Human Research Protections (HRP) strives to ensure that people with disabilities have access to all services and content. If you experience any accessibility-related issues with this form or any aspect of the ZOT IRB application process, email OR-Web-Support@uci.edu for assistance.

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| INSTRUCTIONS |

Complete this form when the non-human subjects research involves de-identified information or de-identified biospecimens.

This information is necessary for the Education and Quality Improvement Program (EQUIP) to conduct a quality assurance review of the self-determination.

Answer all questions succinctly using non-technical language as much as possible.

* If a question is not applicable to the research, state “N/A”.
* If a question is not answered, EQUIP does not know if the question was overlooked. This will result in unnecessary “back and forth” for clarification.

Attach this protocol to the “Basic Study Information” section of the ZOT IRB application.

 1. STUDY OVERVIEW

**Short Title:** Specify the short study title.

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|  Click or tap here to enter text. |

 2. PROCEDURES

**Procedures:** Using lay language, provide a detailed chronological description of the procedures.

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| Click or tap here to enter text. |

**Information Variables:** Provide a complete list of ALL information points, variables, and/or information that will be collected/recorded (i.e. abstraction form).

When utilizing [UCI Health Enterprise Information & Analytics](https://it.health.uci.edu/Enterprise-Data/requestdata.asp) services for the information pull, the following additional information is required:

* ﻿Specify timeframes for each subject eligibility factor, as applicable.
* For diagnoses, procedures, and laboratory tests, provide [standard codes](https://athena.ohdsi.org/) whenever possible, such as ICD-9/10, CPT, LONIC, and SNOMED CT.

*Example Entry:*

* *Birth sex: female*
* *Age: >= 18 years old as of 2020-01-01*
* *The result of the most recent SARS-CoV-2 test (of any type), performed between 2020-01-01 and 2020-12-31, was positive*
* *With any sub-classification of type 2 diabetes (E11\*) diagnosed at any date prior to 2020-01-01*
* *Did NOT have an ED visit between 2020-01-01 and 2020-12-31*

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| Click or tap here to enter text. |

**Information/Biospecimen Source:** Select all that apply and address the required action, as applicable.

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|   | **Source of Information or Biospecimen**  | **Required Action**  |
|   | ​​☐​  | Center for Artificial Intelligence in Diagnostic Medicine (CAIDM)  IRB #20184417  | Signed UC HIPAA authorization or a waiver of HIPAA authorization is required.  |
|   | ​​☐​  | Experimental Tissue Resource (ETR)  IRB #20128716  | Signed UC HIPAA authorization or a waiver of HIPAA authorization is required.  |
|   | ​​☐​  | Health Enterprise Information & Analytics IRB #20128757  | Signed UC HIPAA authorization or a waiver of HIPAA authorization is required.  |
|   | ​​☐​  | IRB approved research  | 1. For UCI IRB approved research, specify protocol number(s).
2. For other research, attach: IRB approved consent form that documents the sharing of information.
 |
|   | ​​☐​  | Other   | 1. Specify source(s).
2. Specify the types of records/biospecimens.
3. Specify whether the information/biospecimen was originally collected for research purposes.
4. Explain how the study team will obtain the records.
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| Click or tap here to enter text. |

**Number of Participants:** For each participant group, use the table below to provide the estimate of the desired number of individuals needed to complete the research. *Insert separate rows for each category/group*.

|  |  |  |
| --- | --- | --- |
| **Category/Group** | **Age Range** | **Max Number of Individuals**  |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

**Max Number:** Explain how the max number was determined (e.g., cohort discovery).

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| Click or tap here to enter text. |