The Ohio State University College of Medicine
Department of Biomedical Informatics

THE OHIO STATE UNIVERSITY
CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

The OSU CCTS New Research Support Service: Setting up a Standard Research Registry

REQUIRED Step 1: Request Registry through CoRR	Step 2: Request Services for Support	REQUIRED Step 3: Meet with RIS Team	REQUIRED Step 4: Complete and Submit Protocol to IRB	REQUIRED Step 5: Define your Registry Requirements	Step 6: IRB Approval Granted/Obtain Access
• **Access the CCTS's service request system – CoRR to create a Registry Project:** https://researchrecord.osu.edu/ • Complete the **Registry Acknowledgement Form**	• **Request Services through the CCTS:** ➢ Biostatistics ➢ Clinical Research Support ➢ Community Engagement ➢ Recruitment and Retention ➢ Regulatory and Ethics ➢ Research Clinics ➢ Research Evaluation Services ➢ Research Informatics Services ➢ Research Concierge	• Meet with **Research Informatics Team** • Provide **Overview** of your **Registry Requirements** • Discuss **Timeline**	• **Complete** all **Required documentation** following policies of **orrp.osu.edu** • Include **Required Registry portal language** in your **Study Protocol**	• **Define** your **Registry Requirements*** • **Meet and/or contact RIS** as needed for assistance	• **IRB Approval** is Obtained • BMI **initiates technical deployment** of Registry
Registry Initiation	***If needed*, Registry Team is Created (along with RIS personnel)**	**Scope and Project Plan is Initiated**	**IRB Submission is Completed**	**Scope is Finalized * Customization (*if needed*) is defined**	**IRB Approval Registry deployment initiated**
1 day	*1 – 2 weeks dependent on availability*	*Within 2-3 weeks of Registry Request*	*Standard IRB timeframe: submission and approval 1 to 2 months**	*Within 4-5 weeks of Registry Request*	*Up to 2 months following IRB approval**

4 to 6 months

Vsn 2.0 February 18 2015

If you have any questions, please contact us
Phone: (614) 366-5212 **Email:** https://ccts.osu.edu/about-ccts/contact-us **Website:** https://ccts.osu.edu/

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New Research Support Service: Standard Research Registry

List of Available Fields to Build Your Registry

Person Data (Demographic Data)	Demographics about a person, including age range, gender, race, ethnicity, etc.
Condition Occurrence (Diagnoses/Symptoms)	All individual instances of the conditions suffered by Persons including ICD-9-CM diagnosis codes, medical claims data, etc.
Death Record	Time when a Person is deceased and causes of death
Encounter (Visit Occurrence)	All Person visits to health care providers, including inpatient, outpatient, and ER visits
Location	Address information.
Medication (Drug Exposure)	Drug exposure includes the following drug details: drug quantity, number of days' supply, period of exposure, and prescription refill data.
Provider	Lists of uniquely identified health care providers (physicians).
Care Site	Select from a list of uniquely identified points of care, or an individual clinical location within the organization.
Observations (Laboratory Results/General Findings, Diagnoses)	Lab observations (i.e., test results) from Medical Claims. Lab and other observations from Electronic Health Records, Chief complaints as captured in Electronic Health Records. General clinical findings. General catch-all categories from various data sources that cannot be otherwise categorized within the entities provided (Drug, Condition, Procedure)
Observation Period	Span of time when a Person is expected to have the potential of Drug and Condition information recorded. For claims data, observation periods are equivalent to enrollment periods to a plan.
Procedure Occurrence (Procedures)	Individual instances of procedures performed on Persons including CPT-4, ICD-9-CM (Procedures), and HCPCS procedure codes.

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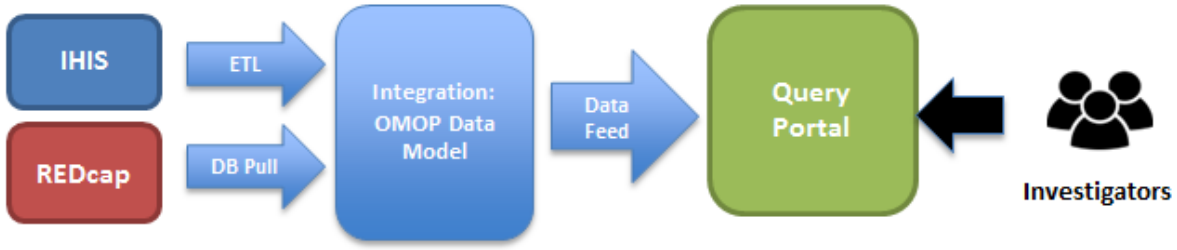
The following includes standard language to be incorporated into your study protocol when requesting a research registry to be included in your study.

IRB Boilerplate Language for your Registry Protocol

A standard registry framework (the "Registry Pipeline") will be used to establish a research registry that will collect research specific data and to integrate this data with subject phenotypic information from their local Electronic Health Record ("EHR"). The "Registry Pipeline" is a software toolset and workflow methodology for the electronic collection and management of clinical and research data. Immediate oversight of the Registry Pipeline will be conducted by the OSU Center for Clinical and Translational Science ("CCTS") and the Department of Biomedical Informatics ("BMI").

The "Registry Pipeline" is a secure, web-based application that leverages REDCap and IHIS for data capture. Research data is sourced from REDCap; clinical data is sourced from IHIS. The "Registry Pipeline" software takes specific data points from the REDCap database as well as extracts IHIS data from the Information Warehouse ("IW") and integrates this data into a standard Observational Medical Outcomes Partnership ("OMOP") , i.e., the registry. A basic query portal will be developed to provide database search queries.



The registry database and application will be installed on an internal OSUWMC network behind the OUSWMC firewall. Users will be permissioned to access the application based on their inclusion as IRB approved research personnel as specified within the protocol. User accounts will be created and managed through the registry applicane. Access to the clinical data for the specified registry will be web-based and is enabled through a basic query portal.

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