*Hendrick Institutional Review Board Application*

FACE SHEET

1. Protocol Name and/or Number
2. Site and Research Staff
   1. Principal Investigator

Title: Phone:

Address: E-mail:

Fax:

* 1. Study Coordinator

Title: Phone:

Address: E-mail:

Fax:

1. Sub-Investigators (if applicable, list below)
2. Number of Studies Principal Investigator has open \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Date of IRB Application Submission ­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator/Designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

STUDY SUMMARY

1. **Protocol Title**
2. **List all Staff/Personnel Involved in this Study:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Title** | **Institutional Affiliation** | **Phone** | **E-mail** |
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1. **Location Information**
   1. Where will this study take place:
   2. Will the PI be conducting or supervising study related activity ay any other sites not under the jurisdiction of this institution’s IRB?

\_\_\_Yes \_\_\_ No

\*If yes, please complete an Additional Study Location Form for each location\*

1. **Protocol Summary/Symopsis** 
   1. Describe in detail the objective of the research.
   2. Please explain the statistical and quantitative methodology.
   3. List the study Inclusion Criteria.
   4. List the study Exclusion Criteria.
   5. How will the inclusion/exclusion criteria be assessed and by whom?
   6. What are the alternative to study participation for the potential subjects?
2. **Study Procedure** 
   1. What will be the duration of subjects’ active participation?
   2. What is the schedule of assessments for participants through the active trial phase?
   3. How long and at what frequency and nature will subjects be follow after the active participation ends?
3. Informed Consent
4. **Subject Information**
   1. Select all potential subjects that will participate in this study:

|  |  |  |
| --- | --- | --- |
| 🞎 Adults | 🞎 Nursing home residents | 🞎 Cognititvely/Mentally impaired |
| 🞎 Fetuses / fetal material | 🞎 Economically disadvantaged | 🞎 Students |
| 🞎 Pregnant women | 🞎 Investigator's staff members | 🞎 Homeless |
| 🞎 Children  🞎 Hospitalized Patients  🞎 Military Personnel | 🞎 Investigator's patients  🞎 Terminally ill | 🞎 Non-English Speakers  🞎 Other (describe) |

* 1. Will subjects who do not speak English be enrolled? \_\_\_\_Yes \_\_\_\_No

If Yes, please describe how subjects will be communicated with:

* 1. Into what languages will the consent form need to be translated:

\_\_\_Spanish \_\_\_Other:

1. **Subject Recruitment**
   1. How will subjects be identified?

🞎 Patient Chart/Database Review

🞎 Referrals from Provider/other source

🞎 Advertising or published recruitment materials

Media for subject recruitment includes (Check all that apply):

🞎 Radio 🞎 Television 🞎 Letters to patients

🞎 Newspaper 🞎 Flyer/Bulletin Board 🞎 Letters to providers

🞎Internet 🞎 Other

🞎 Sponsor-driven recruitment

* 1. If patients will be recruited by sponsor-driven tactic, please describe in detail:

1. **Risks and Benefits** 
   1. Explain potential risks to subjects, including expected frequency, degree of severity, and reversibility.
   2. How will subjects be assessed for adverse events during this study?
   3. Describe the study monitoring plan.
   4. Describe potential benefits of study participation.
2. **Payment to Subjects**
   1. Are subjects being paid for participation in this study: \_\_\_Yes \_\_\_No
      1. If yes, indicate total amount (dollars or equivalent):
      2. Form of payment

🞎 Reimbursement 🞎 Gift Certificate 🞎 Cash 🞎 Check

* + 1. Will subject be required to submit proof of expenses for reimbursement?

\_\_\_Yes \_\_\_No

1. **Informed Consent** 
   1. Who will be responsible for explaining the study to potential subjects?
   2. Is this person an investigator or Sub-Investigator? \_\_\_ Yes \_\_\_No
      1. If No, please include this person(s) on the Delegation of Authority Form.
   3. Describe your process to obtain informed consent.
   4. Are you requesting Waiver or Alteration of Informed Consent? \_\_\_ Yes \_\_\_No
      1. If No, skip to next section.
      2. Why does the proposed research present no more than minimal risk to the subjects?
      3. How will pertinent information be provided to the subjects at a later date if appropriate? Is there a debriefing plan?
   5. Attach the informed consent documents for review. If there are Sponsor consent documents, please include a reference copy and provide any informed consent forms including the IRB’s standard language if necessary.
2. **Confidentiality** 
   1. Are the subjects protected health information (PHI) to include medical record number, visit number, name, date of birth, social security number or any other identifier being sent off site to sponsor? \_\_\_Yes \_\_\_No
      1. If Yes, describe transmission process and explain reasoning.
   2. Will any external identity other than the investigative staff have access to or be provided with confidential medical or health-related information about the subject?

\_\_\_Yes \_\_\_No

* 1. Describe how patient confidentiality will be maintained, including who will have access to raw data.
  2. Will any raw data be made available to anyone other than the Principal Investigator or immediate study staff (e.g., school officials, medical personnel, data analysts)?

\_\_\_Yes \_\_\_No

* + 1. If yes, describe the procedure for sharing data, including with whom it will be shared, how, and why.

*I certify that the information contained above is accurate. I agree to provide the IRB with the information it requires to conduct initial and continuing review of this study including serious or unexpected adverse events on a timely basis and that if the information is not provided, the IRB may suspend the study.*

Principal Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sub-investigator(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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