NINDS Repository Investigator Tracking Data Form

Approval to submit must be renewed at least annually, ideally at the time of IRB re-approval

(A) Investigator Contact Information:

Name:

Institution:

Address:

E-mail:

Phone:

(B) Study Coordinator:

Name:

Institution:

Address:

E-mail:

Phone:

(C) Funding Information:

Funded By: ☐ NINDS ☐ Other *(please specify)*: _____

Grant Number: Start Date: End Date:

Grant Title: _____

Grant Principal Investigator: _____

(D) Sample Collection Disorder Category Information:

Please select one disorder category (subcollection), plus controls if applicable, per application. If more than one disorder category is to be banked please submit a separate application (this form) for each.

Please list all relevant diagnoses

- ☐ **Frontotemporal Degeneration** _____
- ☐ **Parkinsonism** _____
- ☐ **Epilepsy** _____
- ☐ **Cerebrovascular Disease** _____
- ☐ **Motor Neuron Disease** _____
- ☐ **Tourette Syndrome** _____
- ☐ **Dystonia** _____
- ☐ **Huntington's Disease** _____
- ☐ **Population/Spousal/Family-Based Controls** _____
- ☐ **Other (please specify)** _____

(E) Ethnic and Racial Characteristics

*(*Complete section **E** <u>only</u> if submitting blood for genetic studies)*

1. ***Ethnicity:*** Hispanic _____%; Non-Hispanic_____% *(Ethnicity should equal 100%)*
2. ***Race:*** Caucasian_____%; African American/Black_____%; Asian_____%; Pacific Islander_____%; American Indian_____%; Mixed Race_____%; Other_____% *(Race should equal 100%*

(F) Submission Category: *SUBJECT TO APPROVAL BY NINDS.*

☐ Blood ☐ DNA ☐ Other (please specify)_____

(G) Embargo Period:

*(*Complete section **G** only if submitting blood for genetic studies)*

☐ ***I am aware that imposing an embargo period will be pending approval from NINDS.***

Blood for DNA Preparation Options: *(select one)*

☐ Release immediately ☐ Release 1 year after submission ☐ Release 2 years after submission (requires special approval)

(H) Subjects and Study Information:

1. **Is this a case/control study?** ☐ Yes ☐ No

   If yes, please answer the following:

   a. How many cases? Next 12 months _____ Entire Project _____

   b. How many controls *(population + spousal)*? Next 12 months _____ Entire Project _____

2. **Is this a family-based study?** ☐ Yes ☐ No

   If yes, please answer the following:

   a. Describe family structure used to identify families for study (e.g. proband & 1st degree relatives; trios of two parents & affected child; sibling pairs; extended family) *Please be as specific as possible:*

   _____

   b. Total number of **affected** individuals to be ascertained: ***(DO NOT INCLUDE CASE/CONTROL INFO LISTED ABOVE)***

   Next 12 months _____ Entire Project _____

   c. Total number of **unaffected** family members to be ascertained:

   Next 12 months _____ Entire Project _____

3. **If you checked Yes for both 1 and 2 above, list the total number of affected subjects participating in the study. *(1.a+2.b)***

   Next 12 months _____ Entire Project _____

4. **If your study does not fit either of the categories above, please describe and enumerate the subjects that will be submitted?**

   a. How many cases? Next 12 months _____ Entire Project _____

   Please describe these individuals_____

   b. How many non-cases? Next 12 months _____ Entire Project _____

   Please describe these individuals_____

5. **Is this study part of a clinical trial?** ☐ Yes ☐ No

If yes, please describe study design, therapeutic intervention *(if applicable)*, number of subjects, length of trial and additional phenotypic/clinical information, to be obtained *(attach separate sheet).*

(I) Overview of Genetic Information for Biospecimens:

1. Known genetic information **prior** to sample ascertainment:

a. Known genetic syndrome: ☐ Present ☐ Absent ☐ Unknown

(If tested, please specify known genetic syndrome) _____

b. Known mutations or genetic variance in DNA: ☐ Present ☐ Absent ☐ Unknown

(If tested, please specify known mutations) _____

2. Will the samples be screened for known mutations: ☐ Yes ☐ No

If yes, please indicate mutations to be screened: _____

☐ Once confirmed, I will submit data on all known mutations for every submission and how each sample is associated with any dbGaP data. ***(REQUIRED FOR APPROVAL)***

(J) Submitter Benefits:

For acceptable blood submissions that are subject to DNA extractions, you are entitled to 20µg of DNA per unique submission accepted for clinical data.

☐ I am aware that every acceptable blood submission includes acceptable biospecimens and clinical data or longitudinal clinical data submissions, if available, to the NINDS Repository.

Please indicate your preference (select one)

1. ☐ Please send to PI or Study Coordinator. (*please specify)* _____

If shipping address differs from that listed on pg. 1 of this form, please provide below.

Name:

Shipping Address:

Email: Phone:

2. ☐ Please send to a collaborator.

If you checked 2 please provide info below.

Name:

Shipping Address:

Email: Phone:

If you checked 1 or 2 please be aware that DNA will be shipped in batches of at least 10.

3. ☐ Please store to be requested at a later date.

4. ☐ I elect to forego the opportunity to receive back-in-kind samples.

(K) Please acknowledge all of the following:

1. ☐ I have received IRB approval to submit samples to the NINDS Repository.
   COPY OF YOUR APPROVED CONSENT MUST ACCOMPANY THIS REQUEST.
2. ☐ I am submitting from a site in the United States or Canada and I will transfer CDE information to Coriell electronically using the Repository's electronic data entry system, as required, when the sample is submitted.
   Or
   ☐ I am submitting from a site outside the United States or Canada and I elect to transfer CDE information to Coriell using the Repository's electronic data entry system.
   Or
   ☐ This is a large project and I would like to utilize an alternative electronic data transfer system that is custom-designed for my project.
   Or
   ☐ Submission of clinical data is not required by my study, as agreed to by NINDS.
3. ☐ I am aware that to promote sharing I am required to report all publications which refer to a given sample or sample set from the NINDS Repository when published, noting sample or catalog numbers in the publications (send email to ninds@coriell.org).
4. ☐ I acknowledge and agree that my submissions can be distributed according to the terms and conditions of the NINDS Repository MTA. https://catalog.coriell.org/0/Sections/Support/NINDS/assurance.aspx?PgId=307
5. ☐ I agree to share protocols for sample preparation if requested by the NINDS Repository
6. ☐ I will not submit duplicate subjects/samples from my study or other studies.
7. ☐ I have reviewed the Submitter's Guide and the Frequently Asked Questions (FAQs) section of the NINDS Repository Website; see https://catalog.coriell.org/1/NINDS/Additional-Resources/Submitters-Guide

Optional:

☐ I would like to be listed on the website Acknowledgment Page as a submitter to the NINDS Repository. https://catalog.coriell.org/0/Sections/Collections/NINDS/Contributors.aspx?PgId=188&coll=ND

By signing below, I agree to abide by the regulations of the NINDS Repository.

_____ _____

Signature, Principal Investigator ***Date***

Submit to: NINDS Repository
NINDS@coriell.org

If you have any questions about this form please contact a Project Manager at ninds@coriell.org.