

**Using the Virtual Pooled Registry Cancer Linkage System
Phase II Guidance Document for Registry Liaisons
January 10, 2020**

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I: General Information on Phase II Process

Overview: The Phase II process supports a researcher's request for individual-level data from registries and provides a tracking system to monitor the review status of the request. The process of requesting data through the VPR-CLS is facilitated in the following ways:

- **Templated IRB/Registry Application (TIRA):** A single online application that has been adopted by most, but not all, participating registries.
- **List of Additional Documents:** For registries that cannot use the TIRA or registries that require additional documents not routinely uploaded to the VPR-CLS, the Requestor is provided a list of these documents, along with a URL, and person to whom the documents should be sent.
- **Interactive Tracking System:** The VPR-CLS includes a tracking system that is updated by both the Requestor and the VPR Liaison in each registry (see Appendix 1). The tracking system allows the Requestor to monitor approvals and future due dates.
- **Notifications and Reminders:** Based on the status of the request, key dates in the tracking system, and actions taken, both the Requestor and the Registry Liaison receive automated notifications and reminders to ensure timely, forward progress.

Activities handled inside and outside the VPR-CLS: While the VPR-CLS is designed to streamline the application process, there are some activities that occur outside the system.

- **Activities handled within the VPR-CLS:**
 - Submission of TIRA and supporting documents
 - List (and URL) of state-specific applications and additional required documents
 - Data entry for tracking submission, status of review, and future due dates for all registries
 - Upload of select documents
- **Activities handled outside the VPR-CLS:**
 - Submission of state-specific applications and additional documents (tracked in VPR-CLS)
 - Registry and IRB questions for Requestor
 - Notification of IRB Determination
 - Negotiation of Registry DUA
 - Transmission of individual-level registry data to requestor

General Phase II Workflow: The general Phase II workflow proceeds according to the following steps.

1. Requestor reviews Phase I match counts and selects registries to proceed to Phase II
2. Requestor submits TIRA and supporting documents
3. NAACCR reviews TIRA and once approved, TIRA packet (zip file) is released to registries as appropriate
4. Requestor submits state-specific applications and additional documents
5. VPR Liaison prompted to enter IRB/Registry estimated review date(s)
6. IRB and registry reviews proceed according to routine practices
7. Reminders sent to enter status of request after estimated review date has passed
8. VPR Liaison enters registry review status
9. Requestor receives IRB determination via email, enters the IRB review status and uploads the IRB Determination Letter

10. When approved by all parties, VPR Liaison and Requestor notified
11. VPR Liaison uploads Fully Executed DUA, if applicable, and Requestor is notified to review and enter key dates
12. VPR Liaison sends de-identified, individual-level data to Requestor (outside the VPR-CLS)

Specific Phase II Workflows: Each of the Registry Application Groups (definitions in Section II, Table 1) has a detailed workflow that guides how the VPR-CLS processes the request and sends reminders. These workflows take into account the number of reviews (IRB, Registry, or both), the order of reviews, and whether the Templated IRB/Registry Application (TIRA) is used by the reviewing body. It is important that registries familiarize themselves with the workflow and their role in the process. Appendix 1 of these instructions provides detail on the VPR Liaison data entry responsibilities. The specific Phase II Workflows have been sent to registries as a separate document.

II: Edit Registry Profile

The Registry Profile captures information about your registry that is essential for the Phase II VPR-CLS workflow. The VPR Liaison can review and update the Registry Profile using the instructions below.

1. Click the arrow underneath your name in the upper right hand corner and select “Edit Registry Profile”



2. A screen will appear with all the Registry Profile parameters
3. Registry Application Group: 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. Based on your Registry Application Group, there will be a handful of additional questions. A list of Application Groups is provided in Table 1 below.
 - 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).
4. State-Specific Forms: For registries where the TIRA is unable to be used, the VPR-CLS will provide the requestor with a list of registry/IRB forms and their associated URLs (see example 1) that must be completed and submitted according to the normal practices, outside of the VPR-CLS. The URL is pulled from the CaRRI Database and displayed in your profile. Any changes to the URL must be made in the CaRRI Database.
5. Additional Documents: Within the VPR-CLS requestors upload supporting documents that are generally needed for the IRB/Registry review process. These documents, as well as the TIRA (if applicable), are made available in the VPR-CLS. If any additional documents (e.g. DUA, confidentiality agreement, etc.) are required for a complete application packet, they should be added to your registry profile. A list of additional documents will be provided to the requestor within the VPR-CLS (see Example 1) and they will be instructed to submit them outside of the VPR-CLS.
 - a. **PLEASE NOTE:** If a registry or IRB uses their state-specific form, it is not necessary to list the additional documents that the reviewing body requires since the requestor will be following the instructions on the state-specific form or website.
 - b. If there is no URL for the required document, please leave the “Link/URL” field blank and enter a “Description/Instructions” about how to retrieve the document (e.g. Request document from the contact provided).
 - c. Text in the Description/Instructions should be kept simple and succinct.
6. Submit/Confirm Information: Once you have reviewed, edited, and entered all the necessary information, please click on the “Submit/Confirm” button.

Table 1: Registry Application Groups – with number of registries shown in (#)

Group A: Templated IRB/Registry Application used by all reviewing bodies	
	A3: TIRA for Registry (15)
	A4: TIRA for IRB (3)
	A5: TIRA for both IRB and Registry (10)
Group B: Combination of TIRA and state-specific application	
	B1: State-specific IRB Form and TIRA for Registry (2)
	B2: State-specific Registry Form and TIRA for IRB (2)
Group C: State-specific applications only	
	C1: State-specific Registry Form (2)
	C2: State-specific IRB Form (0)
	C3: State-specific IRB and Registry Forms (3)

Example 1: Screenshot of additional applications and forms that will be presented to the Requestor

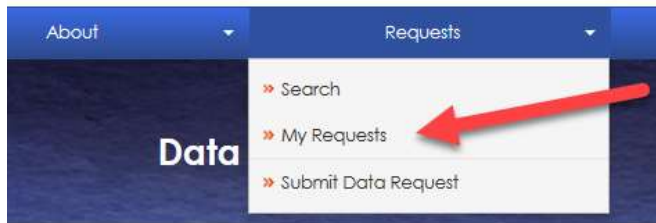
The screenshot shows the NAACCR Data Request portal interface. At the top, there is a navigation bar with 'Home', 'About', 'Requests', and 'Admin'. Below this is a 'Data Request' header. The main content area displays a specific request for '#22 – Childhood Cancer Survivor Study Cancer Registry Linkage'. It includes a progress bar with six steps: 1. Review Matches & Select Registries for Phase II (checked), 2. Fill out the Templated IRB/Registry Application, 3. Complete Additional Required Forms, 4. Monitor Initial Approvals & Data Submission, 5. Renewal Requirements, and 6. Requirements for Publications & Data Destruction. A table below lists various registries and their associated application groups and required forms. The table has columns for Registry, Application Group, Additional Required Forms, Instructions, Form Recipient Name, Form Recipient Email, and Have all forms been submitted?.

Registry	Application Group	Additional Required Forms	Instructions	Form Recipient Name	Form Recipient Email	Have all forms been submitted?
Alaska	A3: TIRA for Registry	Research Agreement		David O'Brien	david.obrien@alaska.gov	Pending NAACCR review and approval of the TIRA.
Nebraska	A3: TIRA for Registry	Confidentiality Agreement Instructions for Request for Data		Christophe Iumva Christophe Iumva	christophe.iumva@nebraska.gov christophe.iumva@nebraska.gov	Pending NAACCR review and approval of the TIRA.
Connecticut	A4: TIRA for IRB	Assurances Training Requirements Confidentiality Agreement	Required for ALL study personnel	Lou Gonsalves Lou Gonsalves Lou Gonsalves	lou.gonsalves@ct.gov lou.gonsalves@ct.gov lou.gonsalves@ct.gov	Pending NAACCR review and approval of the TIRA.
Ohio	A4: TIRA for IRB	Date use agreement		Roberta Stocumb	roberta.stocumb@odh.ohio.gov	Pending NAACCR review and approval of the TIRA.
Rhode Island	A5: TIRA for both IRB and Registry	PI Assurances		Junhie Oh	junhie.oh@healthui.gov	Pending NAACCR review and approval of the TIRA.
South Carolina	A5: TIRA for both IRB and Registry	Biosketch and Certificate of Human Subjects Training	Required for ALL persons listed in the application	Stephanie Chiodini	clugsts@dhcc.sc.gov	Pending NAACCR review and approval of the TIRA.
California	B1: State-specific IRB Form and TIRA for Registry	State IRB Form Confidentiality Agreement	Submission details available online		hc-ccresearch@ou.ed3.ucdavis.edu	Pending NAACCR review and approval of the TIRA.
Seattle SEER Registry	B1: State-specific IRB Form and TIRA for Registry	State IRB Form	Submission details available online			Pending NAACCR review and approval of the TIRA.
North Dakota	B2: State-specific Registry Form and TIRA for IRB	Registry Form		Yun Zheng	yun.zheng@med.und.edu	Pending NAACCR review and approval of the TIRA.
Puerto Rico	B2: State-specific Registry Form and TIRA for IRB	Registry Form		Carlos Torres-Cintón	ctomes@rcpr.org	Pending NAACCR review and approval of the TIRA.
New Hampshire	C1: State-specific Registry Form	Registry Form				CONFIRM
Alabama	C3: State-specific IRB Form and Registry Forms	Registry Form Confidentiality Agreement		Justin George Justin George	justin.george@adph.state.al.us justin.george@adph.state.al.us	CONFIRM
Oregon	C3: State-specific IRB Form and Registry Forms	Registry Form State IRB Form	Submission details available online	Kameny Chan	kinu.chan@dshs.oregon.gov	Submitted: 10/16/2019
Texas	C3: State-specific IRB Form and Registry Forms	Registry Form State IRB Form	Submission details available online	Erin Gardner	erin.gardner@dshs.texas.gov	Submitted: 10/11/2019

At the bottom of the page, there is a contact information section with the text: CONTACT: (217) 698-0800 ext 110, (217) 698-0188, cclerkin@naaccr.org, Contact Us, NAACCR. Below this is a funding statement: Funding for this web site content was made possible in part by a contract with Federal funds from the National Cancer Institute, National Institutes of Health and Department of Health & Human Services under Contract number HHSN261201400004 / HHSN26100002. Additionally, funding for this web site content was made possible in part by a cooperative agreement with Federal funds from the Centers for Disease Control and Prevention Cooperative Agreement number 5NUSDP004917. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NCI and CDC. Copyright © 2017 NAACCR, Inc. All Rights Reserved.

III: Locate a request your registry is participating in

1. Make sure you are logged in
2. Go to the Requests menu and select “My Requests”



3. Then select the request from the list:

Study Title	Requestor	Status
Phase II Workflow - Test 2	Todd Gibson	Phase II TIRA Posted to Registries
Transplant Cancer Match Study	Kelly Yu	Phase II Registries Selected
Childhood Cancer Survivor Study Cancer Registry Linkage	Todd Gibson	Phase II TIRA Posted to Registries
Phase II Workflow - Test 1	Todd Gibson	Phase II TIRA Completed Pending NAACCR Review
The effects of education on cancer in High School and Beyond	Nicole Schmidt	Phase I Approved, Pending Initial Dataset Prep
Sister Study	Sandra Halverson	Phase I Approved, Pending Match at Registries
Cohort Cancer Registry Follow-up Study	Lisa Dunn	Phase I Approved, Pending Match at Registries

4. Click on the request in the list to go to that request

IV: Download TIRA packet

For states utilizing the TIRA, the VPR Liaison will be notified when the TIRA packet is available on the VPR-CLS. The TIRA packet is posted for states to download and share with reviewing bodies that accept the TIRA. The TIRA packet is a Zip file that includes the TIRA and all supporting documents uploaded by the requestor (e.g. study protocol, current letter of approval from researcher’s institutional IRB, consent/assent form or documentation of waiver of informed consent, curriculum vitae for PI/Co-PI, copy of certificate of human subjects training for PI/Co-PI, and a list of requested data items).

To download the TIRA packet for a given request, please do the following:

1. Go to the request
2. On the Documents Tab, there will be a button in the lower left-hand corner labeled “TIRA PACKET DOWNLOAD”
3. Click the button
4. Depending on your browser, the file will be downloaded to your “Downloads” directory or the browser will give you the opportunity to save it where you want.

Home / Search Requests / Phase II Workflow - Test 2 / Documents

#30 – Phase II Workflow - Test 2 Data Reque

Documents | Phase II Process

Status **Select**
Phase II TIRA Posted to Registries (14/14)

Study Documents ✕

- Certificate of Human Subjects Training
- Consent Form
- CV or Biographical Sketch (2)
- Data Items Requested
- IMS DUA
- Institution IRB Approval
- Phase I Request PDF
- Study Protocol
- TIRA application

Match Count Files ✕

- Standard Match Reports

Approval Documents ✕

- State/Local IRB Determination Letter

Latest?	Name
✓	a.txt
✓	New York IRB ap
✓	certificate.of.hu
✓	Data.items.Requ
✓	TIRA.pdf
✓	matchpro-case-
✓	Pls.CV.docx
✓	Waiver of conse
✓	institutional.irb.d
✓	Study protocol c
✓	VPR_Researcher
✓	Phase_I_Reques

V: Update Registry Review or State IRB Information

The VPR Liaisons are responsible for entering key pieces of information related the review and approval process (see Appendix 1). The information entered drives automated reminders that ensure timely, forward progress, so it is essential that information be populated throughout the review process. To update the Registry Review or State IRB information for a request, please do the following:

1. Log into the VPR
2. Go to the request you need to update
3. Select the “Phase II Process” tab
4. To enter information, click on the edit pencil next to the Registry Information section label or the State IRB Information section label



5. When the edit pencil is selected, the screen will refresh and edit boxes will appear for that section:



6. Update the fields necessary
7. Attach any necessary files (see specific instructions on how to attach files)
8. Click the “Save/Attach” button at the bottom of the screen



VI: Attach a file to the Registry Information or State IRB Information section

While editing the Registry Information section or State IRB Information section, there will be an “Attach Files” section.

1. Click the “Browse...” button or “Choose Files” button (text will be different depending on your

ATTACH FILES

Only IRB and Registry determination letters and fully executed DUAs (Research Agreer

File

Attachments

No files selected.

browser) You may upload the following file types: txt, pdf, doc, docx, xls, xlsx, mpc, csv, gz, zip

2. Browse to the file you want to attach and click the Open button on the browse window
3. The file will then be listed under the Attach Files section
4. You must then select the document type:

ATTACH FILES

Only IRB and Registry determination letters and fully executed DUAs (Research Agreements) should be uploaded to this page.

File

Registry.Review.Determination.Letter.docx

Document Type

Attachments

No files selected.

You may upload the following file types: txt, pdf, doc, docx, xls, xlsx, mpc, csv, gz, zip



A dropdown menu is open, showing three options: "Registry Determination Letter", "Fully Executed Registry DUA", and "State/Local IRB Determination Letter". A red arrow points to the first option, "Registry Determination Letter".

5. Once the document type is selected, click the “Save/Attach” button

ATTACH FILES

Only IRB and Registry determination letters and fully executed DUAs (Research Agreements) should be uploaded to this page.

File

Registry.Review.Determination.Letter.docx

Document Type

Registry Determination Letter

Attachments

No files selected.

You may upload the following file types: txt, pdf, doc, docx, xls, xlsx, mpc, csv, gz, zip

APPENDIX 1: Data entry into the VPR-CLS

The following two tables list the key data items and files related to the IRB and Registry review, who is responsible for entering or uploading the information, and why it is important. In general, the VPR Liaison is responsible for entering estimated review dates for both the IRB and Registry review and then tracking the status of the Registry review. The Requestor is responsible for tracking the status of the IRB review.

Table 1: Data entry for the IRB-related information

	Requestor	VPR Liaison	Why Important?
Estimated IRB Review Date		X	Populates tracker; prompts reminder to enter status
Change to IRB Review Date	X		Updates tracker; prompts reminder to enter status
UPLOAD IRB DETERMINATION	X		
State IRB Project ID	X		
Status of IRB Request	X		Populates tracker; notifies registry
Date of IRB Approval/Denial	X		
Reason for IRB Denial	X		
IRB Expiration Date	X		Populates tracker
Continuing Review Due Date	X		Populates tracker

Table 2: Date entry for the Registry-related information

	Requestor	VPR Liaison	Why important?
Registry Project ID (if applicable)		X	
Estimated Registry Review Date		X	Populates tracker; prompts reminder to enter status
UPLOAD DETERMINATION LETTER		X	Optional
Status of Registry Request		X	Populates tracker; notifies requestor
Date of Registry Approval/Denial		X	
Reason for Registry Denial		X	
UPLOAD FULLY EXECUTED DUA		X	Prompts notification for Requestor to review
DUA Fully Executed (Yes/No)		X	Populates tracker
DUA Expiration Date	X		Populates tracker
Data Destruction Date	X		Populates tracker
Date Registry Data Sent		X	Populates tracker
# of Records in Registry File		X	Populates tracker