VPR-CLS Registry Profile: Instructions for Completing and Updating

The Registry Profile captures information on your registry that is essential for the Phase II VPR-CLS workflow. This information is also used to populate tables displayed in the VPR-CLS (see Example 1). The Registry Profile should be updated by the VPR Liaison when requirements change. Please review and update your Registry Profile using the instructions below. Any questions can be sent to Castine Clerkin (cclerkin@naaccr.org).

1. The Registry Profile can be completed by the VPR Liaison(s) in your registry.
2. Click "You are not logged in" in the top right corner and enter your MyNAACCR login credentials.
3. Click the arrow beside your name and select "Edit Registry Profile".
4. Registry Application Group and Associated Questions: Based on previous communication with NAACCR, each registry has been assigned a Registry Application Group. The categories reflect the type of review (registry, IRB, or both) and whether the Templated IRB/Registry Application (TIRA) is able to be used by the reviewing body (see Table 1 below). Depending on the Registry Application Group, one or two associated questions will need to be completed.
    a. **PLEASE NOTE:** Reference to the "registry" forms or review process is a general term that describes any **non-IRB** reviewing body(ies), such as an advisory/research committee, data release committee, etc.
    b. If there are any questions about or changes to your Registry Application Group, please contact Castine Clerkin (cclerkin@naaccr.org).

5. Required Signed Agreements: This is a new section (as of September 2020) that captures the various types of signed agreements (e.g. confidentiality agreement, research agreement, investigator agreement, or data use agreement) in a single location and provides this information to study requestors (see Example 1). For each agreement, please complete the following fields:
    a. **Link/URL:** Enter URL for the agreement. If there is no URL, leave the field blank.
    b. **Document Type:** Select the appropriate name for the agreement from the drop down list or select "Other" and enter the name.
    c. **Submission Time Frame:** Indicate when the signed agreement must be submitted, either pre-review with the submission packet or post-approval prior to data release.
    d. **Reviewing Body:** When there is more than one reviewing body, this field identifies which reviewing body should receive the required signed agreement.
    e. **Description/Instructions:** Enter a description of the document (if not self-explanatory) or pertinent instructions for the researcher. If the "Link/URL" field was left blank, provide information on how to retrieve the document (e.g. Request document from the contact provided). Also, indicate who from the researcher's institution is required to sign the agreement. Text in the "Description/Instructions" should be kept simple and succinct.
    f. **Recipient Name and Email:** Individual that researcher contacts to request/submit forms.

    IMPORTANT NOTE: If more than one signed agreement is required, simply click on the option to "Add Signed Agreements" (below the initial entry form) and complete all associated fields.

6. State-Specific Forms: For registries where the Templated IRB/Registry Application (TIRA) is unable to be used, the VPR-CLS will provide the requestor with a list, and associated URLs, of registry/IRB forms that must be completed and submitted according to the normal practices, outside of the VPR-CLS (see Example 1). This information is automatically pulled from NAACCR's CaRRI Database, which is completed/reviewed during the NAACCR Call for Data process. Please check the URL and, if incorrect, make updates within the CaRRI Database as needed.

7. Additional Documents: **ONLY complete this section for registries and/or IRBs that use the Templated IRB/Registry Application (TIRA)**. This section captures any additional documents required by the TIRA reviewing body, **ABOVE AND BEYOND** the following documents that are submitted in the TIRA packet:
   - Study related: Required signed agreements (from #6 above), the TIRA, study protocol, current letter of determination from researcher's institutional IRB, copy of consent/assent form or documentation of waiver of informed consent, and list of requested data items
   - Personnel related: Curriculum vitae/biosketch and copy of certificate of human subjects training for PI/Co-PI and all persons handling the data

   The VPR-CLS will provide the requestor with a list of additional documents that must be submitted outside of the VPR-CLS (see Example 1). For each document, please complete the following fields:
   a. **Link/URL:** Enter URL for the document. If there is no URL, leave the field blank.
   b. **Document Type:** Enter the appropriate name for the additional document.
   c. **Submission Time Frame:** Indicate when the additional document must be submitted, either pre-review with the submission packet or post-approval prior to data release.
   d. **Reviewing Body:** When there is more than one reviewing body, this field identifies which reviewing body should receive the additional document.
   e. **Description/Instructions:** Enter a description of the document (if not self-explanatory) or pertinent instructions for the researcher. If the "Link/URL" field was left blank, provide information on how to retrieve the document (e.g. Request document from the contact provided). Text in the "Description/Instructions" should be kept simple and succinct.
   f. **Recipient Name and Email:** Individual that researcher contacts to request/submit forms.

   IMPORTANT NOTE: If more than one additional document is required, simply click on the option to "Add Additional Documents" (below the initial entry form) and complete all associated fields.

8. Submit/Confirm Information: Once you have reviewed, edited, and entered all the necessary information, please click on the "Submit/Confirm" button and notify Castine Clerkin (cclerkin@naaccr.org).