**Research Registry or Repository Form**

**Submission Date:** Click or tap here to enter text.

|  |
| --- |
| **When to use this form:** A research *registry* or *repository* is created whenever identifiable or de-identified (coded) human subjects data or specimens are collected and/or maintained for future research purposes. Access to data in a registry or specimens in a repository might be restricted to the original research team on a study for future analysis for new research aims or might available to outside researchers through a request to the registry manager. Use this form for any registries or repositories including recruitment registries, registries or repositories that are created with data from one study or source, or registries or repositories that collect and maintain data from multiple sources or studies. This form will accompany an exempt/non-exempt submission using the appropriate exempt or non-exempt protocol form that outlines pertinent details. Please submit all form and other study materials, to: IRBReview@northeastern.edu  |

**PROTOCOL INFORMATION (for the submission or study that this is part of)**

|  |
| --- |
| **Principal Investigator:** Click or tap here to enter text. |
| **Student Investigator [if applicable]:** Click or tap here to enter text. |
| **IRB Number [if available]:** Click or tap here to enter text. |
| **Protocol Title:** Click or tap here to enter text. |

**REGISTRY OR REPOSITORY INFORMATION**

1. **BASIC INFO**

|  |
| --- |
| **Name of the registry:** Click or tap here to enter text.**Who will maintain the registry (registry manager):** Click or tap here to enter text.**Describe the registry manager’s affiliation:**[ ]  Northeastern University Faculty or Staff[ ]  Other, *please specify*: Click or tap here to enter text. |

1. **REGISTRY CONTENTS**

|  |
| --- |
| **Describe what will be added to or housed in the registry/repository (data elements, specimens, recordings, images, instruments, etc.):** Click or tap here to enter text.**Describe any and all potential identifiers (both direct or indirect) or codes/subject IDs (that can be linked to identifiers) which will accompany data or samples to the registry/repository:** Click or tap here to enter text. |

1. **CONFIDENTIALITY AND ACCESS CONTROLLS**

|  |
| --- |
| **Describe the confidentiality protections for the registry/repository and how access will be controlled** **(e.g., limited number of individuals have access to the data/specimens, password protected, etc.). If data will be processed to prevent re-identifiability, describe this process:** Click or tap here to enter text.**Describe the application process that requestors (including the PI or researchers on the study team) will follow to request access to the data/samples contained in the registry/repository for future research.** *Note that, if identifiable or coded data will be released, documentation of the requestor's IRB approval/determination must be provided to and maintained by the registry manager prior to data release.* Click or tap here to enter text.**Describe the criteria the registry manager will use to evaluate applications from researchers wishing to access the registry/repository and the conditions (if any) that researchers must agree to prior to the release of information or specimens contained in the registry/repository or information/training on use of the registry that applicants will receive:**Click or tap here to enter text.**Describe the format and method by which data and/or specimens will be transferred to researchers/individuals requesting data or specimens:** Click or tap here to enter text.**Describe any safeguards to prevent accidental or inappropriate release of data or specimens:** Click or tap here to enter text. |

1. **DATA STEWARDSHIP**

|  |
| --- |
| **Describe how long the registry/repository will be maintained and how data/specimens will be destroyed when the registry or repository is closed.** *Note that the submission/study will need to remain open and active for as long as this registry is open***:** Click or tap here to enter text.**Describe whether participants will be able to access their data and/or samples from the registry/repository for personal use and, if so, how these requests will be made and processed:** Click or tap here to enter text. |

1. **CONSENT**

|  |
| --- |
| **Describe how participants are allowed to request the data/samples be destroyed/removed from the registry/repository or why it is not allowed or feasible:** Click or tap here to enter text.**Describe whether participants can stipulate how data/specimens can be used and, if so, describe 1) what are the possible stipulations and 2) how these stipulations will be captured during the consent process OR, if there is not a mechanism to capture the participants data use stipulations, explain why this is not necessary:** Click or tap here to enter text.*Please note that the consent process will be outlined in the main study and submitted with all other study materials. Regulations require that informed consent be obtained unless there is documentation of why the study meets the criteria for a waiver of all elements of informed consent. It is expected that details about the registry will be part of the consent process/forms either by adding elements to a study consent form or creating/using a separate registry consent form that explains the registry/repository. These materials must provide all necessary information for participants to make informed decisions about their data's inclusion in the registry. Key information or elements that is often included in registry consent forms:* * *The purpose of the registry/repository*
* *Who is responsible for maintaining/overseeing the registry/repository*
* *What data or specimens will be added to the registry and how long it will be kept in the registry*
* *How the data/specimens might be used or analyzed by NU researchers and/or external researchers (including any genetic tests that will/may occur)*
* *Limitations on how the data/specimens will or will not be used in the future or limitations on who can/cannot request to access the data/specimens*
* *Reasons and methods of recontacting participants or informing them about how data will be used*
* *Confidentiality protections that are in place to protect the data in the registry*
* *Whether and how a participant can withdraw their data from the registry*
* *Whether participation in the registry/repository is required in order to be in the main study (i.e. can participants take part in the study and not give permission for their data be used for future research)*
* *Whether data/specimens could also be submitted to an NIH registry/repository (GWAS) (if relevant) or other external registry/database.*
* *A signature line that clearly documents the participant’s agreement for maintaining data in a registry (waivers of documentation of consent and waivers of all elements of consent can be considered in the context of the relevant regulatory criteria on the exempt/non-exempt form).*
 |