**Research Application**

|  |  |
| --- | --- |
| Project Number | *To be assigned by OptumLabs upon submission* |
| Project Title |  |
| **Principal Investigator** |   |
| **Institution** |   |
| **Email** |   |

All participants on the project team are subject to OptumLabsTM policies, procedures, and all agreements between your institution and OptumLabs. This document will be used for project oversight, accountability, coordination of activities and decision making. In the event of a conflict between this document and any agreements between your institution and OptumLabs, the terms and conditions of any such agreements shall control.

**Research Application Completion Instructions**

# For Preliminary Research Application Review:

* Complete Sections 1-7
	+ Insert contact information, project title, and logo (if desired) on cover page
	+ Provide a general overview of research design in Sections 2-3
	+ Complete Sections 4-7 as far as known; final details for these sections are not expected at this stage
	+ Remaining sections will not be reviewed at this stage
* Please fully read sections 16-19
* Sections highlighted in yellow are generally required; those in green are required as applicable

# For Detailed Research Application Review:

* Review and update the cover page and Sections 2-7 as needed
* Provide detailed research plans in Section 3
* Describe final staffing plan and timelines in Section 6-7
* Complete Sections 8-15
* Please fully read sections 16-19
* Sections highlighted in yellow are generally required; those in green are required as applicable

The PRA is intended to provide an overview of the study for assessment of feasibility and alignment with OptumLabs mission by the Research Review Committee (RRC). The DRA serves as a study protocol. It is understood that the study protocol is a living document and research designs (such as planned study variables or statistical analyses) may change as projects progress. OptumLabs recommends that DRAs be annotated with changes throughout the life of the project so that an accurate account of data set construction, variable operationalization, and statistical analysis is maintained.

We recognize that certain Partners may have existing formats for detailed study protocols. Partners may submit material requested in section 3 in their own format as a supplement to the DRA, provided that: 1) all of the content requested in the DRA is included; and 2) all other DRA sections are completed and submitted along with the supplement.

**Completed PRAs and DRAs should be submitted via email (as a Word file attachment) to:** **researchops@optum-labs.com****.**

1. **Confidentiality & Sharing**

This document is confidential and subject to the confidentiality and antitrust agreements in place between OptumLabs and each Collaborative Organization. Please do not share this document outside of the OptumLabs Collaborative and discussion related to this project should be in compliance with the OptumLabs antitrust policy.

In the spirit of transparency and collaboration that is a cornerstone of OptumLabs, this document may be posted on the OptumLabs Portal and OptumLabs partners would have access to the documents. If you feel it is necessary to keep this document confidential from other partners, please provide a justification in this section.

[*Type here, if applicable*]

1. **Project Summary**
	1. Problem Formulation / Hypothesis

Include background of the research question, health care challenge, or research hypothesis (1-3 paragraphs). Please describe the potential impact of the project relative to one or more Triple Aim goals: improving health, improving the patient experience and/or reducing cost. Please include definitions of any critical concepts that are not general knowledge (e.g. what is a preventable hospitalization) and cite seminal literature, if applicable.

[*Type here*]

* 1. Study Purpose and Objectives

The purpose of this study is [*Type here*]

The specific objectives for this project are:

1. [*Type here*]
2. [*Type here*]
3. [*Type here*]
	1. Data Sources

This study will use the following data from [*Date here*] to [*Date here*]:

[ ]  Enrollment data (see appendix)

[ ]  Physician Claims

[ ]  Facility Claims

[ ]  Facility UB92 detail file (see appendix)

[ ]  Pharmacy claims

[ ]  Race data (see appendix under Consumer Profile)

[ ]  Socioeconomic data (see appendix under Consumer Profile)

[ ]  HRA data

[ ]  AHA data

[ ]  Mortality data (see appendix)

[ ]  Laboratory result data – claims-sourced (see appendix)

[ ]  Clinical data (see appendix)

[ ]  Consumer/Lifestyle data (see appendix)

[ ]  Discharge status field detail (see appendix); if yes, please provide justification:

[*Type here, if applicable*]

Based on the above and the attached research view appendix, this study will utilize:

[ ]  **UNIFIED**\_Clinical\_Claims\_HRA\_*CensusRegion*

[ ]  **STATE-CLAIMS**\_Claims\_HRA\_*State*

[ ]  **DoD**\_Claims\_*State*

[ ]  **SES**\_Claims\_HRA\_*CensusDivision*

[ ]  **LIFESTYLE**

[ ]  **ZIP5**

Study subjects will include:

[ ]  Commercial enrollees

[ ]  Medicare Advantage enrollees

* 1. Expected Funding Source(s)

|  |  |  |
| --- | --- | --- |
| **Organization/Funder** | **Name or number, if applicable** | **Comments** |
|  |  |  |
|  |  |  |
|  |  |  |

* 1. Key Words

[*Type here*]

* 1. Is this study investigator initiated?

[ ]  Yes

[ ]  No

Please explain:

[*Type here*]

1. **Research Plan**
	1. Population, study cohorts, and special subgroups of interest

For PRA, brief overview, describing any special characteristics, e.g. “Type II diabetic patients aged 55 and over, with evidence of at least two oral antidiabetic medications and either commercial or Medicare Advantage coverage.” Include a description of study cohorts/comparison groups or other subgroups of interest (e.g. “Patients new to combination diabetic therapy vs. prevalent combination therapy users,” or “Patients treated with drug class A vs. patients treated with drug class B.”)

For DRA, specify inclusion/exclusion criteria (including dates, codes of interest, temporal relationships between characteristics, continuous enrollment requirements). Please include, if applicable, detailed description of how study cohorts/groups will be defined, including diagnoses, procedures, treatments, exposures, etc. Include description of any relevant matching or sampling techniques,

[*Type here*]

For DRA, detailed description of how study groups will be defined, including diagnoses, procedures, treatments, etc. Include description of any relevant matching or sampling techniques,

Note: This section should describe study groups or cohorts, not stratification that may be conducted during analysis.

[*Type here, if applicable*]

* 1. Variables

For PRA, list of key variables of interest and preliminary plans for operationalizing key measures (if you are unsure of how you will operationalize specific variables, please list here and note).

For DRA, detailed description of how all study variables will be operationalized.

**Key Outcomes, if applicable**

For example, VTE occurrence, COPD exacerbations, frequency of prostate cancer screening, SAEs resulting from treatment, diabetes-related health care costs

[*Type here*]

**Key Indicator(s) of Interest, if applicable**

For example, NOAC vs. warfarin use, adherence to guidelines, firearm injury, time to conversion to insulin. Note that for some studies, cohort is synonymous with key indicator. Outcome measures and patient demographics may also serve as key indicators in some projects.

[*Type here*]

**Demographic and Patient Characteristics**

For example: gender, region, race/ethnicity, Commercial/Medicare

[*Type here*]

**Other Variables, if applicable**

For example: specific comorbid conditions, Charlson comorbidity index, BMI, HbA1c test results, microbiology findings, frequency of spirometry testing, disease severity indicator).

[*Type here*]

* 1. Analysis Plan

Plan for descriptive and multivariate techniques, including any stratification or sensitivity analyses.

For PRA, brief description of planned analyses.

For DRA, detailed analytic plans for DRA by study objective/aim; novel analytic techniques are encouraged and should be noted.

[*Type here*]

* 1. Preliminary Patient Counts

Optional for PRA; required for DRA submission.

[*Type here*]

* 1. Data to be imported to Project Sandbox, if applicable[[1]](#footnote-1)

[ ]  Program codes: SAS, SQL, Stata, R, etc.

[ ]  Code lists: NDC, ICD-9, CPT, HCPCS, etc.

If additional data is required in the sandbox, please describe below:

[*Type here, if applicable*]

* 1. Data to be exported from OLDW1

[ ]  Program codes: SAS, SQL, Stata, R, etc.

[ ]  Code lists: NDC, ICD-9, CPT, HCPCS, etc.

[ ]  Summary tables, charts and results (aggregated data)

1. **Translation Potential**

Acknowledging the momentum to close the evidence-to-practice gap in medicine and science, OptumLabs is committed to facilitating the translation of research findings into real world settings in support of “Triple Aim + 1” goals.

1. Improve outcomes
2. Improve the patient experience
3. Reduce costs in the health care system
4. Improve the experience/work life of health care providers and inform policy discussions (as applicable)

This may occur via programs to change clinical practice, influence policy, improve education and/or enable behavior change opportunities, etc.

Name the translation sponsors or champions in your organization:

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **Email** |
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Describe below how the following stakeholders could benefit from or implement project results that address the “Triple Aim + 1” (or “Quadruple”) goals. Include the expected impact of successful translation:

* 1. Consumers/Patients

[*Type here, if applicable*]

* 1. Payers

[*Type here, if applicable*]

* 1. Providers

[*Type here, if applicable*]

* 1. Life Science Companies

[*Type here, if applicable*]

* 1. Employers

[*Type here, if applicable*]

* 1. State or federal agencies/programs

[*Type here, if applicable*]

* 1. NGOs

[*Type here, if applicable*]

* 1. Medical Societies

[*Type here, if applicable*]

* 1. Your organization

[*Type here, if applicable*]

* 1. Other

[*Type here, if applicable*]

1. **Publication and Dissemination of Results Checklist**

List the communication channels most appropriate for reaching target audiences with key findings.

For PRA, identify preliminary dissemination plan (check the appropriate boxes for known or possible routes of dissemination). For DRA, update this plan.

Please see Section 17 of this document for OptumLabs publication review requirements.

[ ]  Peer-review/professional journal articles; expected article(s), lead author, other authors and target journal(s):

1. [*Type here, if applicable*]
2. [*Type here, if applicable*]

[ ]  Professional meeting presentations/posters/abstracts; targeted meetings:

1. [*Type here, if applicable*]
2. [*Type here, if applicable*]

[ ]  Press release / media coverage

[ ]  Media packages

[ ]  Social media distribution

[ ]  Policy briefs

[ ]  White paper

[ ]  Professional, medical and advocacy group communication: [*Type here, if applicable*]

[ ]  Shared patient and/or provider decision aides

[ ]  Video clips / multimedia

[ ]  Articles or blogs targeting specific stakeholders

[ ]  Other web posts/content

[ ]  Patent applications

[ ]  Investor packages

[ ]  Translation to practice and/or commercialization plan – see section 16 for DRA requirements

[ ]  Other: [*Type here, if applicable*]

1. **Resource and Timeline Planning**

For PRA, complete if known; for DRA, required.

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| --- | --- | --- |
| **Research Project Milestones** | **Description of Milestones** | **Planned Date** |
| **Detailed Research Application (DRA) Submission\*** | Applicant submits the complete DRA to OptumLabs for review.  |  |
| **SOW Completion** | OptumLabs and your institution have signed an SOW for the research project.*Please contact your Partner Relationship Manager with questions about the SOW process and timeline.* |  |
| **Project Initiation\*** | Project planning and provisioning complete. Typically when vDI is provisioned to team (~ 5-10 days after SOW signed) |  |
| **Data Set Completion** | For some projects, this may be very fast (if a standard view is used and population definition is straightforward). Some projects will require significantly more effort to define the data set, establish new views, or even import or link new data. |  |
| **Analysis Complete** | Completion of all statistical and descriptive analysis. Study is ready to move into reporting phase. |  |
| **Submit Report/Manuscript Draft for OL Review\*\*** |  |  |
| **Report/Manuscript Complete\*** | Completion/issuance of the first document that includes analysis and interpretation. Could be a study report, manuscript, abstract, poster or other form of communication. If it is for publication or presentation, this should be the date submitted. *Note: It is recognized that multiple reports may come out of the same project. Depending on the work involved, subsequent reports could become new projects. Some projects may not result in a full report. In this case, a simple closeout report or memo can be issued.* |  |
| **Next Steps** | Discuss for opportunities for translational and/or commercialization transfer based on results of the study |  |
| **Project Completion or****Termination\*** | Final expenditure of resources completed |  |

(\*) Indicates that dates are required

(\*\*) See section 18 for OptumLabs publication review requirements

Please specify if the project start is relative to another event (e.g., SOW signature, one month after receipt of grant, etc.):

[*Type here, if applicable*]

1. **Collaboration, Resource, and/or Staffing Plan**

For PRA, please list planned name, role, staff from your organization, consultants, and potential collaborators (including OptumLabs team members).

For DRA, update planned staff and collaborators and include details related to time commitment and funding source.

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| --- | --- | --- | --- | --- |
| **Role** | **Name** | **Organization** | **Duration (weeks)** | **Time (hrs/week)** |
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***Please complete the following sections for the Detailed Research Application (DRA)***

*The sections below do not need to be completed before the Preliminary Research Application (PRA) submission and will not be considered during PRA review.*

1. **Special Project Related Approvals**
	1. IRB Approval

Will this project require IRB approval from your institution? [*Yes or No*]

If yes, please estimate duration required for IRB approval (if known)

[*Type here, if applicable*]

* 1. Publication Approval

Does any party outside your institution have rights to review, approve, or control dissemination of the reports of this project? Please explain.

[*Type here, if applicable*]

1. **Project Access Authorizations**

List all team members needing access to a project sandbox:

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| **Name** | **Organization** | **Email** |
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1. **Non-Standard Software to be Provisioned to vDI**

Note: Applicant is responsible for contracting and licensing software from vendor or OptumLabs if available. The external cost to the Applicant should be listed in Section 13 of this document (unless terms of contracting or license are confidential). Special costs related to OptumLabs provisioning and supporting the software should be listed in Section 12.b of this document.

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| **Software****(Name and manufacturer)** | **Version Number** | **Name and email of contact who will work with OptumLabs to install** |
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1. **Contingencies, Assumptions, and Risks**

Below, please describe the following:

* Any potential contingencies, assumptions, or risks
* Consequences of those contingencies, assumptions or risk
* Monitoring and mitigation plan

[*Type here*]

1. **Services Requested from OptumLabs**
	1. Staff Services from OptumLabs

Please describe the nature of staff service(s) requested:

[*Type here, if applicable*]

Please fill out the table below, except grayed areas:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Resource Type** | **Rate** | **Estimated hours** | **Total estimated cost** | **Estimated service dates** |
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* 1. Other Services from OptumLabs

 Please fill out the table below, except grayed area:

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| **Service Description** | **Cost** | **Date needed** | **Comments** |
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1. **External Budget and/or Funding for Study**

Estimated project costs for the projects. This is to document that the Applicant has considered the total cost of conducting the project. Unless otherwise specified, the Applicant will be responsible for contracting and payments for the listed products, services, and licenses

Note: Staff salaries do not need to be disclosed. Please note if any salaries related to this study are coming from external sources or partner’s organization staff budget

Please fill out the table below, except grayed areas:

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | **Cost** | **Funding Source** | **Comments** |
| **OptumLabs Sandbox** |  |  |  |
| **Login Fees** |  |  |  |
| **Request for OptumLabs Resources (Section 12a)** |  |  |  |
| **OptumLabs Licensed Software (Section 10)** |  |  |  |
| **Request for OptumLabs Services/Contracting (Section 12b)** |  |  |  |
| **Total** |  |  |  |

1. **Intellectual Property (IP) Plan**

Please fill out the table below regarding intellectual property (IP).

|  |  |  |  |
| --- | --- | --- | --- |
| **Describe possible IP** | **Type of IP (e.g., patent)** | **Individuals claiming IP** | **Organization(s) receiving IP transfer** |
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1. **Project Closeout**

Will you need access to an archive of the project sandbox saved files for more than 3 years after project termination?

[ ]  Yes

[ ]  No

If the above answer is “Yes”, please explain:

[*Type here, if applicable*]

1. **Project Team Responsibilities**

As partners, OptumLabs and your research project team are responsible for various aspects of research projects. By completing this document, you acknowledge and accept that your institution is responsible for the following:

* 1. Collaborating with OptumLabs on an SOW
	2. Assuring your team follows all contracts and policies
	3. Finalizing the research plan
	4. Ensuring project feasibility
	5. Management of budget, timeline, deliverables, and risks
	6. Completing research project analysis as agreed upon in SOW
	7. Status reporting
	8. Summary of study results
	9. Publications, including OptumLabs participation in reviews (see section 17)
	10. Leading Translation to practice and/or commercialization
	11. Project termination

For more information about roles and responsibilities, please consult your institution’s Master Agreement with OptumLabs.

1. **Publication of Research Findings Related to an SOW with OptumLabs**

OptumLabs and your institution have agreed to certain rights and obligations regarding publishing the results of research conducted at OptumLabs.  Unless otherwise agreed in writing between OptumLabs and your institution, you may publish Summary Results subject to the following:

* You must send any proposed document for publication or presentation to OptumLabs at least 30 days before submission or presentation.  Publications include, without limitation, the examples in Section 5 of this document.
* OptumLabs will review the document for various items, including without limitation:
	+ Confidential Information, including certain intellectual property and all individual level data, which must be removed before submission or presentation
	+ Appropriate acknowledgement and description of the OptumLabs data asset and OptumLabs branding
	+ Authorship recognition consistent with the International Committee of Medical Journal Editors (ICMJE) guidelines and recommendations and identification of you as a Visiting Fellow (or similar) at OptumLabs. (E.g., “Pat Smith, MD, PhD, Your-Institution, and Visiting Fellow at OptumLabs”)
* In some cases, OptumLabs may require you to delay submission or presentation to allow protection of intellectual property rights
1. **Conflict of Interest**

Submitters of this PRA/DRA attest that all researchers listed do not have a conflict of interests, or an appearance of a conflict of interests, in the design of this research or the content of subsequent publications, that would be created by any funding from any commercial organization, or organization representing commercial interests, including funding for (a) other projects or programs with which any researcher is involved, or (b) activities carried out by any researcher under another affiliation or association (e.g., separate consulting business).

1. **Template Changes**

OptumLabs may change this template at its sole discretion. Previously approved Research Project Applications will not need to be resubmitted because of a change in this template. Template Updated: July 2016

1. Data and analytic files cannot be directly imported or exported from this virtual desktop environment without specific permissions. Exporting of individual record data from this environment is not permitted. [↑](#footnote-ref-1)