



REFINING THE VPR-CLS: PILOT TESTING, SYSTEM ENHANCEMENT, AND COLLABORATION

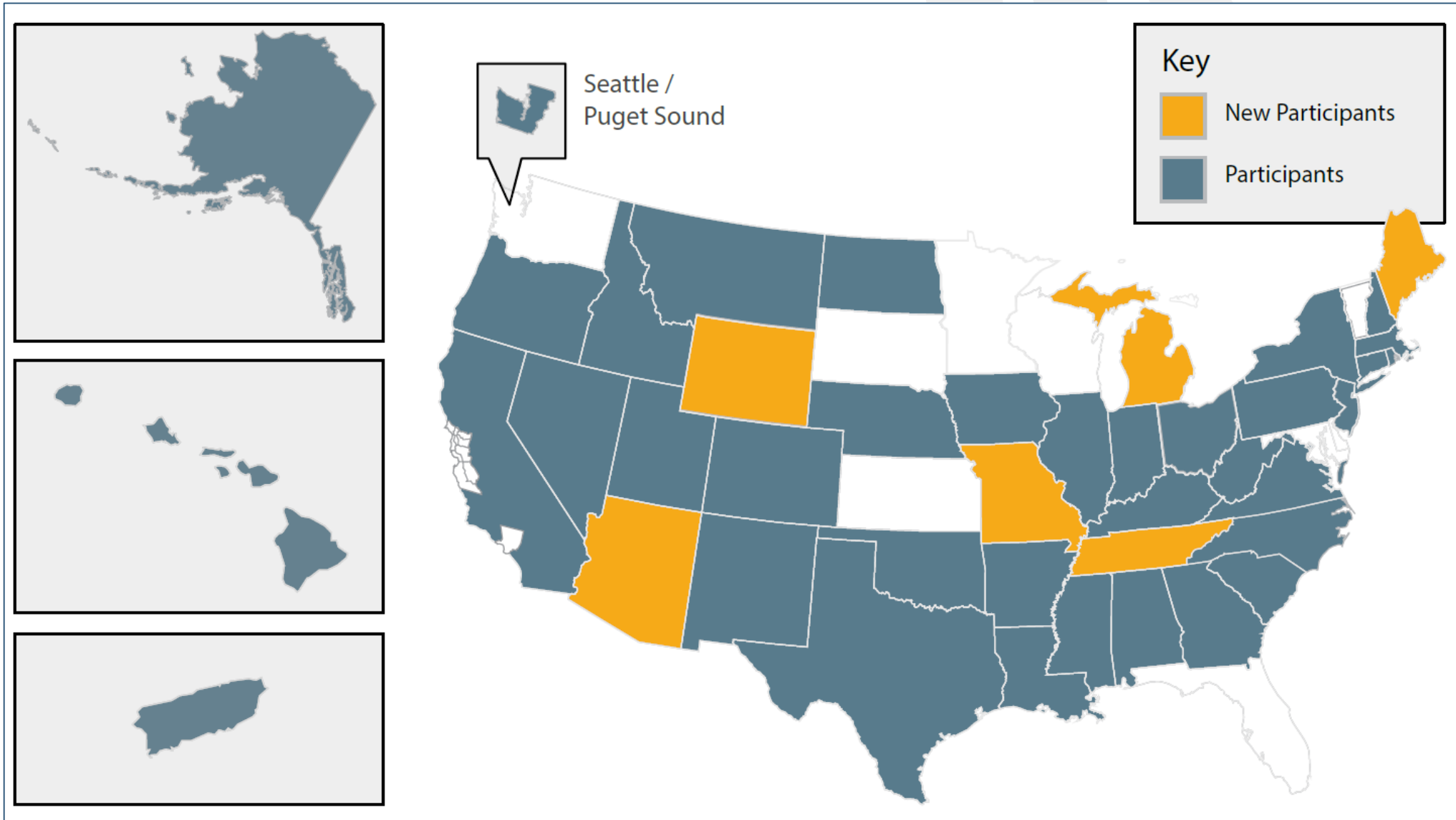
CASTINE CLERKIN, MS, CTR

NAACCR, VPR PROGRAM MANAGER

VIRTUAL POOLED REGISTRY CANCER LINKAGE SYSTEM

- Funded by NCI SEER and managed by NAACCR
- Secure, online system designed to facilitate minimal risk linkages between research studies and multiple U.S. registries
 - Single linkage software (Match*Pro) and standard matching criteria
 - Streamlined process to apply for and track registry/IRB requests and DUAs required for release of individual-level data
- Minimize burden and cost to researchers and registries/IRBs
- Increase ease of access and timely use of registry data

CENTRAL REGISTRY PARTICIPATION



TWO-PHASED APPROACH

- Phase I: Initial linkage & counts
 - Secure sharing of study file
 - Linkage behind registry firewall
 - Standard software & linkage logic
 - Upload of aggregate match counts
 - Six pilot tests, one beta test underway
- Phase II: Request for cancer data
 - Streamlined process for IRB/registry application and data release
 - Tracking of request status
 - Release of individual-level data on matched cases
 - Two initial pilot tests, three beta tests underway

INITIAL PHASE II PILOT TESTING

- Childhood Cancer Survivor Study (over 41K participants)
 - Cancer cases diagnosed in children from 1980-1999 who survived at least 5 years
 - Subsequent cancers via self-report and costly medical record validation
 - Prior attempt at registry linkage, but determined too difficult
 - Currently approved by 27 of 30 selected VPR cancer registries
 - 10,490 cancer cases sent to researcher to date



INITIAL PHASE II PILOT TESTING

- Transplant Cancer Match Study (over 1.2M participants)
 - Cohort data from the U.S. solid organ transplant registry (recipients, candidates, and donors)
 - Evaluating health-related outcomes, including cancer
 - Previously linked with 11 cancer registries (65.7% of U.S. population), expanded to 30 registries (77.8% of U.S. population) with the VPR
 - Currently approved by 27 of 30 selected VPR cancer registries
 - 105,391 cancer cases sent to researcher to date

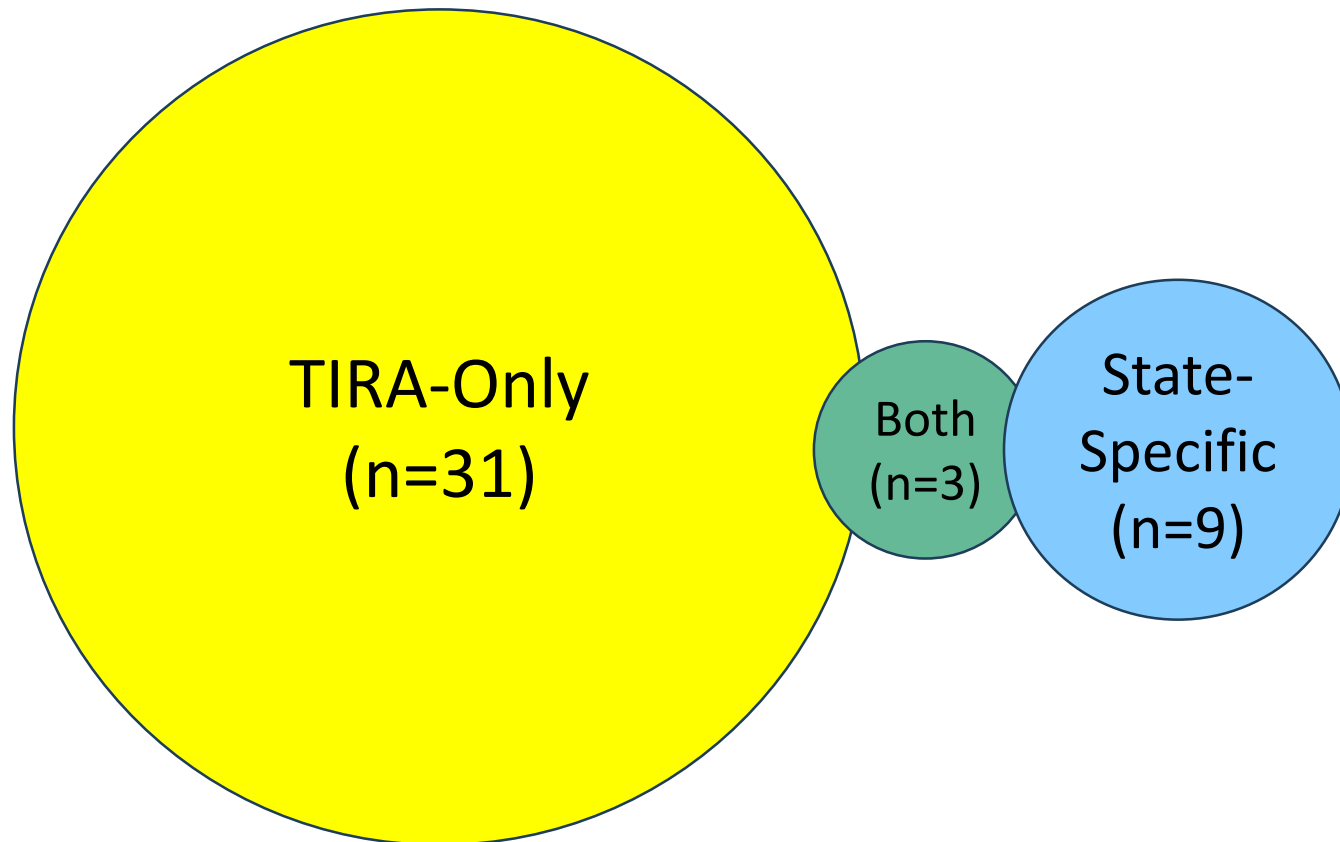


NATIONAL CANCER INSTITUTE

Division of Cancer Epidemiology & Genetics

TEMPLATED IRB/REGISTRY APPLICATION (TIRA)

- Standard application to request release of registry data
- Used in lieu of state-specific applications(s)



58 different applications



TIRA plus 15 different applications

TEMPLATED DATA USE AGREEMENT

- VPR Templated DUA
 - Single DUA that can be adopted in lieu of state-specific DUA
 - Developed by NAACCR Templated DUA Task Force
 - Vetted with registries, legal offices, researchers, NCI Technology Transfer Center
- VPR Templated DUA use among 43 participating registries
 - 21: Able to adopt “as is”
 - 7: Unable to use
 - 5: Maybe, with further edits
 - 6: Under review
 - 4: No DUA required
- Paper format incorporated into VPR-CLS while online process developed

ENHANCEMENTS TO PHASE II PROCESS

Registry	AG	Estimated Processing Time	HQ#	Form Type	Form Name	Description	Send To	All Forms Submitted?
Oklahoma	A5	3-6 months	252	Post Approval	VPR Templated DUA		raffaellae@health.ok.gov	Submitted: 03/10/2021
				IRB	IRB Form(s)	Registry and IRB forms are to be submitted at the same time. Submission details available online.		CONFIRM FORM(S)
Oregon	C3	3-6 months	501	Post Approval	Data Use Agreement	Only submit post-approval documents after approval.	jeffrey.a.soule@state.or.us	CONFIRM FORM(S)
				Registry	Registry Form(s)	Registry and IRB forms are to be submitted at the same time. Submission details available online.	kin.n.chan@state.or.us	CONFIRM FORM(S)
Puerto Rico	B2	1 - 3 months	40	Registry	VPR Templated DUA		ctorres@rcpr.org	Submitted: 06/10/2021
					Registry Form(s)	Submission details available online	ctorres@rcpr.org	

ENHANCEMENTS TO PHASE II PROCESS

Registry/ Notes ?	AG ?	Order of review	Overall Status	Date Registry Forms Submitted	Registry Review Status	Date IRB Forms Submitted	State IRB Review Status	Date P/A Documents Submitted ?	Agreement Status ?	HQ # ?	Records in Registry File	Date File Sent
Hawaii	A5	Concurrent Registry and IRB review	Complete	03/29/21	Approved: 04/15/2021	03/29/21	Exempt: 04/14/2021	N/A	N/A	101	105	05/13/21
New Mexico	A5	Registry Review before IRB review	Pending Approval	03/29/21	Approved: 04/12/2021	03/29/21	Estimated Review: 06/28/2021			211		
Oklahoma	A5	Registry Review before IRB review	Approved, Pending File Transfer	03/29/21	Approved: 04/08/2021	03/29/21	Approved: 04/08/2021	Submitted: 03/10/2021	Confirmed	252		
Rhode Island	A5	Registry Review before IRB review	Pending Confirmed Agreements	06/10/21	Approved: 04/15/2021	06/11/21	Approved: 05/17/2021	N/A	Pending Confirmation	153		

PHASE II: FINAL BETA TESTING

- Cohort Cancer Registry Follow Up Study (n=290K, 60,579 matches)
 - Nurses Health Study I, Nurses Health Study II, and Health Professionals Study
 - Previously sent unconfirmed, self-reported cases to 11 registries based on residence at diagnosis
- Women's Health Initiative (n=162K, 34,068 matches)
 - Prior linkage with one registry
- Sister Study (n=55K, 6,250 matches)
 - No prior linkage with registries



CENTRAL IRB (CIRB)

- NCI has entered into a 3-year contract with Biomedical Research Alliance of New York
- Accredited by AAHRPP
- Serves as the CIRB for:
 - VPR minimal risk studies eligible for expedited review or exemption from review
 - Other NCI-supported projects (e.g. SEER data release request process)
- Kickoff meetings with NCI (June 10th) and with NAACCR regarding VPR infrastructure and process (TBD)



COLLABORATION

- Central cancer registries
- Pilot test research studies
- Information Management Services
- Templated DUA Task Force
- HHS Office for Human Research Protections (OHRP)
- NIH Office of Extramural Research

- **NEW: SEEKING VOLUNTEERS!**
Secondary Data Sharing Workgroup



PLANS FOR LAUNCH

- Finish beta testing system enhancements
- Determine timeframe to incorporate online VPR Templated DUA and CIRB
- Slow, incremental, mindful roll out
- Remain on development site
- Work with existing list of interested NIH- and NCI-funded studies
- Give studies the following options:
 - Proceed with system as it stands
 - Wait and proceed once CIRB and VPR Templated DUA fully in place



The NAACCR logo is displayed in white, stylized, bold, italicized capital letters. A white swoosh underline starts under the 'N' and curves over the 'A' and 'C' before ending under the 'R'. The logo is centered within a large green circle that has a white border. The background of the slide features abstract, overlapping circles in shades of green and grey.

THANK YOU



CCLERKIN@NAACCR.ORG



WWW.NAACCR.ORG