

Attachment B: Questionnaires/Data Collection Instruments

The RoPR data collection system is a web-based collection mechanism. The screenshots included in this document represent all sections that will be visible to users who enter information through the self-registration pathway. The online form has 20 sections.

Users who enter information through the ClinicalTrials.gov pathway (which already received OMB approval) will only see sections 1-8 and 20.

1)

Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Welcome to RoPR - Registry Profile Overview

E-Mail: E-mail is required.

Confirm: SAVE E-MAIL Confirm is required.

This email will only be used by RoPR and will not be distributed.

Registry Description	INCOMPLETE
Registry Classification and Purpose	INCOMPLETE
Contact and Conditions of Access	INCOMPLETE
Progress Report	INCOMPLETE
Related Information	INCOMPLETE
Outcome Measures and Common Data Elements	INCOMPLETE
Study Status	INCOMPLETE
Collaborators	INCOMPLETE
Study Design	INCOMPLETE
Study Outcome Measures	INCOMPLETE
Study Groups and Interventions	COMPLETE
Study Eligibility	INCOMPLETE
Public Health	INCOMPLETE

UPLOAD REGISTRY RECORD

Import and upload XML file

No file chosen

[XML Upload Template](#)
[Registry Profile Schema](#)

UPLOAD

ROPR HELP

[Frequently Asked Questions](#)

[Upload of Registry Profile Help](#)

[Policies and Procedures Documentation](#)

[E-mail Contact for RoPR Administrators](#)

OMB Control Number: 0935-0203 | Expiration Date: 10/31/2015

Public reporting burden for this collection of information is estimated to average 55 minutes per response, the estimated time required to complete the survey. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-XXXX) AHRQ, 5600 Fishers Lane, # 07W41A, Rockville, MD 20857.

2)

Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Registry Description * Required Field

OVERVIEW

Registry Description

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Public Health

PREVIEW

SAVE/RELEASE REGISTRY PROFILE

Registry Version Registry version identifier.

Registry Geography * Identify geographic scope of data collection for the registry. Registry Geography is required.

Registry Location Single Institution / Practice tion to clarify Registry Geography as selected.

Registry Title * Regional ublic. Registry Title is required.

Global

Official Title

Brief Description

Long Description

PREVIOUS NEXT

[Contact the RoPR](#)

3)

Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

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PREVIEW

SAVE/RELEASE REGISTRY PROFILE

Registry Classification and Purpose * Required Field

Registry Classification * *Select all that apply. Enter Other if additional classifications apply.*

<input type="checkbox"/> Disease/Disorder/Condition	<input type="checkbox"/> Product, Drug	<input type="checkbox"/> Transplant
<input type="checkbox"/> Pregnancy	<input type="checkbox"/> Service, Encounter	<input type="checkbox"/> Tumor
<input type="checkbox"/> Product, Biologic	<input type="checkbox"/> Service, Hospitalization	<input type="checkbox"/> Vaccine
<input type="checkbox"/> Product, Device	<input type="checkbox"/> Service, Procedure	
<input type="checkbox"/> Other <input style="width: 150px;" type="text"/>		

Registry Purpose * *Select all that apply. Enter Other if additional purposes apply.*

<input type="checkbox"/> Clinical Practice Assessment	<input type="checkbox"/> Payment / Certification	<input type="checkbox"/> Quality Improvement
<input type="checkbox"/> Effectiveness	<input type="checkbox"/> Post Marketing Commitment	<input type="checkbox"/> Safety or Harm
<input type="checkbox"/> Natural History of Disease	<input type="checkbox"/> Public Health Surveillance	
<input type="checkbox"/> Other <input style="width: 150px;" type="text"/>		

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4)

Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Contact and Conditions of Access

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Interest in Being Contacted?* Identify if the sponsor is interested in being contacted for reasons listed below. *** Required Field**
Interest in Being Contacted? is required.

Yes No

Reasons for Being Contacted Identify sponsor's reasons for being contacted. Enter Other if additional reasons apply.

Collaboration Participation - Investigator

Data Access Participation - Participant

More Information

Other

Organization The primary contact organization.

First Name The primary contact individual's first name.

Last Name The primary contact individual's last name.

Title The primary contact individual's title.

E-Mail The primary contact email.

It is recommended that this e-mail be a department or distribution list so that if the contact person leaves the organization, the e-mail will still be delivered to a person within the department that can respond to the inquiry.

Phone The primary contact phone number.

Ext.

Link to Organization or Registry Site A link to the organization or registry's Web site (including http:// or https://).

Link to Conditions of Access A link to a Web site or document describing conditions of access required by sponsor (including http:// or https://).

Has Data Monitoring? Yes No

5)

Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Progress Report

*** Required Field**

Is Progress Report Available? *

Yes No

Is Progress Report Available? is required.

Progress Report information for the registry may include interim reports, annual reports, results, and/or other related information. If one is available, the following data elements are included in a Progress Report:

- Title *
- Summary *
- Number of Participants in Registry *
- Length of Follow-up *
- Link to Progress Report

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Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Progress Report

*** Required Field**

Is Progress Report Available? *

Yes No

You must add at least one Progress Report.

ADD PROGRESS REPORT

New Progress Report

Title * Title of the Progress Report. Title is required.

Summary * Summary of all relevant progress report information. May include summary of interim reports, annual reports, and/or other related registry progress reports. Summary is required.

Number of Participants in Registry * Actual Progress data identifying the current number of participants in the registry. Number of Participants in Registry is required.

Length of Follow-up * Actual Progress data identifying the length of follow-up data in years, as currently available within the registry. Length of Follow-up is required.

Link to Progress Report A link to the progress report (including http:// or https://).

SAVE CANCEL

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6)

Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Related Information

*** Required Field**
Are Related Links Available? *

Yes No

Are Related Links Available? is required.

Indicate if references to other relevant information are available for this registry. If they are available, the following data elements are included for a Related Link:

- Link *
- Description *

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Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Related Information

*** Required Field**
Are Related Links Available? *

Yes No

You must add at least one Related Link.

New Related Link

Link * A link to a Web site for relevant registry information or to a publication related to the registry (including http:// or https://). **Link is required.**

Description * A title or brief description of the linked page. **Link Description is required.**

SAVE **CANCEL**

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7)

Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

OVERVIEWConditionCategory

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PREVIEW

SAVE/RELEASE REGISTRY PROFILE

Condition or Service of Interest for Registry

Outcome Measures and Common Data Elements - Condition or Service of Interest* * Required Field

Primary disease, condition or service being studied. Use the National Library of Medicine's Medical Subject Headings (MeSH). Select all that apply. Enter Other if additional Conditions apply.

<input type="checkbox"/> Bacterial and Fungal Diseases	<input type="checkbox"/> Muscle, Bone, and Cartilage Diseases
<input type="checkbox"/> Behaviors and Mental Disorders	<input type="checkbox"/> Nervous System Diseases
<input type="checkbox"/> Blood and Lymph Conditions	<input type="checkbox"/> Nutritional and Metabolic Diseases
<input type="checkbox"/> Cancers and other Neoplasms	<input type="checkbox"/> Occupational Diseases
<input type="checkbox"/> Digestive System Diseases	<input type="checkbox"/> Parasitic Diseases
<input type="checkbox"/> Diseases or Abnormalities at or before Birth	<input type="checkbox"/> Respiratory Tract (Lung and Bronchial) Diseases
<input type="checkbox"/> Ear, Nose, and Throat Diseases	<input type="checkbox"/> Skin and Connective Tissue Diseases
<input type="checkbox"/> Eye Diseases	<input type="checkbox"/> Substance Related Disorders
<input type="checkbox"/> Gland and Hormone Related Diseases	<input type="checkbox"/> Symptoms and General Pathology
<input type="checkbox"/> Heart and Blood Diseases	<input type="checkbox"/> Urinary Tract, Sexual Organs, and Pregnancy Conditions
<input type="checkbox"/> Immune System Diseases	<input type="checkbox"/> Viral Diseases
<input type="checkbox"/> Mouth and Tooth Diseases	<input type="checkbox"/> Wounds and Injuries
<input type="checkbox"/> Other <input style="width: 150px;" type="text"/>	

At least one Condition is required.

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Completion Status: 1 of 13 Sections 8% 8 % Completed

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Category of Interest for Registry

ConditionCategory

Outcome Measures and Common Data Elements - Categories * * Required Field

Select all that apply. Enter Other if additional Categories apply.

<input type="checkbox"/> Clinical Assessments	<input type="checkbox"/> Patient Reported Outcomes
<input type="checkbox"/> Demographics	<input type="checkbox"/> Procedures
<input type="checkbox"/> Devices	<input type="checkbox"/> Risk Factors
<input type="checkbox"/> Diagnosis	<input type="checkbox"/> Staging Systems
<input type="checkbox"/> Disease Response	<input type="checkbox"/> Survival Outcomes
<input type="checkbox"/> Events of Interest	<input type="checkbox"/> Treatments
<input type="checkbox"/> Genetic Information	<input type="checkbox"/> Vitals
<input type="checkbox"/> Medications	
<input type="checkbox"/> Other <input style="width: 150px;" type="text"/>	

At least one Category is required.

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Completion Status: 1 of 13 Sections 8% 8 % Completed

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PREVIEW

SAVE/RELEASE REGISTRY PROFILE

Study Status

Record Verification Date*	<small>The date on which the responsible party last verified the clinical study information in the entire RoPR record for the clinical study, even if no additional or updated information is being submitted.</small> --Select-- Year <input type="text" value="2017"/>	* Required Field <small>A Verification Date Must be provided</small>
Overall Recruitment Status*	<small>The recruitment status for the clinical study as a whole, based upon the status of the individual sites.</small> --Select--	<small>A Recruitment Status must be selected</small>
Study Start Date	<small>The estimated date on which the clinical study will be open for recruitment of participants, or the actual date on which the first participant was enrolled.</small> --Select-- Year <input type="text"/>	
Continuous Enrollment	<input type="radio"/> Yes <input type="radio"/> No	
Primary Completion Date	<small>The date on which data collection is completed for all of the primary outcomes.</small> --Select-- Year <input type="text"/> Type --Select--	
Study Completion Date	<small>The date on which data collection is completed for all of the primary and secondary outcomes.</small> --Select-- Year <input type="text"/> Type --Select--	

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Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Collaborators

*** Required Field**

Are Collaborators Providing Support? *

Yes No

Are Collaborators Providing Support? is required.

Indicate if other organizations (if any) are providing support, including funding, design, implementation, data analysis and reporting. The responsible party is responsible for confirming all collaborators before listing them. If there are, the following data elements are included for a Collaborator:

- Collaborator Name *

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Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Collaborators

*** Required Field**

Are Collaborators Providing Support? *

Yes No

You must add at least one Collaborator.

New Collaborator

Collaborator Name * Name of organization providing support

Collaborator Name is required.

SAVE **CANCEL**

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11)

Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR

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Study Design

OVERVIEW

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PREVIEW

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* Required Field

Observational Study Model * Primary strategy for participant identification and follow-up

Time Perspective * Temporal relationship of observation period to time of participant enrollment

Biospecimen Retention Indicate whether samples of material from research participants are retained in a biorepository

Enrollment * The estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study
Number of Subjects Type

Number of Groups/Cohorts Number of study groups/cohorts. Enter "1" for a single-group study.

Target Follow-Up Duration * The anticipated time period over which each participant is to be followed.
 Type

12)

Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Study Outcome Measures

Primary Secondary Other

Primary Outcome Measures * * Required Field

You must add at least one Primary Outcome Measure.

[ADD OUTCOME MEASURE](#)

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Completion Status: 1 of 13 Sections 8% 8 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Study Outcome Measures

Primary Secondary Other

Primary Outcome Measures * * Required Field

You must add at least one Primary Outcome Measure.

[ADD OUTCOME MEASURE](#)

New Primary Outcome Measure

Title * A concise name for the specific measure Title is required.

Time Frame * Time point(s) at which outcome measure is assessed. Time Frame is required.

Description Additional information about the outcome measure, if needed for clarification.

Safety Issue Is this outcome measure assessing a safety issue

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13)

Completion Status: 2 of 13 Sections 15% 15 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Study Outcome Measures

Primary Secondary Other

Secondary Outcome Measures * Required Field

[ADD OUTCOME MEASURE](#)

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Completion Status: 3 of 14 Sections 21% 21 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Study Outcome Measures

Primary Secondary Other

Secondary Outcome Measures * Required Field

[ADD OUTCOME MEASURE](#)

New Secondary Outcome Measure

A concise name for the specific measure.

Title * * Title is required.

Time point(s) at which outcome measure is assessed.

Time Frame * * Time Frame is required.

Additional information about the outcome measure, if needed for clarification.

Description

Is this outcome measure assessing a safety issue

Safety Issue

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14)

Completion Status: 2 of 13 Sections 15% 15 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Study Outcome Measures

Primary Secondary Other

Other Outcome Measures * Required Field

[ADD OUTCOME MEASURE](#)

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Completion Status: 3 of 14 Sections 21% 21 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Study Outcome Measures

Primary Secondary Other

Other Outcome Measures * Required Field

[ADD OUTCOME MEASURE](#)

New Other Outcome Measure

Title * A concise name for the specific measure Title is required.

Time Frame * Time point(s) at which outcome measure is assessed. Time Frame is required.

Description Additional information about the outcome measure, if needed for clarification.

Safety Issue Is this outcome measure assessing a safety issue

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15)

Completion Status: 2 of 13 Sections 15% 15 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Study Groups and Interventions

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Groups Cohorts

ADD GROUP

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* Required Field

Completion Status: 2 of 13 Sections 15% 15 % Completed

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Study Groups and Interventions

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Groups Cohorts

ADD GROUP

New Group

Group/Cohort Label * The short name used to identify the group. Label is required.

Group/Cohort Description Explanation of the nature of the study group (for example, those with a condition and those without a condition; those with an exposure and those without an exposure).

SAVE CANCEL

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PREVIEW

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* Required Field

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Completion Status: 2 of 13 Sections 15% 15 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Study Groups and Interventions

Groups Interventions

* Required Field

Interventions/Exposures

ADD INTERVENTION

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Study Groups and Interventions

Groups Interventions

* Required Field

Interventions/Exposures

ADD INTERVENTION

New Intervention

Intervention Type * The general type of intervention. type is required.

Intervention Name * A brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical study Name is required.

Intervention Description Details that can be made public about the intervention, other than the Intervention Name(s) and Other Intervention Name(s), sufficient to distinguish the intervention from other, similar interventions studied in the same or another clinical study

Other Names (if any) Other current and former name(s) or alias(es), if any, different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention(s), including, but not limited to, past or present names such as brand name(s), or serial numbers

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Completion Status: 0 of 13 Sections 0% 0 % Completed

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PREVIEW

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Study Eligibility

*** Required Field**

A description of the population from which the groups or cohorts will be selected

Study Population Description *

Sampling Method * Select one

Gender Physical gender of individuals who may participate in the protocol

Age Limits

	<small>Age of participants</small>	<small>Unit of Time</small>	
Minimum	<input type="text"/>	<input type="text" value="--Select--"/>	
Maximum	<input type="text"/>	<input type="text" value="--Select--"/>	

Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study.

Accepts Healthy Volunteers?

Eligibility Criteria

Summary criteria for participant selection.

Inclusion Criteria:
-

Exclusion Criteria:
-

18)

Completion Status: 11 of 14 Sections 79% 79 % Completed

ROPR

REGISTRY of PATIENT REGISTRIES

* Required Field

OVERVIEW

Registry Description

Registry Classification and Purpose

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Secondary IDs

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Public Health

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Public Health

Accepts Electronic Public Health Data? Identify if this is part of the CMS public health agency and clinical data registry reporting that will assist in finding entities that accepts electronic public health data.

Yes No

Public Health Measures Supported * Identify the public health measures the entity plans to support.

- Clinical Data Registry Reporting
- Electronic Reportable Laboratory Reporting
- Immunization Registry
- Public Health Registry Reporting
- Specialized Registry Reporting
- Syndromic Surveillance Reporting

Providers Served * Identify the providers served.

- Eligible Hospitals/CAHs
- Eligible Professionals

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19)

Completion Status: 0 of 13 Sections 0% 0 % Completed

ROPR

REGISTRY of PATIENT REGISTRIES

Registry Profile Preview

RoPR ID: 21635

NCT ID - Pending Release to ClinicalTrials.gov

(Click the NCT ID to view the ClinicalTrials.gov details for this record)

Use the Edit Icon to navigate to the specific section.

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PREVIEW

SAVE/RELEASE REGISTRY PROFILE

REGISTRY DESCRIPTION

Registry Title	
Version	
Official Title	
Last Updated On	January 12, 2017
First Received On	January 12, 2017
Brief Description	
Long Description	
Geography and Location	

REGISTRY CLASSIFICATION AND PURPOSE

Registry Classification	
Registry Purpose	

CONTACT AND CONDITIONS OF ACCESS

Interested in Being Contacted	
Organization	
Contact	

20)

Completion Status: 0 of 13 Sections 0% 0 % Completed

ROPR | REGISTRY of PATIENT REGISTRIES

Save/Release RoPR Registry Profile

Last updated: January 12, 2017

I confirm that the RoPR Registry Profile Record is accurate to the best of my knowledge.

I Agree

All Sections must be Complete in order to release the Registry Profile

RoPR Registry Profiles are made available to the public search site <https://patientregistry.ahrq.gov> within 1 day of release, following system validation.

Please complete the corresponding ClinicalTrials.gov record upon exiting the RoPR. Previous versions of the RoPR Registry Profile will be available to the public, though the default view will be the most recent version.

SAVE AND EXIT

Click to save your Registry Profile without releasing to the RoPR public search site

RELEASE AND EXIT

Click to release your Registry Profile to the RoPR public search site

Registry Description	INCOMPLETE
Registry Classification and Purpose	INCOMPLETE
Contact and Conditions of Access	INCOMPLETE
Progress Report	INCOMPLETE
Related Information	INCOMPLETE
Outcome Measures and Common Data Elements	INCOMPLETE
Study Status	INCOMPLETE
Collaborators	INCOMPLETE
Study Design	INCOMPLETE
Study Outcome Measures	INCOMPLETE
Study Groups and Interventions	INCOMPLETE
Eligibility	INCOMPLETE
Public Health	INCOMPLETE

Contact the RoPR