University of Nevada, Reno
Research & Innovation

Research Integrity & Security
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Sub-Project Protocol – Renown OMOP-CDM Database for Retrospective Research

This form should only be completed for sub-projects seeking to use patient-level data from the Renown OMOP-CDM database for non-interventional, secondary research. Sub-projects must follow the data security plan of the master protocol and the Renown-UNR Data Use Agreement. This form should be submitted with a Cover Sheet. Only collaborators listed on the Cover Sheet will be granted access to data.

Please delete the instructions after you complete each section. Do not delete the section headings.

Sub-Project Title: Click or tap here to enter text.

Will researchers interact or intervene with living individuals for research purposes, including for consent or recruitment processes?

☐ Yes. (Stop: This is not the correct form. Complete the Protocol Form for Social-Behavioral-Educational Research or Biomedical Research instead).

☐ No.

The Renown OMOP-CDM database only contains de-identified patient information for which the risk of re-identification is very small. Will researchers attempt to re-identify patients from whom the data was originally collected, alone or in combination with other information?

☐ Yes. (Stop: This is not the correct form. Complete the Protocol Form for Social-Behavioral-Educational Research or Biomedical Research instead).

☐ No.

Are you requesting patient-level data from the Renown OMOP-CDM database? Note that an IRB protocol is not needed for aggregated data requests.

☐ Yes.

☐ No. (Stop: An IRB protocol is not needed. Proceed with a Level 1 Aggregated Data Request from the OMOP-CDM database.)

Background:
Provide a non-technical explanation to justify why the research needs to be done and what will be its relevance (generally this section should not be longer than a few paragraphs). Describe the relevant prior scientific or scholarly literature and gaps in current knowledge. If applicable, describe any relevant preliminary data. References go at the end of this protocol.

Study Aims/Objectives:
List research objectives or specific aims, including hypotheses to be tested.

Study Population:
Describe the characteristics that must be present to include the requested data in the research, such as age range, gender, medical history, or background. List the inclusion/exclusion criteria, which should also be reflected in the data requested section of this form. Specify any interventions, exposures, or outcomes that are pertinent to your request. If applicable, define any comparison or control groups. Define the relevant beginning

and ending timeframe for the request. If known, provide any relevant codes (e.g., SNOMED, ICD-9/10, CPT, HCPCS, RxNorm).

Sample Size:
Provide an estimated sample size (number of patients or records) and an explanation as to how you arrived at that number. If you do not know the sample size, please request a Level 1 Aggregated Data Request from the OMOP-CDM database to determine the population size available for your study.

Data Requested:
Provide a list of the tables and fields from the OMOP-CDM database that are being requested for this project. Create extra table rows as needed or upload the list as a supporting document or spreadsheet. For rationale, describe if the field is being requested for Inclusion, Exclusion, or Results.

Field Name	Description	Rationale

Data Management and Confidentiality Procedures:
Confirm that researchers will follow the data security plan of the OMOP-CDM master protocol as follows:

- Patient-level data will only be stored on HIPAA-compliant secure servers and will only be accessed through secure means in accordance with UNR Med IT policies.
- Patient-level data will not be improperly downloaded or shared with anyone outside of the listed collaborators.
- Aggregated data, results, and figures not containing patient-level data may be extracted from the HIPAA-compliant secure servers.
- Researchers will not attempt to re-identify or contact patients from whom the data was originally collected.
- Researchers will report to the Research Integrity & Security Office or UNR Translational Research Center if they find any data which may permit re-identification of patients.
- Researchers will use data from the OMOP-CDM database for the sole purpose of lawful use in scientific research, and for no other commercial or private purpose.

☐ Yes.

☐ No.

Approach to Analysis:
Provide a brief description of your plan for analyzing the data you are requesting. Consider consulting a statistician before finalizing the protocol, if appropriate for your research.

References:
List all the references used in the background section or other sections of this form.