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: Fax:

(B) Study Coordinator:

Name: Institution:

Address:

E-mail: Phone: Fax:

(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** only 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 ☐ Serum ☐ Saliva

☐ Skin biopsy ☐ Cerebral Spinal Fluid ☐ Other (please specify)_____

☐ Plasma ☐ Urine

(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, and aware that every acceptable submission includes acceptable biospecimens and clinical data or longitudinal clinical data submissions, if available, to the NINDS Repository.***

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

☐ Release immediately ☐ Release 1 year after submission ☐ Release 2 years after submission

(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 blood submissions that are subject to DNA extractions, you are entitled to 20µg of DNA per unique submission accepted for clinical data. For skin biopsy submissions, you are entitled to 1 ampoule of fibroblasts per unique submission accepted for clinical data.

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.

5. ☐ I am submitting under **a Biomarkers program**, DNA will be stored until a later date and my benefits are under the discretion of NINDS.

(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

(*Complete 6 and 7 only if submitting blood for genetic studies)

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
Fax: 856-966-5067

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