**Phase I. Initial Consultation and Feasibility Review**

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| --- | --- | --- | --- | --- |
| **Author**: Karen Baker-James | | | | **Date**: 5/3/2022 |
| **Project Short Name**: Gas exchange data processing | | | | |
| **Requestor(s)**: Christopher Lundstrom | | | **Department**: Kinesiology | |
| **Project Type**: *Select all that apply*   |  |  | | --- | --- | | Quality Improvement / Operational | Patient Recruitment | | Research / Discovery | Feasibility Analysis | | Infrastructure Enhancement | Other – please describe: | | | | | |
| **Expected Use / Result**: *Select all that apply*   |  |  | | --- | --- | | Future Grant Submission | Descriptive Analytics | | Collaboration on Existing Grants | Informatics Methods | | Presentation | Informatics Algorithm | | Database / Registry | Other - please describe: | | Business Intelligence and Reports |  | | Design and Implementation of new Applications/Software/Architecture | | | Submission of Manuscript, Trainings, Manuals, Posters, Publication, Paper, Abstracts, etc. | | | | | | |
| **Date of Initial Meeting**: 4/28/2022 | | **Meeting Participants**: Karen Baker-James, Anton Hesse | | |
| **Requested Services**: *Select all that apply*   |  |  | | --- | --- | | Patient matching algorithm to link patients | Data transformation (i.e., create analysis-ready datasets) | | Database development | Feasibility Analysis Tools (i2b2, TriNetX , SHRINE) | | NLP-PIER access to patient clinical notes | Text de-identification for clinical notes | | Add patients on agreed-upon schedule | Data access, extraction and preparation – include PHI | | Database w/manual data entry capability | Data access, extraction and preparation – de-identified | | Process, extract, encode from clinical notes | Informatics Infrastructure | | Data quality reports | Custom dashboards | | Custom Reports | Project management | | Manuscript and proposal preparation | Application Development | | Advanced Analytics via IHI faculty | Other – please describe: | |  |  | | | | | |
| **IRB Number**: Not Yet Submitted | **Eligible for HRP-595 IRB abbreviated process:**  Yes  No | | | |
| **Protected Health Information:**  Identifiable  Fully de-identified  Limited Data Set | | | | |
| |  |  |  | | --- | --- | --- | | **Required Authorizations:**  IRB approval  AHC-IE Attestation | Dashboard access  HIPPA training | Prep-to-Research Representation  DUA / DTA / BAA | | | | | |

**Background**:

To be completed by Researcher

**Project Objectives and Research Aims**:

To be completed by Researcher

**Expected Added Value, Impact and Outcome**:

The participants are not likely to receive any benefit from the proposed research; however, society and investigators will benefit from the knowledge gained.

**Requested Study Details**:

Design and Methods

To be completed by Researcher

Statistical Analysis

To be completed by Researcher

Clinical Informatics

Provide data from the AHC-IE Clinical Data Repository for patients meeting the inclusion/exclusion criteria specified below.

**Provide alternatives or recommendation**? (Y/N)

**Date Needed**:

**Phase II. Project Plan**

**Project Context**:

Deliverables

In Scope:

* Cohort identification

Out of Scope:

* + - * Process, extract, and encode information from clinical notes
* Data quality reports
* Data transformation (i.e., creation of analysis-ready data sets)
* Statistical support

**Scope**:

Included

* File of patients meeting inclusion and exclusion criteria along with relevant clinical data

Not Included:

* Database with manual data entry capabilities
* On-going maintenance and support beyond one year
* Project management support
* Text de-identification for clinical notes

**Patient Cohort**:

Inclusion Criteria

* Exercise test conducted
  + VO2 MAX FITNESS ASSESSMENT: Proc Code: 94017
* CSC department
  + UCSC IM SIGNATURE PROGRAM: FV:DEPARTMENT\_ID:430000156

Exclusion Criteria

* Opted out of research

**Date Range for Requested Data**:

Length of program ~5 years

**Preliminary Feasibility Results or Approximate Number of Patient Records**:

~600

**Clinical Data Elements:**

PATIENT-RELATED DATA:

|  |  |  |
| --- | --- | --- |
| **Include** | **Data** | **Notes** |
|  | Allergy |  |
|  | Demographics | **Patient ID**  **MRN**  **Sex**  **Age at test** |
|  | Patient medical history |  |
|  | Problem list |  |
|  | Vaccine |  |
|  | Cancer |  |
|  | Genomics |  |
|  | Notes |  |
|  | Smartdata |  |
|  | Treatment Plan |  |
|  | OB Episode |  |
|  | Other: |  |

ENCOUNTER-RELATED DATA:

|  |  |  |
| --- | --- | --- |
| **Include** | **Data** | **Notes** |
|  | Admission/Discharge |  |
|  | Diagnoses |  |
|  | Lab |  |
|  | Location |  |
|  | Medications |  |
|  | OB |  |
|  | Orders |  |
|  | Procedures | **Date of VO2 Max test** |
|  | Provider |  |
|  | Surgery |  |
|  | Vitals |  |
|  | Flowsheets |  |
|  | Visits:   |  | | --- | | Service | | Address | | Anesthesia summary | | Appointment | | ED event | | Surgery event | | Reason for visit | | Smarttool use | |  |
|  | Other: |  |

**Data Storage**:

Data resides in the AHC-IE environment and must be accessed through the data shelter

Data will be stored in REDCap

Data meet the criteria for extraction outlined in one of the BPIC data extraction policies

**Constraints**:

* Requests for data will follow the guidelines described in the [BPIC Data Request Procedures documentation](https://www.ctsi.umn.edu/sites/ctsi.umn.edu/files/bpic_data_request_procedures_1.pdf).

**Assumptions**:

* Cost and timeline estimate good for 30 days from the time it is submitted for approval
* **Requests are subject to reprioritization if not reviewed within 30 days**
* Initial cost estimate is subject to change as new discoveries are made in Execution Phase
* Initial timeline estimate is subject to change if resource availability has changed
* PI will notify BPIC of any outcomes (presentations, abstracts, publications, etc.) resulting from the project. Anniversary reminders will be added to calendars
* PI will secure required approvals (e.g., IRB, DUA, BAA)
* PI is responsible for providing alternate funding source if Invoice Contact does not approve
* **PI, or designee, has availability to provide requirements and timely feedback on all deliverables**
* PI, or designee, is responsive to inquiries and completes assigned tasks as scheduled
* Maintenance and Support budget is the estimated cost for incidentals once the project is closed, such as bug fixes, questions and upgrades
* The IRB has approved a waiver of informed consent and HIPAA authorization
* The PI will provide resources to transform the data (create analysis-ready data sets)
* The PI is responsible for providing statistical support

**Roles and Responsibilities**:

|  |  |  |
| --- | --- | --- |
| **Name or Role** | **Responsibilities** | **Expected Time Commitment** |
|  |  |  |

**Financial Support**:

|  |
| --- |
| **Funding Type**:  MCC / CISS  CTSI  Grant – please describe:  Fee for Service  Contract  Other – please describe: |
| **Funding Source or Chartstring**: |
| **Invoice Contact**: |
| **Invoice Schedule**:  Monthly  Project Close  Other – please describe: |

**Time and Cost Estimate**:

|  |  |  |
| --- | --- | --- |
| **Cost Item** | **Description** | **Estimated Hours** |
| Requirements Gathering | * Identify deliverables, set project expectations, review and obtain PI sign-off * Cohort identification * Define inclusion/exclusion criteria * Identify data elements or tables of interest * Analysis to determine codes for labs, vitals, and encounter types included in output | 0.75 Hours |
| Query Development and Data Extraction | * + Generate tables for the requested data elements from the AHC-IE CDR | 0.75 Hours |
| Data Testing and Validation | * Test data during development * Validate data once output is generated | 0.5 Hours |
| Data Governance & Regulatory | * + Verify that all activity is approved and being performed in accordance with IRB regulations, AHC-IE policies and the Memorandum of Understand (MoU) between Fairview and the University of Minnesota. | *No charge* |
| **Total Hours** |  | 2 Hours |
| **Total Cost** |  | $240 |
| **Estimated Delivery Date** |  | ~ 3 weeks from IRB approval and finalized consultation |
| Maintenance and support for first year\* | Corrections, minor changes upgrades in year 1 |  |

*\* Maintenance and Support is an estimate of how much the client should expect to pay to operate their software on an annual basis. It is not included in the cost of product development*

| **Cost and Schedule Approval** | | |
| --- | --- | --- |
| *I have reviewed the information contained in this document and my signature below indicates an understanding of the purpose of this document and agreement with its contents.* | | |
|  | **Signature** | **Date** |
| Requestor |  |  |
| Funder (if not Requestor) |  |  |
| Team Lead or Supervisor |  |  |
| Portfolio Manager |  |  |