

## RETROSPECTIVE CLINICAL DATA REVIEW FORM

*Use this form **ONLY** for research involving information already collected during the course of standard clinical care. If the research involves data generated by a research study or repository, fill out the Retrospective Research Data Review Form. Please answer each question starting at the beginning, and follow the instructions below each question based on your answer.*

### 1. PURPOSE OF THE STUDY: (provide description, including hypothesis and analysis plan)

We are contributing to a national registry for Patients with Primary Immune Deficiency diseases which is funded by the NIH by a contract to the USIDNet. These are quite rare diseases and the overall clinical picture will be best assembled by collecting registry data. As we are a referral center for such patients, we have collected information on subjects with these defects and continue to see such subjects in the course of clinical activities. Data collection is on a form that asks for demographics and immunologic data, and disease complications. The data is submitted to the Registry with initials and date of birth, so that duplicates submitted by several doctors can be prevented; a unique identifier is used from that time on. The data will be aggregated from many medical centers so that the overall immunologic phenotype and complications can be determined. The plan will be for various publications to be the result of these data collections.

### 2. RESULTS OF THE STUDY ARE TO BE USED FOR:

- Publication  
 Oral/Poster Presentation Pilot  
 Other, please specify \_\_\_\_\_

### 3. STUDY POPULATION: (describe study population, i.e., diagnosis, age group, surgical/medical, etc.)

A group of Primary Immune Deficiency diseases including severe combined immune deficiency, Di George syndrome, common variable immune deficiency, chronic granulomatous disease, leukocyte adhesion deficiency, X-linked agammaglobulinemia hyper IgE syndrome and hyper IgM syndrome. Age: all ages; age at presentation, presenting complaints, surgical, and medical complications/transplant procedures and other treatments.

### 4. WHAT INFORMATION IS TO BE ACCESSED/RECORDED? (Be specific)

Demographic data/Clinical data = medical problems, complications, medical (death, transplant etc) Lab data used to verify the diagnosis = blood counts, immune globulins. No HPI except initials and date of birth, used only to exclude duplicate reports in the final data collections.

### 5. THE RECORDS OF HOW MANY PATIENTS ARE TO BE STUDIED? About 500 from Mount Sinai.

### 6. IS THIS STUDY FUNDED BY FDA OR SUBJECT TO FDA REGULATIONS\*?

YES  NO

If YES, discontinue filling out this form and submit a standard IRB application.

If NO, continue with next question.

\* For instance, research that involves an IND would be subject to FDA regulations; if you are unsure, contact the IRB.

### 7. IS IT YOUR INTENT TO REVIEW, RECORD, OR UTILIZE ANY HIV/AIDS RELATED INFORMATION THAT YOU MAY ENCOUNTER? (This does not mean incidental exposure during review of other information)? YES NO

If YES, you will need to submit an MRR HIV form with this application, accessible on the IRB forms section of the website. Continue on to the next question.

If NO, continue to next question.

**8. WILL THIS STUDY INVOLVE COLLECTION OF DATA TO FORM, OR SHARING OF DATA WITH, A DATA “BANK” OR DATA REPOSITORY? YES  NO**

If YES, discontinue filling out this form and submit a standard IRB application, along with Standard Operating Procedures for the repository.

If NO, continue with next question.

**9. INDICATE THE SOURCE OF MEDICAL RECORD INFORMATION TO BE ACCESSED:**

(check all that apply)

- Paper Hospital Medical Record
- Office Records
- Electronic Medical Record
- Laboratory Records
- Clinical Database
- Other, please specify: \_\_\_\_\_

Continue with next question.

**10. WILL THE HEALTH INFORMATION TO BE ACCESSED BY THE RESEARCH TEAM BE LIMITED ONLY TO INFORMATION ABOUT DECEASED HUMANS? YES  NO**

If YES, stop here. This is not human subject research. Affirm the statement in #23 and submit this application along with the HIPAA Access to Decedent PHI Form (located on the HIPAA section of the IRB website).

If NO, continue with next question. If part of the medical records you will access will be from individuals known to be decedents, you will need to submit the HIPAA Access to Decedent PHI Form with your application (located on the HIPAA section of the IRB website), along with any other form recommended in this application process.

**11 WILL THE MEDICAL DATA TO BE ACCESSED BY THE RESEARCH TEAM CONTAIN ANY OF THE FOLLOWING DIRECTLY IDENTIFYING INFORMATION? YES  NO**

If YES, check off which ones and continue to #16. If NO, continue to #12.

- Name
- Social Security Number
- Medical Record Number
- Address by street location
- Telephone number
- Fax number
- Email address
- Web URLs
- Internet protocol (IP) address
- Health plan beneficiary number
- Account number
- Certificate/license number
- Vehicle Identification number and serial number, including license plate number
- Medical Device Identifiers and serial numbers
- Full face photographic images
- Biometric Identifiers (finger and voice prints)

(This list contains only 16 of the 18 HIPAA identifiers)

**12. YOU’VE INDICATED IN #10 THAT NO DATA WILL BE DIRECTLY IDENTIFIABLE OF ANY INDIVIDUAL SUBJECT’S IDENTITY. WILL THE DATA CONTAIN A LINKED CODE\* THAT SOMEONE COULD REASSOCIATE BACK TO A SUBJECT’S IDENTITY (EVEN IF YOU WILL NOT HAVE ACCESS TO CODE-BREAKING KEY)? YES  NO**

(A code means that the identifying information (e.g. name, SS#) that would enable readily discovery of the identity of the individual to whom the data pertain has been replaced with a number, letter, symbol or combination thereof (i.e. the code) AND a key to decipher the code exists, enabling linkage of the identifying information to the data) If YES, proceed to #14. If NO, continue with #13.

**13. ARE THERE ANY INTERACTIONS, COMMUNICATIONS OR CONTACT WITH PATIENTS IN THIS STUDY BY THE RESEARCH TEAM OR ANY OF ITS COLLABORATORS? (This would include contacting patients to fill in missing data from records, requesting permission to release medical records housed elsewhere, or take an additional data from them. A collaborator is someone who is involved in other activities related to the conduct of this research (e.g. study, interpretation and analysis of data, as well as authorships of presentations or manuscripts related to the research). Simply providing data to a research group does not make someone a collaborator. (OHRP 8/20/04 Guidance on Private Coded Information) YES  NO**

If YES, you've indicated that the data to be accessed in your study contains no way to identify the identity of patients, but you've also indicated that there is to be communication with the patients. Either you have made an error (in which case you should review your answers from the beginning of the form and follow the instructions following each question) or the scope of your project is outside that of this application form (in which case you should contact the IRB).

If NO, stop here. You've indicated you will be accessing data neither directly nor indirectly identifiable to individual subjects (according to Common Rule/MSSM guidelines) which is not human research. Sign this document in #23 and submit it along with applicable GCO forms. Additionally, the data you are accessing may qualify as de-identified data or a limited data set according to HIPAA. It is possible it will require a full HIPAA waiver. Therefore fill out the appropriate HIPAA form (refer to HIPAA wizard and those forms to determine which one to complete.) NOTE: In order for data to be considered de-identified the code used cannot be derived from another identifier (e.g. initials, SSN, MR #, zip code, etc.)

**14. IF THE HEALTH INFORMATION TO BE ACCESSED BY THE RESEARCH TEAM IS LINKED TO A SUBJECT'S IDENTITY ONLY INDIRECTLY VIA A "CODE", DO THE FOLLOWING CONDITIONS ALSO APPLY? YES  NO**

A) The information was not collected (via interaction or intervention with patients/subjects) for the current proposal **AND**

B) The information cannot be identified because:

The code key was destroyed (Please attach a statement from the holder of the key code attesting to its destruction along with this form) **OR**

An agreement is in place between the PI and the provider of the coded information (a.k.a. "honest broker") prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (Please provide this signed agreement along with this form) **OR**

IRB approved operating procedures preclude release of the key **OR**

Another legal protection prevents release of the key (Please provide a statement indicating this)

**AND**

C) The maker of the coded information on or with the data cannot be part of the research team. For instance, the coder cannot be involved in the data analysis, the publication/presentation of the research, etc.

If YES, check off the appropriate box in question 14B and then continue with the next question.

If NO, then continue with question 16.

**15. IS THERE TO BE ANY CONTACT OR COMMUNICATION WITH PATIENTS IN THIS STUDY? (This would include contacting patients to fill in missing data from the records or requesting permission to release medical records housed elsewhere) YES  NO**

If YES, you've indicated that the data to be accessed in your study contains no way to identify the identity of patients, but you've also indicated that there is to be communication with the patients. Either you have made an error (in which case you should review your answers from the beginning of the form and follow the instructions following each question) or the scope of your project is outside that of this application form (in which case you should contact the IRB).

If NO, stop here. Print out and sign this document in #23. Provide detailed written confirmation/statements regarding which criteria apply along any supporting documentation, along with this form and applicable GCO and HIPAA forms.

**16. IS ALL OF THE INFORMATION TO BE REVIEWED PUBLICLY AVAILABLE?**

YES  NO

If YES, proceed to question 18. If NO, proceed to question 17.

**17. IS ALL THE MEDICAL INFORMATION THAT WILL BE VIEWED ALREADY IN EXISTENCE AS OF TODAY'S DATE? YES  NO**

If YES, proceed to question 18.

If NO, you're filling out the wrong application form, since this is a retrospective review form only.

**18. WILL THE MEDICAL INFORMATION BE RECORDED BY THE RESEARCH TEAM (E.G. WRITTEN DOWN, DATA-ENTERED, ETC.) WITH IDENTIFIERS (DIRECT OR INDIRECT VIA CODES THAT COULD LEAD TO THE IDENTITY OF AN INDIVIDUAL)?** Consider carefully whether you need to retain the identity of the subject, or a link to the identity of the subject, with your data in order to accomplish the research goal. YES  NO

If YES, this project will most likely qualify for expedited (administrative) review. Continue with #19.

If NO, this means that you will never be able to link a piece of your collected data back to an individual subject's identity. This is exempt from further human subject review. Complete question #22 and 23, then submit this application form, along with a HIPAA waiver of authorization form, and your data collection sheets, and applicable GCO forms.

**19. HOW WILL THE INFORMATION ON, OR RELATED, TO THE DATA BE STORED IN ORDER TO PROTECT CONFIDENTIALITY?** (be specific about confidentiality measures in place)

The data from Mount Sinai will be recorded on a uniform data collection sheet designed to relate to the specific medical condition the patient has. This data will be then entered into the USIDNET Patient Registry by the Data Manger, Jolene Smith. The patient's information is held on an online system composed of multiple containers, with SSL-encryption access, and anonymous ID handling. All patient information pooled from all medical centers who are submitting data, will be stored on two separate servers at the USIDNet Registry office in Towson Maryland. One will contain the patient's identifying information and a unique identifying number that will be assigned to each patient entered into the Registry. The other server will contain the patient's medical data that will be associated with that specific number only, but will not have any patient specific identifying information. The Registry data is maintained on two Sun System servers that are housed at IDF Headquarters in Towson, MD and these servers are kept separate in a secured room. Jolene Smith, Registry Manager, will have access to the server with the identifying information, and may periodically review this data to exclude the possibility the same patient has been enrolled by more than one submitting physician resulting in duplicated records. The code to the unique number will also be available to Dr. Cunningham-Rundles after it is recorded into the data set. This unique code and number will be stored in her desktop computer, which is password protected in a locked office.

**20. IS A WAIVER OF INFORMED CONSENT BEING REQUESTED?** YES  NO

If NO, an informed consent document will need to be submitted. Continue with #21.

If YES, respond to the following:

A) Explain why the research could not practicably be done if informed consent was required.

Yes. I have asked for this already because data on some patients seen over the past 20 years are still not seen at Mount Sinai and some have been out of touch for years. Some may have died or moved, but they cannot be asked for their consent.

B) Explain why subjects' rights and welfare will not be adversely affected by the waiver of consent

No identifiers will be revealed and only basic clinical and laboratory data retrieved.

C) Is it reasonably foreseeable that the results of this study could yield information important to the care or treatment of individual subjects whose records are to be reviewed? YES  NO

If YES, the PI must agree to contact the IRB in the event of discovering such findings in order to receive counsel on how to proceed. Affirm your understanding of this by signing here:

**Signature of Principal Investigator** \_\_\_\_\_ **Date** \_\_\_\_\_

D) Submit a HIPAA request for Waiver of Authorization along with this form. Now continue with #22.

**21. ARE ALL THE PATIENTS (WHOSE INFORMATION IS TO BE STUDIED) PATIENTS OF YOURS (INCLUDING YOUR RESEARCH TEAM FOR THIS PROJECT)? YES  NO** 

If NO, since not all the individuals whose data you wish to study are patients of yours or your research team for this project, you will need to indicate how the subjects will be identified and contacted for their permission, since you have no existing relationship with them:

For all patients, basic data on the clinical and immunologic problems will be recorded but in the compiled data set there will be no identifiers and no way to derive any information about an individual.

**22. LIST THE INDIVIDUALS' NAMES WHO WILL HAVE ACCESS TO IDENTIFIABLE MEDICAL DATA AND THEIR ROLE IN THIS STUDY (e.g. attending physician, research coordinator)?**

Dr. Cunningham-Rundles, Lissette Estrella, RN, Sarah Martin, RN, Monica-Reiter Wong, RN. Data collectors: Jolene Smith and Richard Hong. Both have now completed the educational requirements, Human Subjects Protection Course and the HIPAA Research course. Their certificates are available.

**23. WRITTEN ASSURANCE**

As Principal Investigator, my signature below provides written assurance that I will collect the specific information I have indicated above, in the method I have indicated above, for a period not greater than the IRB approval period (approximately 1 year) as referenced on my MSSM IRB approval letters. I will not modify the content or method of conducting my research without obtaining prior IRB approval in the form of a modification to the research. Information collected as part of this project will not be reused or disclosed except as required by law, except as authorized oversight of the research, or for other research use except when that research has also been reviewed and approved (or designated as not human subject research) by the MSSM IRB.

**Signature of Principal Investigator** \_\_\_\_\_ **Date** \_\_\_\_\_

**23. ATTACHMENTS**

**Please indicate which of the following items are attached to the application:**

- Protocol (where applicable such as an NIH application or industry sponsored protocol)
- Data Collection Form (when available)
- Statements related to inaccessibility to key codes for coded data (as applicable)
- HIPAA forms (as applicable) Done.
- HIV form (if HIV/AIDS research is proposed)

Is the file stored on the secure Sinai server, or is it stored on the local hard drive (C drive)? Is the dataset stored on the same computer? If it is stored on a different computer, please fully describe this computer set-up and security systems as well. Please describe any additional data security elements in place, such as encryption software.