Retrospective Medical Chart Review Research Protocol (HRP-503R-R01)

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| **Version** | **Date** | **Revisions** |
| R00 | 7/21/23 | Original issue |
| R01 | 12/1/23 | Annual review, add revision table, update logo |

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1.0 Confirmation of Study Design

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| * 1. By checking “YES” below, you are confirming that this research project ONLY involves a retrospective medical chart/record review. For the purpose of research, “retrospective” means the data is already in existence at the time of IRB approval.

[ ]  YES[ ]  NO – This is NOT a retrospective medical chart/record review → This form cannot be used - complete the “HRP-503-Template Protocol” instead* 1. Will you be obtaining consent?

[ ]  YES → This form cannot be used - complete the “HRP-503-Template Protocol” instead[ ]  NO – I am requesting a waiver of consent → Use this form and continue to 2.0 |

2.0 Protocol Title

Include the full protocol title

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3.0 Principal Investigator

|  |  |
| --- | --- |
| Name |  |
| Department |  |
| Telephone Number |  |
| Email Address |  |

4.0 Revision History Table

|  |  |
| --- | --- |
| Version #/Date | Summary of Changes |
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|  |  |
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5.0 Funding 📎

Select funding source below – the funding listed below should match what is listed in Click

[ ]  N/A: There is no funding for this study

[ ]  Grant Funded (e.g. NIH, foundation grant) → Include the grant proposal with this submission📎

[ ]  Grant has multiple aims → Explain the aims covered by this protocol:

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[ ]  Grant is pending (Submit a modification to the study once funding is finalized)

[ ]  Commercial Sponsor – List the commercial sponsor below and include a fee form with this submission (Click Library > General Tab > Fee Form)

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[ ]  Other funding source:

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6.0 Research Repository

Indicate where the research files will be kept, including after the study is closed. The repository should include, at minimum, copies of IRB correspondence (i.e. approval, determination letters, etc.).

|  |  |
| --- | --- |
| Location |  |
| Address |  |
| Department  |  |

7.0 Study Specific Abbreviations/ Definitions

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| --- | --- |
| Abbreviations/Word | Definition |
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8.0 Study Population

This refers to the subject population included in the charts you will be reviewing (e.g. Adults and/or children with diabetes)

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9.0 Objectives

9.1 Describe the purpose, specific aims, or objectives of this research.

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9.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

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10.0 Scientific Endpoints

10.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins, to determine whether the objectives of the study have been met, and to draw conclusions from the data. Include primary and secondary endpoints. Your response should not be a date.

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11.0 Background

11.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature, and describe how it will contribute to existing knowledge. Describe any gaps in current knowledge, and include relevant preliminary findings or prior research by the investigator.

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11.2 Include complete citations or references

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12.0 Local Number of Subjects (i.e. Individual charts/records)

12.1 What is the target number of charts you are looking to include in your research?

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12.2 If applicable, how many charts/records do you expect to screen to reach your target sample?

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12.3 Justify the feasibility of obtaining the proposed number of eligible charts/subjects.

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13.0 Inclusion and Exclusion Criteria

13.1 List the date range of charts/records that will be included.

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|  |

13.2 Describe all of the additional criteria that define which charts/records will be included in your final study sample. Include parameters/procedures that will be used to determine inclusion in the study (e.g. ICD codes) NOTE: This may be done in a bullet-point fashion.

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13.3 Specify age range of subjects to be included:

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13.4 Describe the criteria that define which charts/records will be excluded from your final study sample. NOTE: This may be done in a bullet-point fashion.

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14.0 Vulnerable Populations

14.1 Are you including any of the following special populations?

[ ]  Adults unable to consent/cognitively impaired adults (i.e. Cognitive impairment is known to the PI)

[ ]  Neonates of uncertain viability or non-viable neonates (i.e. Viability status is known to the PI)

[ ]  Individuals who are not yet adults (This option must be checked if you are including charts/records of subjects under 18 years of age)

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Specify age range:

[ ]  Pregnant women (i.e. Pregnancy status is known to the PI)

[ ]  Prisoners (i.e. Prisoner status is known to the PI)

15.0 Data Collection Procedures📎

15.1 List any forms used to collect data (e.g. data collection form, code key) and include these documents with your submission📎.

List the documents below, by name, as they appear in Click:

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15.2 Describe any source records that will be used to collect data about subjects (e.g. electronic medical records) and include the location of the records (e.g. hospital, EMR system name). Include a HIPAA Waiver with your submission (Click Library > Templates > HRP-612-HIPAA-Waiver).

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15.3 Will study results be shared with subjects or others?

[ ]  No

[ ]  Yes → Describe how they will be shared:

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15.4 Are there any other procedures that will be used to complete the chart review that are not otherwise listed above?

[ ]  No

[ ]  Yes → Describe below:

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16.0 Study Timelines

16.1 What is the anticipated duration needed to review all charts and collect all data?

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16.2 What is the estimated duration needed to complete this study (i.e. all data is collected/all analyses have been completed)?

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17.0 Setting

17.1 Describe all facilities/locations where research procedures will be conducted (i.e. reviewing charts/records). Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

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17.2 Will research (chart/record review) be conducted outside of UB and its affiliates?

[ ]  No → Skip to 18.0

[ ]  Yes → Describe the following:

* Site-specific regulations or customs affecting the research
* Local scientific and ethical review structure

NOTE: This question refers to UB-affiliated research taking place outside of UB and its affiliates. UB-affiliated institutions include Kaleida Health, ECMC, UBMD and Roswell Park Cancer Institute.

This does not refer to Multi-Site research (see section 26.0 Multi-Site Research)

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 18.0 Community-Based Participatory Research

Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

18.1 Does this study utilize CBPR?

 [ ]  No → Skip to Section 19.0

[ ]  Yes → answer the questions below

18.2 Describe the involvement of the community in the design and conduct of the research.

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18.3 Describe the composition and involvement of a community advisory board.

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19.0 Other Approvals

19.1 Will any other approvals be obtained prior to commencing the research (e.g. funding agency, hospital approval)?

[ ]  No → This study does not require any other approvals.

[ ]  Yes → Describe below:

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20.0 Resources and Qualifications

20.1 Describe the qualifications (e.g. education, training, experience, expertise, or certifications) of the Principal Investigator and staff to perform the research. When applicable, describe their knowledge of the local study sites, culture, and society.

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| --- | --- |
| Name/Role | Qualifications |
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 20.2 Describe other resources available to conduct the research

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20.3 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full-Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

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20.4 Describe the process to ensure all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties/functions.

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21.0 Data Management and Analysis

21.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

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21.2 If applicable, provide a power analysis.

NOTE: This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

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21.3 Describe any procedures that will be used for quality control of collected data.

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22.0 Confidentiality of Study Data📎

Describe the local procedures for minimizing the risk of a breach of confidentiality of study data and records.

22.1 How will *electronic* data and records be stored? (For example, data and records will be stored on a network drive, UB Box, on an excel sheet, etc.)

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22.2 How will *paper* data and records be stored? (For example, cabinet only accessible to study personnel, etc.) If you will not be keeping paper records, indicate this below.

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22.3 Where will all data and records be stored? (For example, data and records will be stored in #/building)

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22.4 How will the confidentiality of study data and records be protected (e.g. password protection, encryption, physical controls, authorization of access)?

NOTE: Any code keys must be stored in a separate, password-protected file from the data collection form to minimize the risk of a breach of confidentiality.

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22.5 Will the data be coded?

NOTE: If identifiable data will be collected or stored for any amount of time, that data should be coded.

(See “HRP-613-HIPAA-Certificate of Deidentification” and “Tips from the IRB - De-Identified Coded Limited Data Sets” in Click Library > General).

[ ]  No → Explain below:

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[ ]  Yes → Include a separate code key in addition to the data collection form📎

22.6 Describe your procedure for coding the data (i.e. creation of a code key, which links the identifiable data with the coded data)

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22.7 Indicate if you will be recording the following identifiers and where they will be kept.

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| --- | --- | --- | --- |
| List of Identifiers | Not recording | Code Key | Data Collection Form |
| Name |[ ] [ ] [ ]
| Address (all geographic subdivisions smaller than state, including street address, city county, and zip code) |[ ] [ ] [ ]
| All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89) |[ ] [ ] [ ]
| Telephone numbers |[ ] [ ] [ ]
| Fax number |[ ] [ ] [ ]
| Email address |[ ] [ ] [ ]
| Social Security Number |[ ] [ ] [ ]
| Medical record number |[ ] [ ] [ ]
| Health plan beneficiary number |[ ] [ ] [ ]
| Account number |[ ] [ ] [ ]
| Certificate or license number |[ ] [ ] [ ]
| Vehicle identifiers and serial numbers, including license plate numbers |[ ] [ ] [ ]
| Device identifiers and serial numbers |[ ] [ ] [ ]
| Web URL |[ ] [ ] [ ]
| Internet Protocol (IP) Address |[ ] [ ] [ ]
| Finger or voice print |[ ] [ ] [ ]
| Photographic image - Photographic images are not limited to images of the face. |[ ] [ ] [ ]
| Any other characteristic that could uniquely identify the individual.

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Describe:  |[ ] [ ] [ ]

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22.8 Will identifiable data will be stored on the data collection form?

☐ No

☐ Yes → Provide a justification for why this is necessary to conduct the research.

NOTE: Unless necessary, all identifiers should be kept on a code key.

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22.9 How long will the identifiable data be stored?

NOTE: Identifiers should be destroyed at the earliest opportunity, unless there is a health or research justification provided for retaining the identifiers or such retention is otherwise required by law.

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22.10 Who will have access to the identifiable data?

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22.11 How long will the non-identifiable be stored?

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22.12 Who will have access to the non-identifiable data?

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22.13 Who is responsible for receipt or transmission of the data?

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22.14 How will the data be transported?

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|  |

23.0 Study Risks

23.1 Breach of confidentiality is always a risk for identifiable subject data. Are there any risks other than breach of confidentiality?

[ ]  No

[ ]  Yes → Describe these additional risks and the procedures for minimizing these risks:

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|  |

24.0 Potential Benefits of the Research

24.1 Describe the potential benefits of the research

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25.0 Request for Waiver of Consent Process

Check if YES. All boxes must be checked in order for waiver of consent to be granted.

[ ]  The research is NOT FDA regulated.

[ ]  The research does not involve non-viable neonates.

[ ]  The research involves no more than minimal risk to subjects. Describe below:

|  |
| --- |
|  |

[ ]  The research could not practicably be carried out without the waiver. Describe below:

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[ ]  If the research involves using identifiable private information, the research could NOT practicably be carried out without using such information in an identifiable format. Describe below:

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[ ] The waiver will not adversely affect the rights and welfare of the subjects. Describe below:

|  |
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[ ] Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Describe below:

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26.0 Multi-Site Research📎

Definition of multi-site research: A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol (See “HRP-001-SOP-Definitions” in Click Library > Standard Operating Procedures)

NOTE: A site is more than a physical location – it should have its own study team (i.e. Principal Investigator (PI) and research team)

26.1 Is this an investigator-initiated multi-site study?

[ ]  No → Skip to Section 27.0

[ ]  Yes

26.2 List each participating site below and the IRB of record for each site.

NOTE: The IRB of record is the IRB responsible for performing review on behalf of one or more institutions. If any of the participating sites below are ceding review to UB IRB, refer to “HRP-909 Utilization of UB as the IRB of Record on a Multi-Site Study” in Click > Library > Standard Operating Procedures, and upload the required documents with your submission📎

NOTE: Reliance does not apply to Exempt and International Research

|  |  |  |
| --- | --- | --- |
| Participating Site | IRB of Record (If not UB) | UB is the IRB of record |
|  |  |[ ]
|  |  |[ ]
|  |  |[ ]

26.3 Indicate the total number of charts/records to be reviewed across all sites.

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| --- | --- |
| Participating Site | Number of charts  |
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|  |  |
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26.4 Are you the **lead investigator** of this multi-site study?

[ ]  No → Skip to 26.6

[ ]  Yes → Describe the process for ensuring each of the following across all participating sites:

* All sites have the most current version of the IRB documents, including the protocol, and HIPAA Full Waiver.
* All required approvals have been obtained at each site (including approval by the site’s IRB of record).
* All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.
* All engaged participating sites will safeguard data as required by local information security policies.
* All local site investigators conduct the study appropriately in accordance with applicable federal regulations and local laws.
* All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

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26.5 Describe the process for communicating each of the following to participating sites:

* Problems (inclusive of reportable events)
* Interim results
* Study closure

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26.6 Are you a **participating site/investigator** of this multi-site study?

[ ]  No → Skip to 27.0

[ ]  Yes → Describe the local procedures for maintenance of confidentiality:

26.7 Where and how will data be stored locally?

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26.8 How long will the data be stored locally?

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26.9 Who will have access to the data locally?

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26.10 Who is responsible for receipt or transmission of the data locally?

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26.11 How will data be transported locally?

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27.0 Banking data for future use

27.1 Will this study bank Data for Future Use?

[ ]  No → This study will not bank data for future use or research outside the scope of the present protocol → Go to section 28.0

[ ]  Yes → NOTE: If the UBIRB has approved this study to bank data for potential future use outside the scope of this research study, any future use or disclosure of the data that is not described within the approved study must be submitted for review to the UBIRB → Answer all questions in this section.

27.2 List the data to be stored for future use (use or research outside of the scope of the present protocol):

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27.3 Describe where the data will be stored:

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27.4 Describe how long the data will be stored:

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27.5 Describe how the data will be accessed:

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27.6 Describe who will have access to the data:

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27.7 Are there plans to release banked data to individuals or institutions outside of the approved study team members?

[ ]  No → Go to section 28.0

[ ]  Yes → Answer questions below

27.8 Describe the data that could/will be released:

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27.9 Describe the process to request a release of data:

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27.10 Describe approvals required for release of data (Data Use Agreement (DUA), IRB approval):

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27.11 Describe who can obtain data:

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