

## HPHC Data Release for Research Purposes Workflow Procedures

**These procedures pertain to requests for HPHC data external to RSDC.**

HPHC is required to have established processes for the review of all non-routine data disclosures. These include disclosures to HPHCI for research purposes. Please note these disclosures will follow previously established procedures that include VET (Virtual Extract Team) review, escalation to the Privacy & Security Committee for exception requests and review and approval by HPHCI's Privacy Board (IRB).

Requests utilizing RSDC services must follow policies and procedures as outlined on the Institute intranet website located at <https://hphc.jiveon.com/docs/DOC-58470-rsdg-policies-and-procedures>

These procedures are segregated into three distinct activities:

- 1) Pre-Award Research Data Requests
- 2) Post-Award Research Data Requests
- 3) Amendment Requests

To facilitate these requests, we have identified Priyanka Dalvi, Technical Program Manager (TPM), Corporate Information Management, who, along with the HPHCI Investigator will facilitate appropriate reviews and approvals and documentation prior to the use/disclosure of data.

### 1. PRE-AWARD RESEARCH DATA REQUESTS

Requests to use HPHC data as outlined in planned research proposal prior to research award. This is an approval step only - no data is released.

#### A. HPHC BUSINESS UNIT DATA REQUESTS

Investigator contacts the TPM to discuss the feasibility of obtaining the required data should the project be awarded. Investigator will send the Sponsored Programs Application (SPA), Appendix C and the project proposal to the TPM and Business Unit Manager to discuss the details of the request.

- i. If the request is agreed upon by all parties, a Business Unit Request will be entered into ITG labeled **'HPHCI Pre Award Assessment – Study Name/Investigator Name'** along with the proposal, SPA documents, and any other documentation **within one business day of the meeting with the TPM**. The TPM and the Business Unit Manager will be listed in the request and any related research projects will be added as references in ITG.
- ii. TPM will set up a brief conversation with VET to discuss the request to occur **within one business day** after entering the project in ITG, where feasible.
- iii. Once VET has complete information on the request and has reviewed with TPM the evaluation will be finalized **within two business days** and documented in ITG to release

the VET Approval Email. Prior to finalization, VET will note the status of pending requests in the note section of ITG.

- iv. Once the VET approves the initiative, TPM will notify Investigator/Business Unit Manager of VET approval by forwarding the VET approval email with the attached and the signed Routing Sheet Section J form **same day, whenever possible**.

## 2. POST-AWARD RESEARCH DATA REQUESTS

Requests to use HPHC data as outlined in awarded research proposal.

- VET approval required
- IRB approval required

Data can be released at this stage.

### a. HPHC Business Unit Data Requests

- i. Upon receipt of Notice of Grant Award (NGA), Investigator reviews Data Use outlined in SPA to determine if any revisions are required. Investigator completes **Work Plan for all Studies Requiring HPHC Business Unit Support** form and emails to TPM along with the SPA and notification of NGA.
- ii. Concurrently, the Investigator may proceed with IRB submission for approval.
- iii. TPM enters a Business Unit Request into ITG labeled **HPHCI Post Award – Study Name/Investigator Name** for a one-time data release **within one business day of receiving aforementioned documentation**. For iterative releases the BLR enters the service request into the Data Exchange Queue instead of the Business Unit Request Queue using the same naming convention. A separate Service Request (SR) will be submitted for each business unit providing data, attaching the SPA Form, Appendix C and the Work Plan. **Note: it is critical the exact data elements needed be included in these documents.**
- iv. VET will assess for privacy and security requirements (including validating agreements are on file). Note: this may be an iterative process if the data requirements are not fully fleshed out.
- v. Concurrently, Investigator completes addendum to master HPHC/HPHCI Data Use Agreement (if data requested is a Limited Data Set) and submits to Grants Manager for processing.
- vi. Once VET evaluation is complete, BRL and Business Champion are notified via an auto email through ITG.
- vii. BRL forwards VET Approval Email to Investigator and data fulfillers (as appropriate) via email.
- viii. Investigator provides VET documentation to IRB.
- ix. Once all agreements and approvals are in place the data may be released to the Investigator.

## 3. AMENDMENT REQUESTS

Requests to amend protocol for which use of HPHC data has been previously approved.

- VET approval required
- IRB approval required

Data is being released at this stage.

**a. HPHC Business Unit Data Requests**

- i. Investigator contacts TPM and Business Unit Manager to discuss the willingness and feasibility of amending the research proposal.
- ii. If there is agreement to move forward with the amendment, the TPM submits the amendment, updated Work Plan and any relevant appendices to VET for review via ITG service request process **within one business day**. (Follow submission requirements in 2.a.iii above.)
- iii. Concurrently, Investigator completes addendum to master HPHC/HPHCI Data Use Agreement (if amendments to Limited Data Set are being requested) and submits to Grants Manager for processing.
- iv. VET will assess the amendment for all privacy and security requirements.
- v. Once VET evaluation is complete, BRL and Business Champion is notified via ITG system.
- vi. BRL forwards VET evaluation notification to Investigator and data fulfillers (as appropriate) via email.
- vii. Investigator provides VET documentation to IRB.
- viii. Once all agreements and approvals are in place the data may be released to the Investigator.