** **

**LEGACY HEALTH IRB**

**FORM A: LEGACY HEALTH INSTITUTIONAL REVIEW BOARD**

**INITIAL REVIEW APPLICATION**

**Use this form for initial review of new research projects.**

**See “Instructions Form A” for completing this form. Submit this document in word only.**

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

**study summary**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date of Submission:** | Click or tap to enter a date. | | | |
| **Name of Submitter of this Study**  **(name and contact information)** | Name: | Click or tap here to enter text. | Phone: | Click to enter text |
| Email: | Click or tap here to enter text. | | |
| **Principal Investigator Name:** | Click or tap here to enter text. | | | |
| **Protocol Title (one title only):** | Click or tap here to enter text. | | | |
| **Date of Protocol:** | Click or tap here to enter text. | | | |
| **Protocol Version Number:** | Click or tap here to enter text. | | | |
| **Protocol Author:** | Click or tap here to enter text. | | | |

**LAY LANGUAGE DESCRIPTION OF PROJECT** (not to exceed one page).   
Describe the following 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 |
| Click or tap here to enter text. | | |

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

**There should only be one principal investigator (PI) at the legacy site.** All other study staff should be either a sub-investigator, coordinator, or other study staff. In the rare care where investigators are truly functioning as co-investigators, they must each agree to be fully responsible for the conduct of the research and sign this application.

**PRINCIPAL INVESTIGATOR INFORMATION**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name: | Click or tap here to enter text. | | | | | Phone: | Click or tap here to enter text. |
| Email: | Click or tap here to enter text. | | | | | | |
| Mailing Address: | | Click or tap here to enter text. | | | | | |
| PI office at Legacy  *(if different from PI, above)* | | | Phone: | Click or tap here to enter text. | | | |
| Email: | Click or tap here to enter text. | | | |
| Mailing Address: | | Click or tap here to enter text. | | |

**STUDY KEY CONTACT** *(if different from PI)*

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | Click or tap here to enter text. | Phone: | Click or tap here to enter text. |
| Email: | Click or tap here to enter text. | | |

**PI QUALIFICATIONS AND CERTIFICATIONS**

**Indicate all degrees, certifications and current licenses showing the qualifications of the PI:**

|  |  |
| --- | --- |
| MD  DO  RN  PhD  Other(s): |  |

**List license details (must be current) and expiration dates:**

|  |  |  |
| --- | --- | --- |
| **License Type** | **License Number** | Expiration Date |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap to enter a date. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap to enter a date. |

*Click the plus (+) sign at the end of the last row to add more entries*

**List certification details (must be current) and expiration dates:**

|  |  |
| --- | --- |
| **Certification Type** | Expiration Date *(if applicable)* |
| Click or tap here to enter text. | Click or tap to enter a date. |
| Click or tap here to enter text. | Click or tap to enter a date. |

*Click the plus (+) sign at the end of the last row to add more entries*

**List additional credential details (must be current) and expiration dates:**

|  |  |
| --- | --- |
| **Credential Type** | Expiration Date *(if applicable)* |
| Click or tap here to enter text. | Click or tap to enter a date. |
| Click or tap here to enter text. | Click or tap to enter a date. |

*Click the plus (+) sign at the end of the last row to add more entries*

**PI CV ATTACHED:**

Yes **CV Date:** Click or tap to enter a date.  
**Submit your updated CV with a recent date clearly noted on the document.**   
*This requirement applies to all investigators, including students and interns*

**FDA AUDIT HISTORY**

**Is this a clinical investigation or a drug or device trial?**  Yes  No

|  |  |  |
| --- | --- | --- |
| **If yes, indicate whether the PI has ever been audited by the FDA?** | | Yes  No |
|  | If yes, detail findings and/or corrective actions that were taken:  Click or tap here to enter text. | |

**PI’S ROLE AND POSITION AT LEGACY**

|  |
| --- |
| **PI’s Role and Position at Legacy:** Your position and qualifications must be consistent with your ability and privileges to conduct research at Legacy. **Cleary state your active role at Legacy**, e.g. as a physician, RN, other medical personnel, and as an employee or contractor, a medical professional with staff privileges, etc. |
| Click or tap here to enter text. |

**NON-LEGACY RESEARCHERS CONDUCTING RESEARCH AT LEGACY**

Non-Legacy researchers must have Legacy management authorization to conduct the research at a Legacy site using Legacy patients either via a Legacy manager, co-investigator or sub-investigator. Non-Legacy researchers must also provide assurance that a Legacy staff physician will provide medical responsibility of study subjects and will provide assurance from that Legacy physician that they assume medical responsibility for the subjects, if applicable:

|  |  |  |  |
| --- | --- | --- | --- |
| **Please indicate the Legacy personnel who authorizes you to conduct the proposed research:** | | | |
| Name: | Click or tap here to enter text. | **Email:** | Click or tap here to enter text. |
| **Name of Legacy physician who assumes medical responsibility of study subjects:** | | | |
| Name: | Click or tap here to enter text. | **Email:** | Click or tap here to enter text. |
|  | | | |

**CONFLICTS OF INTEREST INFORMATION FOR PI AND STUDY STAFF**

For the PI AND each study staff, list all potential or actual conflicts of interest of PI or study staff regarding significant financial interests related to this research project. A financial conflict of interest is not inherently wrong, but all conflicts of interest need to be disclosed to the IRB to assist them in managing potential investigator bias, and the IRB must analyze each conflict of interest to determine whether a reasonable person would believe that the conflict offers an incentive to the investigator to breach a duty to subjects or to society. If it is determined that the conflict offers such an incentive, the Board must determine how the conflict should be addressed, by determining whether any or some of the actions should be taken:

* A finding that the conflict of interest, while present, is not likely to bias the investigator’s decision-making and does not require further action;
* A finding that disclosure to subjects or others is necessary (usually by modifying the consent form to provide this information to subjects and other);
* A finding that controls on the conflict are needed, such as having the consent process performed by someone other than the conflicted party, or additional monitoring, or having the data analyzed by someone outside of the research staff, or other such measures;
* A finding that the conflict is unacceptable and must be eliminated in order for the research to proceed.

|  |  |  |  |
| --- | --- | --- | --- |
| **PI/Study Staff Name and Role**:  Click or tap here to enter text. | | **If yes, give details** | **Exact $ amount of financial interest** |
| **Patent** – Did you invent the device or drug being tested? | Yes  No | Click or tap here to enter text. | Click to enter $amt. |
| **Licensed Invention** – Do you receive royalties related to your invention? | Yes  No | Click or tap here to enter text. | Click to enter $amt. |
| **Financial Interest** – Do you have any financial interest in the sponsor of the study? | Yes  No | Click or tap here to enter text. | Click to enter $amt. |
| **Salary and/or payment for services (outside conduct of the study)** – consulting fees, teaching, presentation, travel expenses or honoraria from the sponsor of the study. | Yes  No | Click or tap here to enter text. | Click to enter $amt. |
| Other (equity interest, intellectual property, incentive payments for recruitment) | Yes  No | Click or tap here to enter text. | Click to enter $amt. |

*Click the plus (+) sign at the end of the last row to add entries for other study staff*

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

**PI AND STUDY PERSONNEL TRAINING IN HUMAN SUBJECT RESEARCH**

List all study personnel who will have contact with subjects and/or involved in collecting data from subjects and involved in data analysis by name and role (sub-investigator, coordinator, technician, statistician, receptionist, etc.), and indicate whether they will be authorized to consent subjects and indicate date and format of Human Subject Research Protection (HSRP) training (CITI, etc.).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Role** | **ConsentinG** | **HSRP Training TYPE** | **Date Completed** |
| Click or tap here to enter text. | Select a role | Yes  No | Select Training Type | Click or tap to enter a date. |
| Click or tap here to enter text. | Select a role | Yes  No | Select Training Type | Click or tap to enter a date. |
| Click or tap here to enter text. | Select a role | Yes  No | Select Training Type | Click or tap to enter a date. |
| Click or tap here to enter text. | Select a role | Yes  No | Select Training Type | Click or tap to enter a date. |
| Click or tap here to enter text. | Select a role | Yes  No | Select Training Type | Click or tap to enter a date. |
| Click or tap here to enter text. | Select a role | Yes  No | Select Training Type | Click or tap to enter a date. |
| Click or tap here to enter text. | Select a role | Yes  No | Select Training Type | Click or tap to enter a date. |
| Click or tap here to enter text. | Select a role | Yes  No | Select Training Type | Click or tap to enter a date. |

*Click the plus (+) sign at the end of the last row to add more entries*

|  |  |
| --- | --- |
| **THE PI AND ALL STUDY STAFF MUST BE ABLE TO CONFIRM OR PROVIDE UPON REQUEST DOCUMENTATION OF HUMAN SUBJECT RESEARCH PROTECTION (HSRP) TRAINING PRIOR TO THE START OF THE RESEARCH. THERE ARE NO EXCEPTIONS.** | |
| Enter PI Initials | As PI, I confirm that all current and future study staff will have completed human subject research training prior to working on the research project, and that documentation of training will be provided on request. |

**DOMAIN 2: SUBJECTS OF THE RESEARCH**

**GenderS and AGE range of the target population**

Provide information about the targeted subject population, select all groups to be included:

**Genders:**  Females

Males

All genders (including LBGTQ+)

Other gender identities: Click or tap here to enter text.

**Ages:** Overall age range: Click or tap here to enter text.

Pediatric - age range: Click or tap here to enter text.

Children/Minors - age range: Click or tap here to enter text.

Mature Minors (14-17) - age range: Click or tap here to enter text.

**INCLUSION OF VULNERABLE SUBJECTS**

Provide information about whether any subjects to be enrolled will be from vulnerable groups. Provide a brief justification or rationale for their enrollment.

(Note that enrollment of **minors** requires special risk/benefit findings by the IRB, that enrollment of **cognitively impaired subjects** may require the use of a Legally Authorized Representative (LAR), that **prisoners** should not be enrolled unless the study concerns prisoners or prisons, and that the enrollment of **pregnant women and their fetuses** may require special findings by the IRB).

|  |  |  |
| --- | --- | --- |
| **Select all vulnerable groups to be included** | | **Rationale for enrollment of each vulnerable population:** |
|  | Fetuses | Click or tap here to enter text. |
|  | Pregnant women | Click or tap here to enter text. |
|  | Subjects capable of pregnancy | Click or tap here to enter text. |
|  | Children/Minors | Click or tap here to enter text. |
|  | All genders including LBGTQ+ |  |
|  | Other gender identities |  |
|  | Prisoners | Click or tap here to enter text. |
|  | Wards of the State (in foster care or juvenile facilities) | Click or tap here to enter text. |
|  | Cognitively Impaired | Click or tap here to enter text. |
|  | Unconscious | Click or tap here to enter text. |
|  | Adult Subjects with Legally Authorized Representative (LAR) | Click or tap here to enter text. |
|  | Poor/Uninsured/Underinsured | Click or tap here to enter text. |
|  | Employees of Legacy or Site | Click or tap here to enter text. |
|  | Institutionalized | Click or tap here to enter text. |
|  | Stigmatized populations | Click or tap here to enter text. |
|  | Sensitive or legal risks (e.g. sex abuse, drug users) | Click or tap here to enter text. |
|  | Unrepresented or marginalized populations | Click or tap here to enter text. |
|  | Other: Click or tap here to enter text. | Click or tap here to enter text. |

**EXCLUSION OF SUBJECTS**

Provide information about whether any subjects are excluded from the study that might otherwise benefit from participation, e.g., women of child-bearing potential, or mature minors, or unrepresented or non-English speaking subjects. If so, please provide an explanation or rationale for excluding such subjects.

|  |
| --- |
| Click or tap here to enter text. |

**NUMBER OF SUBJECTS AND DURATION OF PARTICIPATION**

Provide the number of subjects to be enrolled at Legacy sites, number of sites and number to be enrolled nationally; provide the duration of the study for subjects undergoing procedures or data gathering.

|  |  |
| --- | --- |
| Total enrollment at Legacy: | Click or tap here to enter text. |
| Total number of sites: | Click or tap here to enter text. |
| Total enrollment at all sites: | Click or tap here to enter text. |
| Duration of the study for subjects: | Click or tap here to enter text. |
|  |  |
|  |  |

**DOMAIN 3: LEGACY RESEARCH SITE(S) FOR THIS STUDY**

**List all Legacy sites and services where research will be conducted, including all sites where subject data will be collected, stored and analyzed.**

IRB approval of the research includes the specific site(s) where the research will be conducted. If site information changes during the course of the study, you will need to notify Legacy IRB and request approval of the new site(s).

Indicate the site(s) where the PI is located and confirm that subjects will only be consented by listed and approved Legacy study staff or indicate other non-Legacy staff involved in the research and their location:

|  |  |
| --- | --- |
| **Study Site Information (list all Legacy sites)** | |
| **Site(s) of the Research** *(List name and address)* | **Legacy Manager/Supervisor at each site** *(Include name and email)* |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |

*Click the plus (+) sign at the end of the last row to add more entries*

|  |  |  |  |
| --- | --- | --- | --- |
| **The PI is located at** Choose an item. **Legacy site(s).** | | | |
| **All subjects will be consented at all sites by Legacy study staff only:** | | | Yes  No |
|  | If NO, please give details: Click or tap here to enter text. | | |
| **Are there study staff who are NOT employed by Legacy:** | | Yes  No | |
|  | If YES, please give details: Click or tap here to enter text. | | |

**See next page for specific Legacy sites.**

**DOMAIN 3: LEGACY RESEARCH SITE(S) FOR THIS STUDY - CONTINUED**

**LEGACY SITES AND SERVICES**

|  |  |
| --- | --- |
| **STUDY SITES:** | |
|  | Legacy Emanuel Medical Center |
|  | Randall Children’s Hospital at Emanuel |
|  | Legacy Good Samaritan Medical Center |
|  | Legacy Salmon Creek Medical Center |
|  | Legacy Meridian Park Medical Center |
|  | Legacy Mt. Hood Medical Center |
|  | Legacy Unity Center |
| ☐ | Legacy Silverton |
| ☐ | Legacy Research Institute |
| ☐ | Investigator’s Office or Clinic |
| ☐ | Legacy GoHealth Clinics (specify location): |
| ☐ | Other Legacy Site(s): |
| ☐ | Other Non-Legacy Sites(s): |

**LEGACY MANAGER PERMISSION TO CONDUCT THE STUDY**

**All researchers must have permission to conduct the research from the manager or supervisor of the Legacy department in which the research will be conducted.** For each department, please list the manager or supervisor of each of the sites and departments in which the research will be conducted:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Department** | **Manager Name** | **Title** | **Phone** | **Email** |
| Click to enter text. | Click to enter text. | Click to enter text. | Click to enter text. | Click to enter text. |
| Click to enter text. | Click to enter text. | Click to enter text. | Click to enter text. | Click to enter text. |

*Click the plus (+) sign at the end of the last row to add more entries*

**PI Confirmation:** **Appropriate Legacy Department Manager(s) listed above have been apprised of this research and agree that the study may be conducted in their department:**   Yes  No  N/A

|  |
| --- |
| If No or N/A, please give details: |
| Click or tap here to enter text. |

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

**sponsor and funders of this research**

A “sponsor” is defined asa person who takes responsibility for and initiates a research project of clinical investigation.

* The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization.
* The sponsor does not usually conduct the investigation unless the sponsor is a sponsor-investigator.
* The “funder” of the research, i.e., the entity that is providing financial support for the study. The funder may be external or internal to Legacy or the PI or Legacy department may be self-funding the study.
* If this study is federally funded (in whole or part) indicate this and list which agency is supplying that funding, e.g. NIH, NSF, etc.

|  |  |  |  |
| --- | --- | --- | --- |
| **SPONSOR(s) of the Research** *(Include name and contact info)* | **FUNDER(s) of the Research** *(Include name and contact info)* | **Federally Funded?** | **Federal Agency** |
| Click or tap here to enter text. | Click or tap here to enter text. | Yes  No | Enter text |

**Is this research a Sponsor-Investigator Study?**  Yes  No

**FDA OVERSIGHT**

**Is this study subject to Food and Drug Administration oversight:**  Yes  No

If YES: Type of test article:  Drug  Device  Other (details): Click or tap here to enter text.

**ClinicalTrials.gov registration**

**Indicate if this study is to be registered on** **ClinicalTrials.gov:**  Yes  No :

If YES, provide the trial registration number: Click or tap here to enter text.

**IRB DEFERRAL/MULTISITE STUDY/CENTRAL IRB**

**Is this study a multisite study overseen by a central IRB:**  Yes  No

If YES, give details of the central IRB *(name and contact info)* Click or tap here to enter text.

**Are you are seeking a deferral to an external IRB outside of Legacy IRB:**  Yes  No

If YES, submit the all following documents to Legacy IRB with this application: 1)Approved Protocol, 2) Approved Consent Form, 3) Central IRB Initial Review Approval form, 4) IRB Reliance Agreement, 5) PI CV.

**NOTE: No Legacy deferral will be considered without Legacy review of central IRB approval documents.**

**DOMAIN 5: RESEARCH TYPE RESEARCH PROCEDURES**

**Research Type (select all that apply)**:

|  |  |
| --- | --- |
|  | FDA device study - Device/ IDE/HUD/NSR Device/Exempt Device/Assay Device |
|  | FDA drug study - IND/Drug/Vaccine/Biologic |
|  | FDA Treatment/Compassionate Use/Treatment Use/Emergency Use |
|  | FDA Emergency research under 21 CFR 50.24 -- Exception from Informed Consent (EFIC) |
|  | FDA HUD or FDA HDE |
|  | Clinical Trials: Phase I-IV: first-in-humans to post marketing |
|  | “Pilot” or feasibility study |
|  | Pragmatic Clinical Trials: designed to test the effectiveness of multiple standard-of-care interventions |
|  | Oncology study – Interventional therapy – drug/device/radiation/behavioral |
|  | Alternative or Complementary (CAM) – Interventional therapy |
|  | Retrospective Chart Review |
|  | Registry- Retrospective or prospective data gathering of subjects |
|  | Tissue/Specimen Banking/Repository: collection of tissues or specimens for future research |
|  | Genetic Information collected from subject or about subject’s family |
|  | Genetic Research on subject and/or subject’s family |
|  | Genome-Wide Association Study (GWAS) |
|  | Surgical: research on investigational surgical techniques |
|  | Cosmetic: research on cosmetic surgical techniques or cosmetic products |
|  | Behavioral/Social-Behavioral/Survey/Interview/Focus Group/Observational |
|  | Behavioral/Social-Behavioral/ RCT: interventions to gather data on behaviors of subjects |
|  | Outcomes Research/Quality Improvement/Program Improvement |
|  | Observation; no intervention or interaction with subjects; data collection only of observed behavior |
|  | Deception Research |
|  | Illegality/Stigma: e.g., drug use and other behaviors risking legal consequences |
|  | Health Policy Trial: trials that test innovations in the delivery of services for patients or providers |
|  | Usability or “look and feel” research of device or treatment modality, not testing efficacy or safety |
|  | Case study (1-2 patients only) or research that does not meet the definition of human subject research |
|  | Not human subject research: research using de-identified data only that does not meet the definition of human subject research |
|  | Other *(give details):* Click or tap here to enter text. |

**DOMAIN 6: RESEARCH RISKS AND PROCEDURES**

**Research design risks (select all that apply)**:

List the research design risks and procedures of this research, but do not list the specific risks already set out in the consent form or protocol.

|  |  |
| --- | --- |
|  | Pilot/Feasibility: research on a small number of subjects intended to gather data only for future research. |
|  | Intervention via test articles or therapies or subjects being randomized to various study arms. |
|  | Blinded or double-blinded study. |
|  | Placebo or Sham surgery controlled. |
|  | Research enrolling vulnerable populations: Children/Minors, Pregnant Women/Fetus, Prisoners, Legacy Employees, Students, Transgender, Poor, Uninsured, Non-readers, Sensitive populations (stigmatized, marginalized, unrepresented), subjects requiring surrogate consent, unconscious or subjects with cognitive impairment. |
|  | “Big Data” study using large volume of confidential or HIPAA protected patient data. |
|  | Use of data normally protected by standard medical privacy or confidentiality, a breach of which could cause embarrassment or reputational harm to a subject. |
|  | The research involves investigational (experimental) treatments related to Click or tap here to enter text.. |
|  | The research involves departure from standard clinical care procedures related to Click or tap here to enter text.. |
|  | The research is greater than minimal risk because the probability and magnitude of harms or discomforts anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. |
|  | The consent form clearly describes all specific physical, psychological, social, economic, or other risks to the subjects, including the nature of risks, the seriousness of risks, and incidence or probability of the risks. |
|  | The PI (or knowledgeable study staff) will always be available to discuss and answer questions about the risks, benefits and procedures of the proposed research with each subject. |
|  | This study requires special credentialing and training for Click or tap here to enter name(s)., which has been adequately obtained by the PI and/or relevant study staff, and documentation of such credentialing is or will be available upon request prior to initiation of the study. |
|  | Will a Data Safety and Monitoring Board (DMSB) be used?  Yes  No  Give details for both YES & NO answers: Click or tap here to enter text. |
|  | Will a Medical Monitor be utilized?  Yes  No  Give details for both YES & NO answers: Click or tap here to enter text. |

**DOMAIN 6: RESEARCH RISKS AND PROCEDURES – CONTINUED**

For a **drug study,** indicate the following:

|  |  |
| --- | --- |
|  | **IND Study:** The drug has an in IND # Click to enter #. Documentation is available from the sponsor and indicates that the IND # has been obtained and the study may begin. |
|  | **IND Exempt Study (package insert or other documentation is required)**  NOTE: The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if **all** the following apply:   1. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug; 2. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product; 3. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product; 4. The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and 5. The investigation is conducted in compliance with the requirements of Sec. 312.7 (Promotion of investigational drugs) |
|  | **On-Label Study (package insert or other documentation is required):** The drug is being used on-label and not investigational in any way. |
|  | **Dietary Supplement Study:** An herb or dietary supplement be used for investigational purposes. |
|  | **Placebo-controlled study:** Some subjects in this drug study will receive study drug that contains placebo. |
|  | **Other Drug Study:** The drug is called Click or tap here to enter text. and its regulatory status is Click or tap here to enter text.. |

**DOMAIN 6: RESEARCH RISKS AND PROCEDURES – CONTINUED**

For a **device study**, indicate the following:

|  |  |
| --- | --- |
|  | **Non-Significant Risk (NSR) Study:** The device is called Click or tap here to enter text. and the research considers that the use of this device in this study to meet the criteria for a Non-Significant Risk (NSR) study. The protocol or a separate statement is submitted showing how this study meets the criteria for a NSR Study. Note: a NSR study is not equivalent to a minimal risk study. |
|  | **Significant Risk (SR) Study:** The device is called Click or tap here to enter text. and has IDE # G Click or tap here to enter text. and that the study may pose significant risks to subjects; and therefore this study is greater than minimal risk. **Required FDA documentation is attached** |
|  | **510(k) Device Study:** The device is called Click or tap here to enter text. and has a 510(k) approval # Click or tap here to enter text. and it is being used and studied according to its approved indication.  **Documentation is attached.** |
|  | **PMA Device Study:** The device is called Click or tap here to enter text. and has a PMA approval # Click or tap here to enter text. and it is being used and studied according to its approved indication.  **Required FDA documentation is attached.** |
|  | **Diagnostic Device Study:** The device is a diagnostic device and in this clinical investigation the testing is 1) noninvasive, 2) does not require an invasive sampling procedure that presents significant risk, 3) does not by design or intention introduce energy into a subject, 4) is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure. |
|  | **Device Usability Study:** The device is called Click or tap here to enter text. is being studied for consumer preference or usability testing only, and a) and the testing is not for the purpose of determining safety or effectiveness. |
|  | **HUD Use:** The device is called Click or tap here to enter text. and is a Humanitarian Use Device (HUD) and has HDE # H Click or tap here to enter text. . The HUD is not being used investigationally but is being used per its HUD approval. |
|  | **HUD Study:** The device is called Click or tap here to enter text. and is a Humanitarian Use Device (HUD) and has HDE # H Click or tap here to enter text.. The device is being studied for safety and efficacy in order to obtain pre-market approval within the approved labeling. Because this is research, subjects will be consented via a research consent form. |
|  | **HUD Study (new use):** The device is called Click or tap here to enter text. and is a Humanitarian Use Device (HUD) and has HDE # H Click or tap here to enter text., but the device is being researched for a new use outside the approved labeling. Thus, the IDE regulations must be followed. |
|  | **Other Device Study:** The device is called Click or tap here to enter text. and its regulatory status is Click or tap here to enter text.. |

**Domain 7: Consent Process and Form**

**informed Consent Process**

**Provide specific details for each aspect of informed consent, which begins at recruitment. All recruitment advertisements and scripts must be described and submitted for review and approval**:

|  |  |  |  |
| --- | --- | --- | --- |
| How are eligible subjects identified? | | Click or tap here to enter text. | |
| How are eligible subjects recruited? | | Click or tap here to enter text. | |
| Will the principal investigator be available for questions from the subject? | | Yes  No If NO, give details:  Click or tap here to enter text. | |
| Where will subjects be consented | | Click or tap here to enter text. | |
| Who will go over the consent form with the subject? | | Click or tap here to enter text. | |
| How will subjects be provided the opportunity to review, ask questions and consider the information contained in the consent form? | | Click or tap here to enter text. | |
| Will some subjects be consented via a surrogate or proxy consent (legally authorized representative)? | | Yes  No  If YES, explain why some subjects will be enrolled by surrogate consent and how the research benefits the subject:  Click or tap here to enter text. | |
| How long the subject will be allowed to read and consider the consent form information? | | Click or tap here to enter text. | |
| Can the subject take the consent form home to discuss with family members? | | Yes  No | |
| Will subjects received a copy of the consent form they sign? | | Yes  No | |
| How will technical language in the consent form be explained or clarified for subjects? | | Click or tap here to enter text. | |
| Have you submitted a consent form for all subjects based on the Legacy Consent Form Template? | | Yes  No If NO, give details:  Click or tap here to enter text. | |
| Consent form checks: | |  | |
| Yes  No | Does it contain the LegacyHealthletterhead or logo? | |  |
| Yes  No | Does it clearly provide the title of the research? | |  |
| Yes  No | Does it indicate the site(s) at which the research will be conducted? | |  |
| Yes  No | Is it dated? | |  |
| Yes  No | Does it correctly provide for the signatures of all subjects to be enrolled in the research? | |  |

**Domain 7: Consent Process and Form - CONTINUED**

**Waiver of documentation of Consent request:**

**Are you requesting a waiver of documentation of consent (no signature)?**  Yes  No

|  |
| --- |
| If YES, provide a detailed explanation of the reason for this request: |
| Click or tap here to enter text. |

Please note that **a waiver of documentation of consent for research is not a waiver of consent.** Rather, it means that you will utilize either verbal consent (by use of a script), an information sheet without a signature line, or an on-line request to participate in the research or some other alternative informed consent. **A waiver of documentation of consent requires that certain criteria be met before the IRB can grant a waiver to enroll subjects without their signature on a consent form under 45 CFR 46.117(c) or 21 CFR 56.109(c)(1) for an FDA study.**

**Waiver of Consent request**

**Are you requesting a waiver of consent for all or some subjects?**  Yes  No

|  |
| --- |
| If YES, provide a detailed explanation of the reason for this request: |
| Click or tap here to enter text. |

**A** **waiver of consent for research requires that certain criteria be met** **before the IRB will grant a waiver under 45 CFR 46.116(c).** A detailed written rationale for a waiver consent must satisfy the following criteria:

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; and
4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**Domain 8: PROTECTION AND CONFIDENTIALITY OF DATA**

**DATA**

**Identify the type of data to be collected** **(select all that apply):**

|  |  |
| --- | --- |
|  | Confidential Medical Information directly from subject |
|  | Confidential Medical Information directly from subject about subjects’ family (e.g. family genetic information) |
|  | Confidential Medical Record information (e.g., Epic) |
|  | HIPAA or Protected Health Information: |
|  | Genetic information |
|  | Tissue or bodily fluids to be tested or banked |
|  | Illegality (data, including statements, related to crimes e.g., drug use, firearms, etc.) |
|  | Photographs |
|  | Audio or video recordings |
|  | Notes from interviews, surveys, or focus groups |
|  | Identifying marks or tattoos from the body |
|  | Social Media or Internet data e.g., social media information |
|  | Telephone or GPS data |
|  | Genome-Wide Association Study (GWAS) |
|  | Sensitive or embarrassing information or data (provide details):  Click or tap here to enter text. |
|  | Other (provide details): Click or tap here to enter text. |

**Domain 8: PROTECTION AND CONFIDENTIALITY OF DATA - CONTINUED**

**BIO-SPECIMENS**

Indicate if bio-specimens are to be collected:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Blood |  | Tumor |  | Tissues |
|  | Bodily Fluids (provide details): Click or tap here to enter text. | | | | |
|  | Other (provide details): Click or tap here to enter text. | | | | |

**Future Research Plans**

**Indicate how data or bio-specimens will be used for future research (select all that might apply):**

|  |  |
| --- | --- |
|  | Data/Specimens will be banked for further research purposes related to the subject’s condition |
|  | Data/Specimens will be used for future research unrelated to the subject’s condition |
|  | Data/Specimens will be stored indefinitely for unspecified future use in research |
|  | Data/Specimens will be banked for distribution to other researchers |
|  | Data/Specimens will be stored and make available for research via purchase |
|  | Specimens to be collected will possibly be used for commercialization purposes  Provide details: Click or tap here to enter text. |
|  | Specimens to be collected for commercial use and sold to other researchers  Provide details: Click or tap here to enter text. |
| **The Consent form states how subject samples/data will be used in the future on page:** Page #. | |

**DATA Access**

**Indicate who may have access to the data for regulatory purposes (select all that apply):**

|  |  |
| --- | --- |
|  | National coordinating offices |
|  | Multi-study evaluation center or sites |
|  | Pharmaceutical firms |
|  | FDA, OHRP, Other Government Agencies (provide details): Click or tap here to enter text. |
| **The Consent form tells subjects who will have access to the data for regulatory purposes on page:** Page#. | |

**PROTECTION OF DATA/SPECIMENS**

**Indicate how data or specimens of subjects will be protected** **(select all that apply):**

|  |  |
| --- | --- |
|  | De-identified at a Legacy site before sharing with sponsor |
|  | Anonymized data |
|  | Maintained behind a firewall (provide details): Click or tap here to enter text. |
|  | Only accessed by study staff |
|  | Encrypted Legacy computer or Legacy laptop computer |
|  | Other encrypted device (describe in detail): Click or tap here to enter text. |
|  | Secured and locked cabinets (indicate location and access): Click or tap here to enter text. |
|  | Redcap or similar system (indicate system): Click or tap here to enter text.. |
|  | Certificates of Confidentiality (CoC) from DHS or Privacy Certificate from DOJ will be obtained |
|  | Data Sharing – business agreements or data sharing agreements **(attach copies)** |
|  | Other (Provide details): Click or tap here to enter text. |

**Domain 8: DATA CONFIDENTIALITY PROTECTIONS FOR THE SUBJECT – CONTINUED**

**Plan if data security is breached or violated (*describe in detail*):**

|  |
| --- |
| Click or tap here to enter text. |

**STORAGE OF DATA/SPECIMENS**

**Indicate how data or specimens of subjects will be stored and protected after study is complete:**

|  |  |
| --- | --- |
|  | Data/specimens will be destroyed the end of the study to ensure subject confidentiality |
|  | Data/specimens will be kept with the PI only at the end of the study to ensure subject confidentiality |
|  | Data/specimens will be kept confidential but will never be used for another research project |
|  | Data/specimens will be kept in storage until the investigational product is approved by the FDA |
|  | Data/specimens will be kept until publication of the results |
|  | Other (Provide details): Click or tap here to enter text. |

**DATA ANALYSIS**

Indicate **t**he analysis to be done or cite the protocol section:

|  |
| --- |
| Click or tap here to enter text. |

**DATA OWNERS, PUBLICATION PLANS AND ACKNOWLEDGEMENTS**

|  |  |
| --- | --- |
| **List all Research Data Owners and Users**  (anyone who will have access to and use the data collected for this study) | Click or tap here to enter text. |
| **Detail the Sponsor or Investigator publication/presentation plan for this data** (dissemination of data resulting from the research) | Click or tap here to enter text. |
| **Detail the Sponsor or Investigator plan for Legacy Health acknowledgement as research site**  (if none, provide explanation) | Click or tap here to enter text. |

**CONSENT FORM INFORMATION**

|  |  |
| --- | --- |
| Yes  No | The submitted consent form used in this study adequately and fully informs subjects of the use of their information and samples consistent with the above answers. |

**DOMAIN 9: DOCUMENTS TO BE REVIEWED BY THE IRB**

**SUBMIT THE RELEVANT DOCUMENTS YOU WANT REVIEWED WITH THIS APPLICATION:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Document** | **File name** | **Version number** | **Document Date** |
|  | Cover letter (encouraged but not required) | Click or tap here to enter text. | V# | Select date |
|  | LRI Initial Review Application (this document) | Click or tap here to enter text. | V# | Select date |
|  | PI’s CV (updated and dated) | Click or tap here to enter text. | V# | Select date |
|  | Protocol with final date and version number (do not submit tracked or edited versions) | Click or tap here to enter text. | V# | Select date |
|  | Investigator’s Brochure (if needed) | Click or tap here to enter text. | V# | Select date |
|  | Advertisements, Flyers, Brochures or other recruitment materials | Click or tap here to enter text. | V# | Select date |
|  | Screening Script | Click or tap here to enter text. | V# | Select date |
|  | Telephone Script | Click or tap here to enter text. | V# | Select date |
|  | Consent Form (on Legacy template only) | Click or tap here to enter text. | V# | Select date |
|  | Assent (on Legacy template only) | Click or tap here to enter text. | V# | Select date |
|  | Information Sheet (on Legacy template only) | Click or tap here to enter text. | V# | Select date |
|  | Waiver of Consent Request | Click or tap here to enter text. | V# | Select date |
|  | Other Subject Materials (detail):  Click or tap here to enter text. | Click or tap here to enter text. | V# | Select date |
|  | Human Subject Research Protection Training documentation of all study staff | Click or tap here to enter text. | V# | Select date |
|  | Other: Click or tap here to enter text. | Click or tap here to enter text. | V# | Select date |
|  | Other: Click or tap here to enter text. | Click or tap here to enter text. | V# | Select date |

*Click the plus (+) sign at the end of the last row to add more ‘Other’ entries*

**DOMAIN 10: PRINCIPAL INVESTIGATOR ASSURANCES AND AGREEMENTS**

**PRINCIPAL INVESTIGATOR ASSURANCES:** The PI makes the following assurances to the Legacy IRB and agrees to the following by signing in the space provided below:

1. I attest that all the answers in this form are accurate.
2. I attest that when requesting approval of HIPAA full and partial waivers of authorization for protected health information, I am providing written assurance that:
   1. 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
   2. The research could not practicably be conducted without the waiver or alteration; and
   3. The research could not practicably be conducted without access to and use of the protected health information.
3. I agree that protected health information will not be re-used or disclosed to any other person or entity except as permitted under IRB approval.
4. I agree that I will read and abide by all of the Board requirements contained in the IRB Approval and other Legacy Health IRB correspondence that I receive and that if one or more of the Board’s requirements are not acceptable to me, I may ask the Board to reconsider its requirements, but may not enroll subjects until the issue is resolved by the Board.
5. I agree that only the Legacy IRB may grant approval of the research to be conducted, and that the conduct of the research may not begin until the Board grants final approval.
6. I agree that I will promptly report to the Legacy IRB office any proposed changes in the activity, changes in the informed consent form, unanticipated problems involving risk to subjects or others, including adverse reactions to biologicals, drugs, radioisotope labeled drugs, or to medical devices, injury or harm.
7. I agree that I will retain the documentary evidence of informed consent for at least three years after the proposed activity has been completed or discontinued.
8. I agree that the Legacy IRB is obligated to continually review study activity and I agree to furnish the Board relevant information for re-approval of this research as needed and that failure to provide the information may result in the expiration or termination of IRB approval.
9. I agree to accept responsibility for the ethical conduct of the project and the protection of the rights and welfare of the subjects.
10. I agree that all study staff will have undergone training in human subject protection training prior to participating in the research and that documentation of staff training will be kept on file for inspection if requested.
11. I agree that IRB approval applies to research ethics and regulations only. IRB approval does not obligate Legacy or any of its Mangers or Departments to proceed with activation of the study.
12. I agree to obtain Legacy Manager 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.
13. I agree that as PI for this study I am responsible for identifying and ensuring that resource impacts from this study on any Legacy Department are properly negotiated.
14. I agree that a copy of this approval and other study documents can be sent to the Legacy Manager/Supervisor of the site in which the research will be conducted as identified in Domain 3 of this form.
15. I agree that all Legacy institutional policies will be followed during the conduct of this research.

**PRINCIPAL INVESTIGATOR SIGNATURE REGARDING ASSURANCES:**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Principal Investigator/Project Director signature |  | Date |

**END OF LEGACY IRB INITIAL REVIEW APPLICATION**

**SUBMIT FORM TO:**

[irbsubmissions@lhs.org](mailto:irbsubmissions@lhs.org)

**QUESTIONS?**

**Paul Newton, JD, CIP**

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Research Administration

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