**LEGACY HEALTH INSTITUTIONAL REVIEW BOARD**

**INITIAL REVIEW APPLICATION AND APPROVAL DOCUMENT**

The questionnaire is based on DHHS regulatory requirements and Legacy Health’s policy for the protection of human subjects and the administration of research studies. **Upon final approval of this study, you will receive this form with the IRB Chairperson’s and the Vice President of Research’s signature and it will serve as your approval document.**

**Protocol – Full Title:**

**Principal Investigator:**

# LEGACY HEALTH IRB APPROVAL

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**V.P. of Research, Legacy Health DATE**

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## Chairperson, Legacy IRB DATE

Initial Review Date: Study Expiration Date:

Final Approval Date:

**PI Address:**

**PI Telephone:**

**PI e-mail:**

**Funding Source / Sponsor:**

**Please submit the following documents for review:**

1. **Protocol – Version & Date:**
2. **Consent form**

* **Initial Version & Date:**
* **Final Approval Version & Date:**
* **Assent Form: Other Consent Forms:**

1. **Investigator’s Brochure: Version & Date:**
2. **PI’s CV – date:**
3. **Other materials (specify):**

Legacy IRB Tracking Number (for internal use only)

1. **ABSTRACT OF PROJECT:** A descriptive summary of the objective and method of the project in lay terminology (in 150-300 words)
2. **DESCRIBE THE CHARACTERISTICS OF THE SUBJECTS TO BE USED:**

Adult Subjects: Yes  No

Pediatric Subjects Yes  No

Sex: Male  Female  Age Range: to years

**Total enrollment at Legacy:**    

**If multi-site study, number of sites nationally:**     **Total Enrollment Nationally:**

1. **SPECIAL SUBJECT GROUPS:**

Will subjects be primarily from any of the following groups?

Minors:  Fetuses:  Pregnant Women:  Prisoners:  Cognitively Impaired:

**If any of these apply, explain the necessity for using these particular groups:**

1. **CONFIDENTIALITY OF DATA ON THE SUBJECT:**

(a) Will identifiable subject data be transmitted to a person or office not associated with this institution? (e.g. national coordinating offices, multi-study evaluation center, pharmaceutical firms, etc)

Yes  No

If yes, provide details as to how PHI will be protected:

(b) How will the confidentiality of the data be maintained?

Yes  No  De-identified at a Legacy site before sharing with sponsor

Yes  No  Maintained behind a firewall

Yes  No  Only accessed by study staff

(c) When will all data be de-identified?

Yes  No  At the end of the study

Yes  No  When the investigational product is approved by the FDA

Yes  No  Upon publication of the results

Other:

(d) Will bio-specimens be gathered?

For study purposes? Yes  No

If yes, state the purpose:

For bio-banking? Yes  No

If yes, provide bio-bank contact information:

(e) Is this study registered on ClinicalTrials.gov?

Yes  No  If yes, provide number:

1. **STUDY COSTS and COMPENSATION:**

**COSTS**: Will this study involve costs, which exceed those encountered in the normal course of medical treatment? Yes  No

If "Yes," identify the costs and who will pay for them:

**COMPENSATION**: Will this study provide research subjects with monetary or other inducement for participation? Yes  No

If “Yes,” identify inducement and provide justification:

1. **RISKS TO SUBJECTS:**

In the consent form describe any physical, psychological, social, economic, or other risks to the subjects. These risks must be represented in the consent form in easy to read paragraphs or in a chart providing details of the Nature of Risk, Seriousness of Risk, and Incidence or Probability. Attach the investigator’s brochure or peer reviewed literature which supports this risk profile.

Will there be Data Safety and Monitoring Board?

Yes  No

If yes, provide contact information:

Will a medical monitor be utilized?

Yes  No

If yes, provide contact information:

How will safety information be gathered at the local site?

In the hospital: Yes  No

At study visits: Yes  No

By telephone: Yes  No

Other:

1. **INFORMED CONSENT:**

Where will the subject be consented?

Doctor’s Office

Hospital

Other:

Will consent be sought by a surrogate of Legally Authorized Representative?

Yes  No

If yes, explain the circumstances:

Are you are requesting a waiver of any elements of informed consent?

Yes  No  If yes, provide justification:

1. **RECRUITMENT:**

Will subjects be recruited by physician referral?

Yes  No

Will medical records be used to identify potential subjects?

Yes  No

If yes, explain how that will be done:

Will subjects be recruited using advertisements?

Yes  No

If yes, attach advertisement and state where the advertisement will appear.

Will you use a receptionist’s script?

Yes  No

If yes, attach script and state who will use it:

1. **INVESTIGATOR’S EXPERIENCE/QUALIFICATIONS :**

(a) Are you a physician and active member of the Legacy medical staff? Yes  No

**If "No", attach written assurance from a staff physician who assumes the medical**

**responsibility for the subjects, if applicable.**

(b) For Clinical (Drug & Device) trials only:

Have you ever been audited by the FDA? Yes  No

If yes, were there corrective actions?

(c) Human Subject’s Training within the last three years (attach certificate)

CITI  Big Brain (OHSU)  NIH  Other

1. **STUDY SITES and SERVICES**

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 Research Institute

Other:

SERVICES:

Pharmacy

Laboratory

Surgery

Imaging

Radiation Therapy

Infusion Clinic 10. **ASSURANCES:**

1. I will promptly report to the Office of Research Administration any:
   1. proposed changes in the activity,
   2. changes in the informed consent form,
   3. unanticipated problems involving risk to subjects or others, including adverse reactions to biologicals, drugs, radioisotope labeled drugs, or to medical devices,
   4. injury or harm.
2. I will retain the documentary evidence of informed consent for at least three years after the proposed activity has been completed or discontinued.
3. The Institutional Review Board is obligated to continually review this activity. Therefore, I agree to furnish the Board relevant information on request.
4. I agree to accept responsibility for the ethical conduct of the project and the protection of the rights and welfare of the subjects.
5. **CONFLICT OF INTEREST:**

List all potential or actual conflicts of interest especially significant financial interests related to this research project. Conflicts of interest need to be disclosed to the IRB to assist them in managing potential investigator bias.

(Initial Yes or No)

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** |  |
|  |  | **Patent – Did you invent the device or drug being tested?** |
|  |  | **Licensed Invention – Do you receive royalties related to your invention?** |
|  |  | **Financial Interest – Do you have any financial interest in the sponsor of the study?** |
|  |  | **Salary and/or payment for services (outside conduct of the study) – Do you receive consulting fees, travel expenses or honoraria from the sponsor of the study?** |

DISCLOSURE - If you have initialed any of the above and have a significant financial interest (i.e. over $5,000 in the last year) provide details on a separate sheet.

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Principal Investigator/Project Director Date

12. **ADMINISTRATIVE REVIEW:** (required only if study involves Legacy patients, facilities or resources; not required if study only involves private practice patients who do not enter a Legacy facility)

I have reviewed and approved the proposed study as feasible and relevant to the goals and objectives of this department. I can assure that this department has the resources available to support the proposed study so that it is conducted according to clinical standards as they are currently practiced at the Legacy Health.

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Director/Administrator Date

##### *ATTACHMENT A*

### INVESTIGATIONAL DRUG USAGE

1. Will an investigational (unapproved) drug be used? Yes     No

**If “No,” proceed to #2**

**If “Yes,”**

* + 1. Attach the data on previous human experience, animal studies, and laboratory tests.
    2. Give name of the firm that holds the IND:
    3. Give the IND number:

1. Will an approved drug be used in an unapproved manner for investigational purposes? Yes     No

**If “Yes,”** Attach the data on previous human experience, animal studies and laboratory tests.

1. Will an herb or dietary supplement be used for investigational purposes?

Yes     No

**If “Yes”:**

1. Attach the data on previous human experience, animal studies and laboratory tests.
2. Identify the manufacturer of the substance:
3. Attach information related to the formulation.

##### *ATTACHMENT B*

### INVESTIGATIONAL DEVICE USAGE

1. Will an unapproved investigational device be used? Yes  No

**If “No,” proceed to #2**

**If “Yes,” then**

1. Give name of the firm that holds the IDE:
2. Give the IDE number:
3. Give HCFA reimbursement code:
4. Will an approved device be used for gathering safety and efficacy information for uses other than those for which it is approved? Yes  No

If Yes, what was the device originally approved for?

1. Will a 510(k) device be used for gathering safety and efficacy information?

Yes  No  Give 510(k) approval #:

1. If you are requesting the IRB to make a “Non-Significant Risk” (NSR) determination please attach justification.
2. Will the device require sponsor/vendor support in the Operating Room?

Yes  No

**If “Yes**,” **specify who will be involved and provide details as to their involvement in the study procedure.**

6. Will a Humanitarian Use Device (HUD) device be used? Yes  No

**If “No,” proceed to #7**

**If “Yes,” then**

* 1. Give name of the firm that makes the HUD:
  2. Give the HUD number:

**Attach documentation on previous human experience, animal studies, and laboratory tests. If available, attach a photograph or drawing of the device.**

1. Credentialing and Training: Does this device require credentialing, privileging or training? Yes  No

**If “Yes,” attach documentation indicating that this has been accomplished or an assurance that such credentialing, privileging or training will be completed prior to initiation of the investigation.**

##### *ATTACHMENT C*

**STUDY PERSONNEL**

List all study personnel who will have contact with subjects or exposure to PHI, by name and role (co-investigator, coordinator, technician, statistician, receptionist, etc.), indicate whether they will be authorized to consent subjects and indicate date and format of human subject’s training (CITI, Big Brain, NIH, other).

**Name Role Consenting Training**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Yes  No | CITI  Big Brain (OHSU)  NIH  Other  In Process |
|  |  | Yes  No | CITI  Big Brain (OHSU)  NIH  Other  In Process |
|  |  | Yes  No | CITI  Big Brain (OHSU)  NIH  Other  In Process |
|  |  | Yes  No | CITI  Big Brain (OHSU)  NIH  Other  In Process |
|  |  | Yes  No | CITI  Big Brain (OHSU)  NIH  Other  In Process |
|  |  | Yes  No | CITI  Big Brain (OHSU)  NIH  Other  In Process |
|  |  | Yes  No | CITI  Big Brain (OHSU)  NIH  Other  In Process |
|  |  | Yes  No | CITI  Big Brain (OHSU)  NIH  Other  In Process |
|  |  | Yes  No | CITI  Big Brain (OHSU)  NIH  Other  In Process |
|  |  | Yes  No | CITI  Big Brain (OHSU)  NIH  Other  In Process |