SUPPLEMENTAL ACCESS TO NJH REPOSITORIES	NJH IRB

IRB IDENTIFIER (CPA) #:

HS#:	CTRC# (if applicable):	DATE:
PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:	PHONE/(DIRECT) EXTENSION:	
IRB CONTACT:	PHONE/EXTENSION:	

The purpose of this form is to request supplemental data from NJH repositories for recruitment, medical history collection, or creation of a historical control group. Follow the correct submission process as defined immediately below.

- For new studies involving contact with subjects, include this form with the New Protocol Application.
- For new studies with no subject contact, this form is not appropriate. Complete the Application for Research on Data and/or Specimens.
- For existing studies, include a Change/Update form to amend the current approval.

PART 1: DATA

1.1. SOURCES

1.1.1 For sources at National Jewish Health, check the boxes for all sources of proposed data or specimens

☐ **National Jewish Health Research Database (NJHRDB)**

☐ **ILD Repository: Complete the ILD Application**

☐ **Other:** _____
For access to other current NJH IRB-approved repositories, the PI for the repository must submit a Change/Update form and letter to the IRB granting access to the identifiable data.

1.2. SUBJECT POPULATION

1.2.1 How many subjects are needed from the repository/database? _____
Explain your rationale:

1.2.2 List the INCLUSION criteria for data selection:
Age range: _____
Dates of service: _____
Other (e.g., gender, diagnosis, test results, etc.): _____

1.2.3 List the EXCLUSION criteria for data selection:

1.2.4 List the variables to be collected or analyzed for the study. This question need not be answered if a Data Capture Form or Variable List is attached to this application. ☐ **FORM ATTACHED** ☐ **N/A**

1.2.5 If requesting patient data from the National Jewish Health Research Database, will you require names of the treating physicians as a variable? ☐ **N/A** ☐ **YES** ☐ **NO**

If YES, explain purpose:

1.2.6 Will highly sensitive or personal information be collected or tested (e.g., HIV status, mental health issues, abortions, sexual behavior, sexually transmitted diseases, substance abuse, other stigmatizing diagnoses/behaviors, etc.) ☐ **YES** ☐ **NO**

If YES, list and explain:

PART 2: PURPOSE

2.1 Why are you requesting supplemental data? (Mark all applicable boxes.)

☐ **Data Collection from Medical Records for enrolled subjects.**

Have subjects already provided informed consent and HIPAA authorization for collection of their health information for this specific study? ☐ **YES** ☐ **NO**

If NO, informed consent and authorization must be obtained from each subject before health information can be collected.

Explain, if necessary:

☐ **Identification of prospective new subjects.**

Are you only requesting records of patients with whom you have a treatment relationship? ☐ **YES** ☐ **NO**

If NO, complete Waiver of Informed Consent and Waiver of HIPAA Authorization (HIP-020) forms. If permission is granted, the PI cannot contact these individuals directly without receiving a signed HIP-001 from each subject.

Explain, if necessary:

☐ **Creation of a historical comparison group. Complete Waiver of Informed Consent and Waiver of HIPAA Authorization (HIP-020) forms.**

Explain, if necessary:

Each purpose marked above must be consistent with the New Protocol Application and/or Protocol. If not, submit amendments to the appropriate documents.

Explain, if necessary:

PART 3: INVESTIGATOR'S STATEMENT

For research involving requests to access data at National Jewish Health, I understand that:

- IRB approval of my request for access to data does not guarantee that the owners/guardians of data will grant access. IRB review only determines whether the research meets human subjects protection and privacy requirements.
- If seeking contact information for recruitment purposes, I verify that I will only contact patients with whom I (or my co-investigators) have an existing treatment relationship or a signed authorization for research recruitment.
- For applications to the NJRDB or ILD, the IRB will communicate all approvals to those organizations on behalf of the Investigator. Failure to receive or maintain IRB approval may result in withdrawal of privileges for access to these organizations.

I verify that I have reviewed responses provided in this application form and I agree with the Investigator's Statements.

_____ _____

Investigator's Signature **Date**

IRB Office Communication to Data/Specimen Owners:

Study approval date: _____ Expiration date: _____

☐ Investigator is eligible to receive identifiable information

☐ Investigator is eligible to receive a limited data set (dates, geographic identifiers, but no direct identifiers)

☐ Investigator is not eligible to receive direct or indirect identifiers

☐ Investigator is requesting access to ILD data. **Additional permission must be sought by ILD before release**.

Comments:

Experienced IRB member signature: _____ Date: _____