**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**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_**

## 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 [ ]  |