# VPR-CLS Process Checklist for Researchers

## (November 26, 2024)

The below checklists are intended to assist requestors in navigating and tracking the registry linkage process using the Virtual Pooled Registry Cancer Linkage System (VPR-CLS). The VPR-CLS includes automated workflows, notifications, and reminders for both requestors and registries to ensure the linkage and date release process moves forward without delay. Requestors are encouraged to respond to VPR-CLS notifications in a timely manner. Contact Castine Clerkin (cclerkin@naaccr.org) , VPR Program Manager, with any questions.

## Checklist 1: Establish VPR Account Access

| | Description of Task | Date Completed |
|---|---|---|
| ☐ | Create an IMS Login Service Account (one per user) – See attached PDF: 'VPR-CLS.Setup.Instructions.for.MFA.2023_01_04.pdf' | |
| ☐ | Verify IMS Login Service Account and notify IMS (vprcls@imsweb.com) and Castine Clerkin (cclerkin@naaccr.org ) that IMS Login Service Account is active | |
| ☐ | Upon IMS notification, log into the VPR-CLS (https://apps.naaccr.org/vpr-cls) using the IMS Login Service Account and set up Multi-Factor Authentication (MFA) on cell phone. See attached PDF: 'VPR-CLS.Setup.Instructions.for.MFA.2023_01_04.pdf' | |
| ☐ | Fully log into the VPR-CLS using the following instructions:<br>1. Go to the VPR-CLS website: https://apps.naaccr.org/vpr-cls<br>2. In the upper right click "You are not logged in"<br>3. Click "Log In"<br>4. Click on the "IMS Login Service"<br>5. Enter your username and password and click Login<br>6. You will then be prompted to enter a 6-digit code. Open the Google Authenticator app on your cellphone and enter the 6-digit code that is displayed under the "loginservice.imsweb.com" label and click "Verify". | |
| ☐ | Review the content on the VPR About Tab, particularly the tabs for "Preparing a Study Data File" and "Requestor Documents" | |
| ☐ | Have one person (primary study contact) initiate the Phase I Request on the VPR Home Page (see Checklist 2 below) | |
| **PLEASE NOTE:** Only one user (the primary study contact) should submit the Phase I request. Once the Phase I request is submitted, other users can be added to the request and are able to view and edit as needed. Instructions for adding users to the request are located on the VPR-CLS About Tab, under Requestor Documents. | | |

## Checklist 2: Complete Phase I Request Process

| | Description of Task | Responsible Party | Date Completed |
|---|---|---|---|
| ☐ | Submit VPR Linkage Request (Phase I & TIRA), including the following supporting documents:<br>- Partially executed DUA with IMS<br>- Study protocol, with section(s) on registry linkage highlighted in document<br>- Current IRB approval, exempt determination, or documentation of Not Human Subjects research from researcher's institution<br>- Consent form that addresses registry linkage or documentation of waiver of informed consent<br>- PI's Curricula Vitae<br>- Copy of Certificate of Human Subjects Training for PI/Co-PI and all persons handling individual-level registry data, either raw registry files or linked to Study PII.<br>- List of requested variables<br>- Copy of study's data management and sharing plans, if applicable | Requestor | |
| ☐ | NAACCR initiates review of VPR Linkage Request | NAACCR | |
| ☐ | While NAACCR review is underway, requestor creates and validates the study file according to the instructions on the VPR-CLS About Tab, under Preparing a Study Data File | Requestor | |
| ☐ | Modify VPR Linkage Request, if needed | Requestor | |
| ☐ | NAACCR approval of VPR Linkage Request | NAACCR | |
| ☐ | VPR Research Review Committee (RRC) reviews and votes to proceed with registry linkage | Research Review Committee | |
| ☐ | Upon notification of RRC approval, upload encrypted study file in required format | Requestor (or assigned designee) | |
| ☐ | IMS initiates validation of study file, provides feedback if needed, and creates linkage configuration file | IMS | |
| ☐ | Pre-test linkage and creation of instructions in Idaho | Idaho registry | |
| ☐ | Additional test linkage in GA, KY, and NC | Test registries | |
| ☐ | Encrypted study file is posted for all registry download | IMS | |
| ☐ | Registries perform linkage behind their firewall and upload resulting match count reports to the VPR-CLS | Registries | |
| ☐ | Requestor reviews Phase I match counts | Requestor | |

## Checklist 3a: Complete Overall Phase II Process

|  | Description of Task | Responsible Party | Date Completed |
|---|---|---|---|
| ☐ | Requestor selects registries for Phase II | Requestor | |
| ☐ | NAACCR reviews registry selection | NAACCR | |
| ☐ | Central IRB reviews VPR Linkage Request for relying registry IRBs and notifies requestor of approval | Central IRB | |
| ☐ | VPR Linkage Request released to all registries that have no other document/agreements needed to initiate their review | Automatic upon CIRB approval | |
| ☐ | Requestor completes additional required forms (Step 2 of Phase II Process Tab) and submits according to instructions on Step 2 of the Phase II Process Tab | Requestor | |

## Checklist 3b: Complete Registry-specific Phase II Process

| Below steps are completed for each registry, so columns for checkboxes and Date Completed are not included.  All this information will be tracked in the VPR-CLS.  For more details on the Phase II Process, please refer to the Phase II Guidance Document located on the VPR About Tab, under Requestor Documents. | |
|---|---|
| **Description of Task** | **Responsible Party** |
| Registries enter estimated IRB/registry review dates and navigate review process. | Registry |
| Registry enters status of registry review; Requestor enters status of IRB review and uploads IRB determination letter to registry's data entry tab (click on registry name anywhere in Phase II Process Tab). | Researcher and Registry |
| Upon a registry's full approval, requestor submits post-approval documents according to instructions on Step 2 of the Phase II Process Tab. | Requestor |
| Registry navigates post-approval documents for review and signature. | Registry |
| Registry uploads fully executed DUA to their data entry screen and confirms that all agreements are in place. | Registry |
| Requestor is notified to review DUA and enter DUA expiration date and data destruction date on registry's date entry screen. | Requestor |
| Registry exports matched cases from Phase I results and securely sends data to requestor contact noted on the VPR Linkage Request, Section IV, and logs transmission of the data. | Registry |