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**LEGACY HEALTH IRB**

**FORM B: RETROSPECTIVE CHART REVIEW APPLICATION**

**Use this form for retrospective data gathering projects only.**

**See “Instructions Form B” for completing this form.**

**There are 10 domains that must be completed for this form.**

**study summary**

|  |  |
| --- | --- |
| **Date of Submission** |     |
| **Name of Submitter of this Study**(name and contact information)  |     |
| **Principal Investigator**  |     |
| **Protocol Title (**one title only) |     |
| **Date of Protocol** |     |
| **Protocol Version Number**  |     |
| **Protocol Author** |     |
| **Note all documents to be approved:*** Written Protocol
* Consent forms
* Data elements form
* Principal Investigator’s CV
* Other
 |     |
| **Lay Language** Description of Project (not to exceed one page). The following should be described in lay language:* Purpose of the research
* Scientific question
* Hypothesis
* Key Health question
* Subject population
* Data analysis plan
* Estimated duration of the study
* Publication plans
 |     |

**DOMAIN 1: PRINCIPAL INVESTIGATOR AND STUDY STAFF**

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| --- | --- |
| **Principal Investigator** **(PI)** name, degrees and credentials  |     |
| **PI’s training** in human subject protection e.g., CITI |     |
| **PI’s affiliation and role** with Legacy Health (must be specific) |     |
| **PI Address**  |     |
| **PI Phone number** |     |
| **PI email**  |     |
| **PI Conflict of Interest** disclosure (declare all financial interests in this study)* Financial Interest
* Patent or License
* Invention
* Payments for consulting
 |     |
| **Study Contact** (if different from PI)  |     |
| **Study Staff Name** and human subject protection training e.g., CITI, etc. |     |
| **Study Staff Name** and human subject protection training e.g., CITI, etc. |     |
| **Study Staff Name** and human subject protection training e.g., CITI, etc. |     |
| **Study Staff Name** and human subject protection training e.g., CITI, etc. |     |
| **Study Staff Conflict of Interest** disclosure (declare any staff financial interests in this study)* Financial Interest
* Patent
* Invention
* Payments for consulting
 |     |

**DOMAIN 2: SUBJECTS OF THE RESEARCH**

|  |  |
| --- | --- |
| **Target Population** to be enrolled(describe planned population)  |     |
| **All Ages** |     |
| **All Genders** (including LBGTQ+) |     |
| **Number of subjects** to be enrolled |     |
| **Vulnerable Populations** (select all that apply):* prisoners
* children
* pregnant women and their fetuses
* low income
* marginalized
* unrepresented
* cognitively impaired
* uninsured
* employees
* institutionalized
* undereducated
* stigmatized
* sensitive or legal risks (e.g., sex abuse, drug users, etc.)
 |     |
| **Subjects to be excluded**(specify and provide rationale for exclusion) |     |

**DOMAIN 3: RESEARCH SITE(S) FOR THE STUDY**

|  |  |
| --- | --- |
| **PI’s Office Address, phone number and email** |     |
| **Sites** (select all that apply):* Legacy Emanuel Medical Center
* Randall Children’s Hospital
* Legacy Good Samaritan
* Legacy Salmon Creek
* Legacy Meridian Park
* Legacy Mt. Hood
* Legacy Research Institute
* Legacy GoHealth Clinics (specify locations)
* Legacy Unity Center
* Investigator’s Office or Clinic
* Other Legacy site(s) (specify)
* Other Non-Legacy site(s) (specify)
 |     |
| Any research sites not at Legacy sites? (provide details) |     |
| Name and email of Manager or Supervisor at Legacy site |     |

**DOMAIN 4: JURISDICTION AND SPONSOR(S)/FUNDER(S) OF THE RESEARCH**

|  |  |
| --- | --- |
| **Name of Legacy Health Manager/Supervisor** who has provided permission for this research to be conducted | Name:    Title:    Department:    Email:    Phone Number:     |
| **Sponsor** |     |
| **Legacy Foundation sponsor/funding**(yes/no) |     |
| **Funder** (if different from sponsor) |     |
| **Source of Funding** (if external) |     |
| **Federally Funded** (indicate agency) |     |
| **FDA Research** (yes/no)  |     |
| **Multisite Study** (yes/no) |     |
| **Research Data Owners and Users**(list all who will have access to and will use the data collected for this study)  |     |
| **Sponsor’s plan(s)** for dissemination of data resulting from the research |     |

**DOMAIN 5: RESEARCH TYPE**

|  |  |
| --- | --- |
| **Retrospective Chart Review** of (select all that apply):* FDA product (drug, device, biologic)
* Standard clinical care/procedure
* Specimens
* Data (brief description)
* Genetic Information
* Social/Behavioral
* Demographic Info
* Treatment Outcomes
* Provider/Staff data
* Other (brief description)
 |     |
| **Date range of charts to be accessed** (must currently exist -- not prospective) |     |
| **Approximate number of patient charts** to be accessed  |     |
| **How was the number of patient charts determined to be useful** to answer the scientific question?  |     |
| **Main source(s) of charts** to be accessed (must be specific):* Epic
* Epic Link
* Lab
* Imaging,
* LH financial
* Hospital Records
* Clinic Records
* Provider/Employee data
* Citrix Gateway
* Internet
 |     |
| **Other data sources** (must be specific) |     |
| **Name of manager(s)** who has oversight of records to be accessed(Provide names and email addresses) |     |

**DOMAIN 6: RESEARCH RISKS**

|  |  |
| --- | --- |
| **Gathering/recording of data for this research poses risks of** (select all that apply):* Breach of Privacy
* Breach of Confidentiality
* Use of patient medical data
* Use of HIPAA information
* Vulnerable population data
* Highly sensitive data (sex abuse, crimes, legal risk)
* Stigma/embarrassment
* Use of information of provider departure from standard clinical care
* Legacy employee data or info
* Big Data collection
* Other (describe)
 |     |
| **Describe additional protections** designed to minimize risks in this research  |     |

**DOMAIN 7: CONSENT PROCESS OR WAIVER REQUESTS**

|  |  |
| --- | --- |
| **Consent Process** involves (select all that apply):* Recruitment of subjects (describe)
* Advertisements/Flyers
* Emails
* Recruitment database
* “Cold calls”
* Letters to patient
* Informed Consent with full consent form
* Informed consent with Information Sheet only
 |     |
| **Waiver of signed consent form/signature request**Please note: A waiver of a signature or form is not a waiver of consent.A detailed written rationale for a waiver of form/signature must satisfy these criteria (describe in detail how your request meets the criteria):  | An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern:

or(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context:    In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. |
| **Waiver of Consent request** A detailed written rationale for a waiver consent must satisfy all four criteria (describe in detail how your request meets the criteria). Write your justification for a waiver request for each criterion.  | An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:1. The research involves no more than minimal risk to the subjects:
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects:
3. The research could not practicably be carried out without the waiver or alteration:
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation:
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**DOMAIN 8:** **PROTECTION AND CONFIDENTIALITY OF DATA**

|  |  |
| --- | --- |
| **Data to be collected** (describe in detail or list submitted data collection sheets or forms) |     |
| **Data collection details**(describe process of obtaining targeted data)  |     |
| **Protected Health Information** (List PHI to be collected) |     |
| **Non-PHI Information to be collected** |     |
| **Data Protection plan**(Location of data collected, stored and retained  |     |
| **Security of collected data**(Explain in detail the storage of the collected data – laptop, encrypted device, Redcap or similar system, locked cabinet, data transfer methods, when will data be destroyed if no longer needed, de-identification of data, etc.)  |     |
| **Data Analysis** (Data analysis to be done) |     |
| **Data Use Plan**(Describe how data will be used to create new knowledge) |     |
| **Data Access**(Describe who may access the data for all purposes) |     |
| **Plan if data security is breached or violated** (Describe in detail) |     |
| **Publication/Presentation Plan for this data**(Provide plans for dissemination of data resulting from the research) |     |
| **Plan for Legacy Health credited of acknowledged** as research site  |     |

**DOMAIN 9: REVIEW BY THE IRB**

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| --- | --- |
| **List the documents that need review and approval by the IRB*** IRB Application form
* Protocol (dated and final form)
* Consent Form or Information Sheet
* Subject materials
* Advertisements, etc.
* Recruitment scripts
* PI’s CV
* Data elements forms
* CITI Training Documents of all staff
* PI Assurance Signature
* Other
 |     |

**DOMAIN 10: PRINCIPAL INVESTIGATOR ASSURANCES**

The PI assures the Legacy IRB of the following by signing in the space provided below. **This page (Domain 10) may be electronically signed or can be signed and scanned and submitted as a pdf.**

* I attest that all the answers in this form are accurate.
* I attest that when requesting approval of HIPAA full and partial waivers of authorization for protected health information, I am providing written assurance that:

(A)the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

(1) an adequate plan to protect the identifiers from improper use and disclosure;

(2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(3) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

* I agree that I will promptly report to the Legacy IRB office any proposed changes in research activity, changes in the informed consent form for process, unanticipated problems involving risk to subjects or others, or breaches of confidentiality
* I agree that the Legacy IRB is obligated to continually review this activity and I agree to furnish the Board relevant information for re-approval of this research as needed.
* I agree to accept responsibility for the ethical conduct of the project and the protection of the rights and welfare of the subjects.
* I agree that all study staff will have undergone training in human subject protection training prior to participating in the research. Documentation of staff training will be kept on file for inspection if requested.
* I agree that IRB approval applies to research ethics issues only. IRB approval does not obligate Legacy or any of its Managers or departments to allow the conduct of the study.
* I agree to obtain Legacy departmental permission from the head of the department in which this research will be conducted. I understand that failure to obtain such permission may result in IRB approval to be suspended or terminated.
* I agree that I will read and abide by all of the Board requirements contained in the IRB Approval.

**PRINCIPAL INVESTIGATOR SIGNATURE REGARDING ASSURANCES:**

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Principal Investigator Date

**SUBMIT FORM TO:**

irbsubmissions@lhs.org

**QUESTIONS?**

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