation of whether the research participant will be able to withdraw their materials from future studies. |
| Yes  No | Explanation of provisions in place for protecting the privacy and confidentiality of research participants. |
| Yes  No | A Certificate of Confidentiality has been obtained for sensitive genetic information stored in the repository (if applicable). |
| Yes  No | For a research repository: a statement is included in the consent that the specimens may be used in research that may result in new discoveries and that the donor subjects do not retain any property rights to their materials or receive any financial benefits. |
| Yes  No | A material transfer agreement has been drafted for data/specimens being sent to another institution (if applicable). |

|  |  |
| --- | --- |
| Yes  No | A Data Use agreement has been drafted for data being sent to another institution (if applicable). |
| Yes  No | The process for maintaining the repository if the responsible investigator leaves the institution is explained. |
|  | |
| **Informed Consent Process Considerations** | |
| Yes  No | For a non-research repository: a clinical consent was obtained for the initial collection and storage of materials. |
| Yes  No | For a non-research repository: permission of participants has been obtained prior to releasing data or specimens to investigators for research purposes. |
| Yes  No | For a research repository: the IRB reviewed the consent process and documentation (unless waived) of the explanation/description of subsequent use of materials/data. |
|  | |
| Notes: | |