



## **IRB APPLICATION INSTRUCTIONS**

Please read this instructional document carefully when preparing an IRB application.

**(USE the IRB Application template, not this instructional template, to provide responses to questions)**

### **GENERAL INFORMATION:**

The IRB meeting schedule and submission deadlines will be available on the Institutional Review Board at (TBA). Address all correspondence to the IRB Office, V-A 310. For telephone assistance please call 512-505-3019.

All of the appropriate forms must be typed and accurately completed. Any application that is not completed properly, or submitted on outdated forms, may be returned to the investigator, possibly resulting in a delay in the review process.

Specific submission requirements are provided on the application checklist.

**NOTE:** If you will be applying to the Research Standards Committee and Institutional Review Board (RSC&IRB) to provide any type of support for this study **you must also submit** this application and supporting documents to Sara Summers for review and approval by the HT RSC&IRB. For question related to HT RSC&IRB submission contact Sara Summers at 512-505-3085 or [ssummers@htu.edu](mailto:ssummers@htu.edu). Detailed requirements are noted below.

### **HT RSC&IRB SUBMISSION REQUIREMENTS:**

1. Signed paper version of the below application to the Chair of the HT RSC&IRB, A-V Alumni Hall Room 310.
2. Electronic version of the application through email to Ms. Jaya Soni at [ssummers@htu.edu](mailto:ssummers@htu.edu)
3. Electronic Version of the Study Proposal (See additional Template).
4. IRB Approval Letter and Consent Form(s) (when obtained if not available when initially applying for support).
5. Funding Source
  - a. Industry Support. If your protocol will receive any industry support, attach the following documentation to this application:
    - i. a copy of the initial correspondence (and other relevant correspondence) between the investigator and the industry representative indicating whether the study was initiated by the industry or the investigator; and,
    - ii. a copy of the itemized budget that has been agreed upon by the investigator and the industry.
  - b. NIH funded projects, attach the following documents:
    - i. a copy of your most recent Summary Statement, and,
    - ii. award letter and approved budget with budget justification for the entire funding period.
  - c. Foundation Support/Another non-NIH Source. Attach the following documents:
    - i. a copy of the scientific review(s) of your project, and,
    - ii. award letter and budget with budget justification.
6. Principal Investigator CV.

### **REPORTING REQUIREMENTS:**

All key personnel must be knowledgeable of the [IRB policies](#) for reporting unanticipated problems that involve risks to subjects (e.g. physical, psychological, economical, breach of confidentiality, invasion of privacy, adverse events, etc.) or others, non-compliance with the approved protocol, adverse event reporting, and the process for filing an allegation of non-compliance with IRB requirements.

### **TRAINING or CENTER GRANTS**

Submit 1 copy of the following:



1.13 If expedited review, which category below is applicable (If 9, attach the IRB letter stating the minimal risk determination):?

**Direction:** Note the expedited category under which review is being requested. If applicable attach a copy of the IRB approval letter that states that the study is minimal risk. **Note** that for category 9 the study cannot involve prisoners, investigational drugs, or investigational devices.

Research Categories:

1. **Clinical studies of drugs and medical devices** only when condition (a) or (b) is met.
  - a. (a) Research on drugs for which an investigational new drug application
2. **Collection of blood samples** by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - b. from other adults and children<sup>2</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of **biological specimens** for research purposes by **noninvasive means**.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction;

4. **Collection of data through noninvasive** procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging

5. Research involving materials (**data, documents, records, or specimens**) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
6. Collection of data **from voice, video, digital, or image recordings** made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
8. **Continuing** review of research previously approved by the convened IRB as follows:
  - a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
  - b. where no subjects have been enrolled and no additional risks have been identified; or
  - c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

| SECTION 2– RESEARCH PERSONNEL INFORMATION                    |   |             |   |                                       |  |           |          |                   |
|--|---|-------------|---|---------------------------------------|--|-----------|----------|-------------------|
|  | PRINCIPAL INVESTIGATOR<br>(last, first)   |             | STUDY COORDINATOR<br>(last, first if other than PI) |                                       | CONTACT PERSON<br>(last, first if other than PI or SC) |           |          |                   |
| 2.0 Name:  | <p><b>Direction:</b> Provide the contact information requested for the principal investigator, study coordinator and contact person. If there is no study coordinator or contact person indicate NA. If no contact person is listed the study coordinator will be considered as such. If no study coordinator is listed the PI will be considered as such.</p>  |             |   |                                       |  |           |          |                   |
| 2.1 Degree(s) Held   |   |             |   |                                       |  |           |          |                   |
| 2.2 Professional Licenses (type& #)                          |   |             |   |                                       |  |           |          |                   |
| 2.3 Professional Certifications                              |   |             |   |                                       |  |           |          |                   |
| 2.4 Job Title  |   |             |   |                                       |  |           |          |                   |
| 2.5 Department   |   |             |   |                                       |  |           |          |                   |
| 2.6 Room Number  |   |             |   |                                       |  |           |          |                   |
| 2.7 Mail Code  |   |             |   |                                       |  |           |          |                   |
| 2.8 Phone Number   |   |             |   |                                       |  |           |          |                   |
| 2.9 Emergency Number   |   |             |   |                                       |  |           |          |                   |
| 2.10 Fax Number  |   |             |   |                                       |  |           |          |                   |
| 2.11 Pager Number  |   |             |   |                                       |  |           |          |                   |
| 2.12 E-mail Address  |   |             |   |                                       |  |           |          |                   |
| 2.13 Date of HS Training                                     | <p><b>Direction:</b> Provide the date that human subjects training was completed. All key personnel (principal investigator, co-investigators, administrators, study coordinators, individuals who will obtain consent) associated with this application are required to complete a human subjects protection training session. HT personnel must complete the CITI Requirements if their last completed training occurred more than three years ago. If possible, attach a copy of the training completion certificate. All training is verified prior to IRB approval being granted. If all personnel have not completed training, project approval may be granted as contingent upon the requirement being satisfied. <b>If the study contact person is someone other than the PI or coordinator, and the contact person's only involvement is administrative in nature, e.g. ensuring that documents get submitted to the IRB, maintaining the regulatory binder for the PI, the contact person does not have to complete the training, although it is recommended. If the study contact person is administrative only, please note that on this application.</b></p> |             |   |                                       |  |           |          |                   |
| 2.14 Other Affiliations of PI                                | Indicate if the PI has affiliations with any of the institutions with which we have a cooperative IRB review agreement in place   |             |   |                                       |  |           |          |                   |
| 2.15 Off-hours/weekend contact information (Optional):       | <p><b>Direction:</b> If provided this information will allow IRB reviewers to contact you with questions related to the review of the study during off-hours or weekends. If you do not want to be contacted off-hours or on weekends indicate NA.</p>  |             |   |                                       |  |           |          |                   |
| SECTION 3 – COLLABORATING INSTITUTIONS / MULTI-CENTER TRIALS |   |             |   |                                       |  |           |          |                   |
| 3.0  | <p>Are there any collaborating sites involved with this study? If no skip to question 3.3. If yes, answer all questions in this section. <b>Direction:</b> Provide a yes or no response. If other institutions are collaborating/cooperating in this study (i.e. staff at other sites will receive professional recognition or publication privileges), respond with yes. This question does not pertain to multi-site national trials in which institutions are not directly collaborating with each other in the conduct of the study.</p>  |             |   |                                       |  |           |          |                   |
| 3.1  | <p>If collaborating with other sites, provide the name of each institution, including HT, and place an x under the column(s) that describes the type of involvement for each institution. <b>Direction:</b> Provide the information requested. You may provide additional comments if they will help to clarify the various roles that institutions will play, for example recruitment will occur at both sites but HT is expected to have the 80% of subject recruitment. Also provide the date that the other institution obtained IRB approval or indicate that it is pending. PI's are encouraged to keep copies of all initial and on-going IRB approvals from collaborating sites.</p>  |             |   |                                       |  |           |          |                   |
|  | Institution's Name  | Recruitment | Enrollment / Consenting Subjects                    | Interactions (e.g. survey, interview) | Interventions (e.g. needle stick)                      | Follow-up | Analysis | IRB Approval Date |
| Additional Comments:   |   |             |   |                                       |  |           |          |                   |
| Information on multi-center trials                           |   |             |   |                                       |  |           |          |                   |

| 3.2   | Will HT serve as the statistical center, operational center or lead institution? <b>Direction:</b> If yes, indicate which role HT will serve and complete and attach Appendix C. Proceed to 3.4 if HT is the lead institution otherwise skip to section 4.                        |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
|---|---|--|---|---------------------------|--------------------------|---------------------------|--------------------------|---------------------------|--------------------------|----------------------|--------------------------|
| 3.3   | If HT is the lead institution, describe the plans for communication among sites in terms of protocol modifications, unanticipated problems and interim results: <b>Direction:</b> Describe how HT will monitor the activity at other sites and convey information to other sites. |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| 3.4   | If HT is the lead institution, describe the plans for communication among sites in terms of protocol modifications, unanticipated problems and interim results: <b>Direction:</b> Describe how HT will monitor the activity at other sites and convey information to other sites. |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| <b>SECTION 4 – PROJECT CHARACTERISTICS, SUMMARY AND DESIGN</b>  |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| 4.0 <b>Provide the anticipated time frame during which the study will be conducted:</b>   |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;"><b>Expected Start Date</b> (mm/dd/yyyy):</td> <td style="width: 50%; padding: 5px;"><b>Expected Completion Date</b> (mm/dd/yyyy):</td> </tr> <tr> <td style="height: 20px;"></td> <td></td> </tr> </table>  |   | <b>Expected Start Date</b> (mm/dd/yyyy): | <b>Expected Completion Date</b> (mm/dd/yyyy): |                           |                          |                           |                          |                           |                          |                      |                          |
| <b>Expected Start Date</b> (mm/dd/yyyy):  | <b>Expected Completion Date</b> (mm/dd/yyyy):   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
|   |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| 4.1 <b>Provide the general therapeutic area and sub-area(s) that best describe your study</b> (e.g., cancer, gastrointestinal, pancreatic or psychiatry, addictive behaviors, gambling).  |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%; padding: 5px;">Primary Area</th> <th style="width: 33%; padding: 5px;">Sub- Area</th> <th style="width: 33%; padding: 5px;">2<sup>nd</sup> Sub- Area</th> </tr> </thead> <tbody> <tr> <td style="height: 20px;"></td> <td></td> <td></td> </tr> </tbody> </table>  |   | Primary Area                             | Sub- Area                                     | 2 <sup>nd</sup> Sub- Area |                          |                           |                          |                           |                          |                      |                          |
| Primary Area  | Sub- Area   | 2 <sup>nd</sup> Sub- Area                |   |                           |                          |                           |                          |                           |                          |                      |                          |
|   |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| 4.2 <b>Place an X after the applicable study phase:</b> (definitions provided below)  |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 12.5%;">Phase I</td> <td style="width: 12.5%;"><input type="checkbox"/></td> <td style="width: 12.5%;">Phase II</td> <td style="width: 12.5%;"><input type="checkbox"/></td> <td style="width: 12.5%;">Phase III</td> <td style="width: 12.5%;"><input type="checkbox"/></td> <td style="width: 12.5%;">Phase IV (Post Marketing)</td> <td style="width: 12.5%;"><input type="checkbox"/></td> <td style="width: 12.5%;">Not a clinical trial</td> <td style="width: 12.5%;"><input type="checkbox"/></td> </tr> </table> |   | Phase I                                  | <input type="checkbox"/>                      | Phase II                  | <input type="checkbox"/> | Phase III                 | <input type="checkbox"/> | Phase IV (Post Marketing) | <input type="checkbox"/> | Not a clinical trial | <input type="checkbox"/> |
| Phase I   | <input type="checkbox"/>  | Phase II                                 | <input type="checkbox"/>                      | Phase III                 | <input type="checkbox"/> | Phase IV (Post Marketing) | <input type="checkbox"/> | Not a clinical trial      | <input type="checkbox"/> |                      |                          |
| 4.3 <b>For post-marketing trials, describe any post-marketing commitments imposed on the use of this drug by the FDA.</b>   |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| 4.4 Provide 2 or 3 sentences describing your project in lay terms. <b>Direction:</b> This information should be a general overview of the study and will be used primarily to orient lay IRB members to the purpose of the project.   |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| 4.5 Provide either a flow diagram or outline of the experimental design addressing the elements noted below. <b>Direction:</b> Provide the requested information. Responses 4.7, 4.8 and 4.9 combined should not exceed the equivalent of five pages. For <b>expedited and exempt applications only</b> , you may refer to the protocol but <b>must provide specific page #s and locations</b> for each item referenced (e.g. flow diagram: see protocol pages 5-6 starting with section title study schema)  |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| Flow diagram or outline including a time line of the study from initiation through data analysis, procedures (including a time sequence of when those procedures that involve human subjects will be performed and how they will be monitored),:  |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| Description of sample size:   |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| Estimated enrollment per year:  |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| Primary and secondary outcomes and endpoints:   |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| 4.6 Describe methods of analysis, sample size supported by appropriate power calculations. <b>Direction:</b> Provide the requested information. Responses 4.7, 4.8 and 4.9 combined should not exceed the equivalent of five pages. For <b>expedited and exempt applications only</b> , you may refer to the protocol but <b>must provide specific page #s and locations</b> for each item referenced (e.g. methods of analysis: see protocol pages 7 starting with section title analysis.)  |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| 4.7 Provide the age range or description of subjects and justification for the age selection: <b>Direction:</b> If there are specific age criteria note them and justify, e.g. subjects will be between the ages of 18 – 45 because the condition under study typically manifests in this age bracket, or all subjects will be of age 18 and above so that legally effective informed consent may be obtained, or a general description such as third and fourth grades will be included because the topic studied relates to their curricular activity.  |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |
| 4.8 Are there any other non-clinical factors that will exclude subjects, e.g. race/ethnicity, gender, language? If so, justify why the exclusion is necessary. <b>Direction:</b> Justification for exclusions based on demographics should have a scientific basis, e.g. women are excluded because the disease being studied effects predominately men.  |   |  |   |                           |                          |                           |                          |                           |                          |                      |                          |

**SECTION 5 –PROTECTION AGAINST AND MINIMIZATION OF RISKS (45 CFR 46.111(A)(1))**

5.0 List all procedures to be performed on human subjects. Also list alternative therapies or procedure that may be advantageous to the subject. Discuss the risks and benefit of any alternative therapy. **Direction:** Provide the information requested. Note that if no reasonable treatment alternatives are available the ICF must state that choosing not to participate is an alternative option. The investigator must use the least risky procedures that are appropriate to the purpose of the research study. When appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes. Provide a general assessment of the risk/benefits of alternative options, e.g. procedure x has demonstrated effectiveness however it is much more invasive and the time to recuperate is much more extensive.

|                                     |
|-------------------------------------|
| Non-Experimental Procedures:        |
| Experimental Procedures:            |
| Alternative Options:                |
| Risks and Benefits of Alternatives: |

5.1 Describe the potential risks associated with the proposed research, the procedures to protect against or minimize potential risks and assess the likelihood of the risk occurring and if it were to occur the seriousness to the subject. **Direction:** The assessment of risk must include physical, psychological, economic (e.g. loss of employment or insurance), social (e.g. stigmatization), legal (criminal behaviors) or other (e.g. drug toxicities) risks associated with the proposed research. For each risk identified there must be procedures in place to protect against or minimize the possibility of the risk being realized. To minimize procedural risks the investigator must use the least risky procedures that are appropriate to the purpose of the research study and when appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes. If a particular category of risk does not pertain indicate “none” under the type of risk and proceed to the next risk category.

|                 |  |                          |                                       |
|-----------------|--|--------------------------|---------------------------------------|
| Physical Risks: | Procedures to Protect Against / Minimize Risks | Likelihood of Occurrence | Seriousness to Subject if Risk Occurs |
|                 |  |                          |                                       |

|                      |  |                          |                                       |
|----------------------|--|--------------------------|---------------------------------------|
| Psychological Risks: | Procedures to Protect Against / Minimize Risks | Likelihood of Occurrence | Seriousness to Subject if Risk Occurs |
|                      |  |                          |                                       |

|                 |  |                          |                                       |
|-----------------|--|--------------------------|---------------------------------------|
| Economic Risks: | Procedures to Protect Against / Minimize Risks | Likelihood of Occurrence | Seriousness to Subject if Risk Occurs |
|                 |  |                          |                                       |

|               |  |                          |                                       |
|---------------|--|--------------------------|---------------------------------------|
| Social Risks: | Procedures to Protect Against / Minimize Risks | Likelihood of Occurrence | Seriousness to Subject if Risk Occurs |
|               |  |                          |                                       |

|              |  |                          |                                       |
|--------------|--|--------------------------|---------------------------------------|
| Legal Risks: | Procedures to Protect Against / Minimize Risks | Likelihood of Occurrence | Seriousness to Subject if Risk Occurs |
|              |  |                          |                                       |

|              |  |                          |                                       |
|--------------|--|--------------------------|---------------------------------------|
| Other Risks: | Procedures to Protect Against / Minimize Risks | Likelihood of Occurrence | Seriousness to Subject if Risk Occurs |
|              |  |                          |                                       |

5.2 Identify all research related activity that is not part of standard of care for which there will be a charge, provide the estimated amount to be charge, and indicate who will be responsible for payment, e.g. subject, sponsor, charged to departmental funds. **Direction:** Provide the requested information. Any item for which the subject must pay must also be disclosed within the informed consent form. If there will be no charges for research related activity provide a statement to that effect.

| Research Activity (including medication): | Estimated Amount to be Charged | Party Responsible for Payment |
|---|--------------------------------|-------------------------------|
|   |                                |                               |

Comments:

5.3 Describe any other costs that may be incurred by the subject due to participation in this study, e.g. subject will be responsible for all travel costs, lodging etc. **Direction:** Provide the requested information. For research related injury, if the subject must first pay the expenses and then seek reimbursement, that must be described here and disclosed in the informed consent form. If there are any conditions upon which payment by the sponsor is contingent, those conditions must also be stated in the ICF. If there are no additional costs incurred provide a statement to that effect.

Additional Information for Investigational Devices (includes, but is not limited to: tape recorders, cell phones, video cameras, mp3 players, etc)

5.4 Will the study involve the use of an investigational device? **Direction:** Provide a yes or no response. If no skip to 5.15, if yes complete 5.5 -5.7. When possible submit IDE safety reports.

5.5 Provide Name, IDE number and manufacturer. For studies involving IDEs for which any component has not been previously marketed also attach confirmation from the manufacturer of compliance with federal regulations and [Good Manufacturing Practices](#) and of IDE approval from the sponsor. **Direction:** Provide requested information and attach supporting documents: **If the investigator/HT is the sponsor** of the IDE the PI must request an audit by a Research Compliance Monitor (RCM) with the Human Subjects Protection Office prior to submitting the application for review and approval. The RCM will inspect the storage facility for the drug and review with the PI the additional obligations of the sponsor. The documentation of this meeting must be attached to the application.

| Device Name | IDE Number | Manufacturer of IDE | Sponsor of IDE | Indicate Confirmation of GMP Attached or device already marketed | Confirmation of IDE Approval Attached |
|-------------|------------|---------------------|----------------|--|---------------------------------------|
|             |            |                     |                |  |                                       |

5.6 Indicate whether the device is considered a significant risk or non-significant risk (NSR) device. **Direction:** For NSR devices, the sponsor must provide the IRB with a description of the device, reports of prior investigations with the device, the proposed investigational plan, a description of patient selection criteria and monitoring procedures. The sponsor must also inform the IRB if other IRBs have reviewed the proposed study and what determination was made by those IRBs. Information pertaining to investigational devices can be found in federal regulation [21 CFR 812](#).

5.7 Describe plans for maintaining inventory of the investigational device and tracking its use. Also submit the signed statement of investigator responsibilities for IDEs. **Direction:** Respond accordingly and provide signed statement.

|   |
|---|
| <b>Where will the device be stored?</b>                               |
| <b>Describe measures in place for inventory control:</b>              |
| <b>Describe measures for monitoring / tracking use of the device:</b> |
| <b>How and by whom will the device be used:</b>                       |
| <b>Describe plans for return of unused devices to the sponsor:</b>    |

**SECTION 6 – REASONABLENESS OF RISKS IN RELATION TO BENEFITS, IF ANY (45 CFR 46.111(A)(2))**

6.0 Place an x after the level of overall risk that, in the opinion of the PI, is associated with this study. Comments may also be provided to justify the assessed risk level. [Guidelines for assessing risk](#) are available on the HSPO / IRB website. **Direction:** Provide the requested information. Note that the IRB makes the final determination as the level of risk involved with a study. Additional comments are optional. Requests for exempt status or expedited review must be determined to be of minimal or less risk. All studies requiring initial review by the convened board must also have scientific review. If not already conducted by the RSCI, FDA, NIH or cooperative group, provide additional copies of material as noted above for review by the HSPO Scientific Review Committee.

| <i>Risk Level</i>                   | <i>x to select</i> | <i>Comments</i> |
|-------------------------------------|--------------------|-----------------|
| <i>None:</i>                        |                    |                 |
| <i>Minimal:</i>                     |                    |                 |
| <i>Slight Increase Over Minimal</i> |                    |                 |
| <i>Moderate:</i>                    |                    |                 |
| <i>High</i>                         |                    |                 |

6.1 What benefit, if any, may be gained by the subject and/or society? Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others. **Direction:** Provide the requested information. Note that per OHRP, receiving free study drug is not considered a benefit. Payment for participation is not a benefit.

6.2 Discuss the importance of the knowledge that may be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may result. **Direction:** Provide the requested information.

**SECTION 7 – SUBJECT SELECTION / RECRUITMENT DATA (45 CFR 46.111(a)(3) &(a)(7)(b))**

7.0 Place an x after the type(s) of human subjects that are likely to be recruited for this study. If the category is followed by a letter, and the study is not eligible for exempt status, complete the corresponding form to certify that the additional protections required for vulnerable populations have been met. **Direction:** Investigators are encouraged to provide additional information about the subject populations. For example, for terminally ill subjects indicate life expectancy ranges in the additional comments area. For chart review studies, indicate that the only involvement of subjects is via review of charts. Investigators must be aware that if any subject enrolled in a study subsequently becomes a prisoner IRB review under Subpart C must occur or the subject must be withdrawn. Investigators may wish to request prospective review under Subpart C if the characteristic of the study population is such that incarceration is likely to occur. Studies proposing to involve prisoners require full board review under Subpart C of the Common Rule. Studies proposing to involve prisoners must be reviewed by Panel 02.

|   |  |   |  |  |  |
|---|--|---|--|--|--|
| <b>Pregnant Women or Fetuses</b><br>(B204 or B207)                  |  | <b>Children/Adolescents</b> (D404, D405, D406 or D407)          |  | <b>Prisoners</b> (C )                                |  |
| <b>Neonates of uncertain viability or non-viable</b> (B205 or B207) |  | <b>Decisionally Impaired</b> (S and (D404, D405, D406 or D407)) |  | <b>Hospital Inpatients- Including Prisoners</b> (C ) |  |
| <b>Abortuses</b> (B206 or B207)                                     |  | <b>Viable Neonates</b> (D404, D405, D406 or D407)               |  | <b>Hospital Inpatients–No Prisoners</b>              |  |
| <b>UHC Employees</b> (S)  |  | <b>Educationally Disadvantaged</b> (S)                          |  | <b>Outpatients</b>                                   |  |
| <b>UHC Students</b> (S)   |  | <b>Economically Disadvantaged</b> (S)                           |  | <b>Terminally Ill</b> (S)                            |  |
| <b>Other (describe)</b>   |  |   |  |  |  |

7.1 Explain why the inclusion of any vulnerable populations (pregnant women, fetuses, neonates, prisoners, children, adolescents, HT students, HT employees, decisionally impaired, terminally ill, economically disadvantaged, educationally disadvantaged) identified in 7.0 is necessary: **Direction:** Vulnerable populations should be included in studies only when scientifically justified, e.g. for a study of Alzheimer’s disease, it is reasonable to include decisionally impaired subjects. Vulnerable populations cannot be included for convenience sake.

7.2 What is the maximum number of subjects to be enrolled at or by HT? If HT enrollment is anticipated to be 250 or more, complete and submit Appendix D. **Direction:** Indicate the maximum number of subject for which you are seeking IRB approval to enroll. This includes subjects enrolled at the HT as well as subjects enrolled by HT personnel at other sites, for example HT approved studies conducted in a foreign country. Do not use per year numbers, e.g. five per year. Subjects are generally considered enrolled at the time of screening so select a number high enough to allow for those subject who screen out because they do not meet eligibility criteria. If needed, a request for modification may be submitted at a later date to increase the HT enrollment limit. (Note: subjects who

screen out are to be reported as withdrawn for screening failure at the time of continuation.)

7.3 Explain on what basis it is reasonable to expect that recruitment goals will be met. **Direction:** Provide information about the target subject population and how the PI has determined that such a population is accessible for recruitment.

7.4 What is the national expectation for enrollment? **Direction:** If this is a multi-center trial indicate the national enrollment expectation if known. If not applicable, indicate NA.

**Data Collection and Recruitment Methods**

7.5 Place an X after the source(s) of information that will be used within the study to collect data. Describe any other sources that are not listed. Attach data collection forms. **Direction:** Provide the requested information. Directly identifiable specimens are those with a direct link (such as name or medical record number) to the identity of the individual from whom the sample was derived. Coded/linked samples are not identifiable in and of themselves but there is mechanism available, e.g. a master list kept apart from the sample, to link the sample back to the individual who provided it. Any data from prisoners will require review under subpart C and the corresponding worksheet must be completed.

|  |  |   |  |
|--|--|---|--|
| Medical interventions                    |  | Medical records –excluding prisoners      |  |
| Existing directly identifiable specimens |  | Medical records –including prisoners (C ) |  |
| Existing de-identified specimens         |  | Existing coded specimens                  |  |
| Lab results                              |  | Waste material                            |  |
| Interviews                               |  | Research registry*                        |  |
| Focus groups                             |  | Surveys                                   |  |

Other sources of information(provide description):

\*Provide the name and IRB number of the registry that will be used:

7.6 Place an X after all methods and materials that will be used to recruit subjects and describe how recruitment strategies will be implemented. Note: All materials for and methods of recruitment must receive IRB approval prior to use, including final versions of recorded ads for which a script is provided. It is acceptable to identify a recruitment method and note the IRB approval will be sought when the material is developed. Direction: Describe all methods and provide all material that will be used to recruit subjects. Some sample responses are noted below. If applicable, include a description of proposed outreach programs for recruiting women and minorities as subjects in clinical research. If specific individuals will be directly recruiting subjects provide their name and relationship to the subjects, e.g. subjects will be recruited by Drs. X, Y and Z who are the treating physicians by mailing letters or holding discussions with patients, and / or subject will be recruited via general newspaper advertisements and broadcast messages.

| Methods/Materials       | X to Select | Description of Implementation |
|-------------------------|-------------|-------------------------------|
| Closed to Enrollment    |             |                               |
| Radio spots             |             |                               |
| Newspapers              |             |                               |
| Magazines               |             |                               |
| Broadcast messages      |             |                               |
| Purchased mailing lists |             |                               |
| Patient base            |             |                               |

|                   |  |  |
|-------------------|--|--|
| Flyers            |  |  |
| Proband           |  |  |
| Phone Calls       |  |  |
| Web postings<br>* |  |  |

Other methods, materials and strategies that will be used for subject recruitment (provide description):

Describe any outreach programs for recruiting women and minorities into clinical research trials:

**\*Note:** Listing an approved and active clinical trial on the web does not require IRB approval when the posting is limited to the following elements: title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. IRB review and approval must be sought if any additional information is to be posted. The IRB may conduct random audits of web postings to ensure compliance with these terms.

Generally, any advertisement to recruit subjects should be limited to:

- the name of the principal investigator;
- an accurate description of the condition under study and/or the research purpose e.g. if a placebo is to be used in a drug study, the advertisement should describe the study as a comparison of the drug to the placebo; if investigational products are to be used they must be identified as such and not represented as new treatments
- in summary form, the eligibility criteria that will be used to admit subjects into the study;
- a straightforward and truthful description of the benefits, if any, to the subject from participating in the study;
- if applicable, a statement that compensation is available or a statement of how much compensation is available and how it will be paid, e.g. "Participants may receive up to \$100 paid in equal installments over 4 visits"
- the amount / length of time or other commitment required of the subjects
- the location of the research and the person to contact for further information
- the IRB number

If the study involves the use of FDA regulated investigational products (drugs or devices) no claims can be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation, or that the drug or device is in any way equivalent or superior to any other drug or device. Such representation would not only be misleading to subjects but would also be a violation of the FDA's regulations concerning the promotion of investigational drugs ([21 CFR 312.7\(a\)](#)) and of investigational devices ([21 CFR 812.7](#))

7.7 Describe any financial or other compensation that will be paid to the subjects and the disbursement schedule for such compensation. **Direction:** Provide the requested information. In general compensation should not be structured in such a way the subjects must complete the study in order to receive any compensation since that structure may create an undue influence for the subject to remain on study. A staged approach is recommended, e.g. partial payment after week two, six and eight and final payment upon completion. For study in which subject participation is for a short period of time, e.g. 2 or 3 visits within a 1 month time frame, it may be acceptable to hold payment till the end of participation.

**SECTION 8 – INFORMED CONSENT PROCESS (45 CFR 46.111(A)(4)) (45 CFR 146)** The IRB is interested in the entire process of obtaining consent. The consent form is only one piece of that process. Investigators should provide a thorough description of the consent process including any special provisions that will be incorporated into it, e.g. for individuals whose decision making capacity may decline over time, the consent process will be conducted at each visit to determine if a legally authorized representative must become involved, or for subject just diagnosed with cancer a minimum 24 hour waiting period will be exercised between the consent discussion and the signing of the consent document to ensure subjects have had enough time to consider the risk of the study and are not consenting out of desperation.

8.0 Have you requested exempt status or a waiver of the requirement to obtain consent? If yes skip to section 10. If no and study is open to new enrollment complete all items in this section. If no and study is closed to new enrollment but subjects remain on active treatment, respond to item 8.9 and if applicable 8.12 ) **Direction:** Provide a yes or no response.

8.1 Provide the version reference of the consent document to be reviewed? **Direction:** Note the version of the consent

document in the footer. There should be a link between the consent document and the protocol, e.g. version 1 of the protocol links with version 1 or 1.1 of the consent.

8.2 Who will be authorized to obtain consent/assent/authorization? **Direction:** Individuals authorized to obtain consent must be designated by name. All individuals authorized to obtain consent must be fully knowledgeable of the study protocol and able to respond to questions from subjects. Individuals authorized to obtain consent must complete training in the protection of human subjects in research. If possible, attach a copy of the training completion certificate for each person who will be obtaining consent.

| Name of those authorized | Fluent in Language(s) | Date of Human Subjects Training |
|--------------------------|-----------------------|---------------------------------|
|                          |                       |                                 |

8.3 Are non-English speaking subjects likely to be consented? If so describe the plans for ensuring that information is presented in a language understandable the subject/legally authorized representative (LAR). Translated consent forms must be submitted to the IRB. If not, explain why. **Direction:** Provide requested information and documents. For example, Spanish speaking subjects are likely to be enrolled because the study is being conducted off-site in a predominately Spanish neighborhood. The PI and coordinator are both fluent in the language and will be able to conduct the consent process in either English or Spanish. Translated documents (certified by an agency or appropriately back-translated) are included for approval with this submission. OR, Non-English speaking subject are not likely to be enrolled because the subject pool will come from a demographic area and/or physician's practice group for which English is the predominate language used.

8.4 Who will provide consent / permission? **Direction:** indicate whether the subject will provide direct consent or whether the consent/permission will be obtained from parents or legally authorized representatives. If obtained from an LAR documentation of such status must be obtained and maintained. When research is conducted in Texas the persons who meet the above definition are a child's parent(s), court-appointed conservators or guardians, individuals designated as having power of attorney for health care, or individuals designated as health care representatives. Consent from next-of-kin is not acceptable absent one of the prior designations.

In Texas when a patient authorizes another to consent to medical treatment and/or decisions on his/her behalf, said consent extends to research in the following contexts:

- If a legal guardian has been appointed for a patient, informed consent is obtained from the named individual, providing that the guardian has been given the authority to consent to medical treatment or medical procedures.
- If a power of attorney (which specifically includes medical treatment and/or decisions) has been given to an individual, informed consent is obtained from the named individual.
- If a health care representative, as that term is defined in Connecticut General Statutes § 19a-570(5), has been appointed for a patient, informed consent is obtained from the named individual provided that the procedures involved in the research are the type of procedures that normally occur in the context of medical care.

Mentally retarded adults who have been declared incompetent must have an appointed legal guardian provide consent to participate in research. The natural parents of the adult are not authorized to give permission unless they have been appointed legal guardian(s). If a mentally retarded adult has not been declared incompetent, the principal investigator must decide if the subject is capable of understanding the elements of informed consent. A family member or other representative may be asked to co-sign. If the investigator determines the subject is not capable of providing consent, a legal guardian must be appointed and must provide consent before the subject can be enrolled.

8.5 If consent will be obtained from LARs, describe the process for ensuring that the LAR is in fact the child's parent(s), court-appointed conservator or guardian, or individual designated as having power of attorney for health care, or individuals designated as a health care representative. Consent from next-of-kin is not acceptable absent one of the prior designations:

8.6 Will anyone other than the subjects be a part of the consent process? **Direction:** Explain whether there will be any individual other than the subject involved in the consent process, for example for studies involving decisionally impaired individuals indicate whether a legally authorized representative will be present, if the PI is electing to have the consent process witnessed describe that process etc.

8.7 How will the privacy of the subjects be maintained throughout the consent process? **Direction:** The consent process must be conducted in a setting and location that affords sufficient privacy to the subject. Describe the setting in which consent will be obtained and how that setting affords such privacy. For example, the consent process will be conducted in the private office of the PI. **Note, privacy refers to the individual not to the confidentiality of data** which is addressed elsewhere in the application.

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| <p>8.8 Describe in detail <u>the process</u> for obtaining consent, including steps that will occur, the estimated length of the discussion, and how will it be ensured that subjects / LARs have had enough time to consider their decision regarding participation? <b>Direction:</b> Describe in detail the process for obtaining consent. The consent process must afford sufficient time to subjects for consideration of participation. For example for subjects just diagnosed with a terminal disease the PI could impose a minimum 24 hour waiting period between the consent discussion and the signing of the document. For minimal risk studies it is acceptable for consent to be obtained following the consent discussion and the opportunity for subjects to ask questions. For example, it is acceptable to state something to the effect of “The coordinator and the potential subject will review the consent form together. The coordinator will read each section to the subject, elaborate on the section and then ask the subject if s/he has any questions on that section. After any questions have been answered the coordinator will move to the next section of the document and repeat the process. After the last section has been reviewed the subject will be ask to summarize the research project in his/her own words. If the subject provides an accurate summary s/he will be asked if s/he would like more time to consider their decision to participate and whether s/he would like to sign and date the consent form. If the summary is not accurate the coordinate will go over the relevant sections again. It is estimated that the initial consent discussion will take one hour. Statements such as “they’ll have as much time as they want” are not sufficient responses.</p>   |
| <p>8.9 How will on-going consent of the subjects (or LARs) continue to be obtained throughout the conduct of the study? <b>Direction:</b> Because consent is an ongoing process, not just the signing of the consent form, explain how the consent of the subject will be maintained over the course of the study. For example “at each visit the procedure to be performed will be verbally explained to the subject and verbal confirmation of the subject’s decision to continue participation will be obtained and noted in the research record, or because the study involves subjects whose decision making capacity may decline over time, the consent process will be conducted at each visit to assess the subject’s understanding and to determine if a legally authorized individual is required to become involved.” If on-going consent is not an issue because the study involves only one visit provide a statement to that effect.</p>   |
| <p>8.10 Will any screening activity occur prior to consent / authorization being obtained? <b>Direction:</b> Explain how consent and authorization will be addressed in relation to any screening activities required to determine eligibility, e.g. potential subject will sign consent and authorization specific to screening activity and will subsequently sign separate consent and authorization to participate if determined to be eligible, or all screening for eligibility is done as part of routine clinical care so no separate consent or authorization is required, or a partial waiver of <b>consent and HIPAA</b> authorization has been requested to allow for preliminary phone screening for calls initiated by potential subjects. Those deemed eligible will sign a <b>consent and authorization</b> form at their first study visit.</p>   |
| <p>8.11 Describe the process of obtaining assent from children or decisionally impaired adults. <b>Direction:</b> If assent is being sought describe the process for doing so, otherwise indicates NA. When describing the process indicate if the child/decisionally impaired person will be present for the full informed consent discussion with the parent/legally authorized representative or whether a separate assent session will be held. Children and those individuals who are not competent to provide consent should be given the opportunity to <i>assent</i> to participate in the research project. <i>Assent is a knowledgeable agreement to participate in the project.</i> Adequate provisions should be made for soliciting the independent, non-coerced assent from children or decisionally impaired persons who are capable of a knowledgeable agreement. In cases where assent is obtained from a child or decisionally impaired subject, consent must also be obtained from a parent or a legally authorized representative. In accordance with the ethical principal of respect for persons, if the person from whom assent is sought refuses, the person should not be enrolled, even if the parent or legally authorized representative gives permission. (The IRB may make an exception to this guideline in studies related to life-threatening illnesses when eligible subjects may benefit from research treatment protocols.) Alternatively, if the person from whom assent is sought agrees to participate, the person may not be enrolled if the parent or legally authorized representative does not give permission. In rare circumstances, depending on the nature of the study and the age and circumstances of the child, the IRB may waive the requirement for parental or legally authorized representative permission.</p> <p>The scenarios outlined below pertaining to the assent of children are general and may be altered by the IRB depending on the nature of a specific study and the mental and physical status of the children involved. The assent or consent of the child may not be required in all situations. The IRB will determine, in accordance with Subpart D, whether one or both parents must sign an informed consent form. One parent may sign for research falling under category 46.404 which is research involving no greater than minimal risk or 46.405 which is research involving greater than minimal risk but holding out the prospect of direct benefit to the subject.</p> <p>If the subject is 12 years of age or older, the child signs the consent form and a parent or guardian also signs the consent form. No assent statement is required.</p> <p>If the child is between 7-12 years of age, and the study is a therapeutic trial the child does not have to sign and the parents sign the consent form. If the study is not a therapeutic trial, the parents or guardians sign the consent form</p> |

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|  | <p>and the subject signs an assent statement that is either included at the end of the consent form after the signature lines or as a separate document.</p> <p>If the child is less than 7 years of age, the parent or guardian signs the consent form, the subject signs nothing. No assent statement is required.</p>  |
| 8.12   | <p>Provide any additional comments regarding the consent process. <b>Direction:</b> This is an opportunity for the PI to clarify any consent related issues. Response to this element is optional.</p>  |
| <p><b>Ensuring There Is No Undue Influence Within the Consent Process</b></p>  |   |
| 8.13   | <p>Describe the plans to minimize the possibility of coercion or undue influence during the consent process: <b>Direction:</b> Respond accordingly depending on the academic nature of your study. For example, because subjects will be recruited primarily from the PI's physician practice, the co-investigator will approach subjects about the possibility of participating and conduct the consent process. This will minimize the possible effect of doctor / patient influence.</p>   |
| 8.14   | <p>What benefit, if any, is to be gained by the research personnel for subject recruitment into the study, e.g. payment for enrollment? If applicable, disclose the value of the benefit and explain how it is justified. <b>Direction:</b> Any payment received for enrollment should not exceed the expected administrative costs associated with the management of subjects enrolled in a study. Payments to investigators and research staff that are tied to the rate or timing of enrollment (i.e. bonus payments) are designed to accelerate recruitment and are prohibited as they may create undue influence in the enrollment process. Likewise, investigators of an approved IRB study may not offer or receive payments for the referral and ultimate enrollment of subjects into a study. For example, investigators may not award a treating physician with a financial payment or other incentive for referring a subject to a study. Likewise, investigators may not accept payment or other incentives for referring a subject to another study.</p> |
| <p><b>SECTION 9– INFORMED CONSENT DOCUMENTATION (45 CFR 46.111(A)(5) AND .117(C))</b></p>  |   |
| 9.0  | <p>Will consent be documented via use of a consent form? <b>Direction:</b> Provide a yes or no response. If yes skip to section 10. If no, respond to 9.1 – 9.2, or 9.3 – 9.4, as applicable to your study, to request a waiver of the requirement to document consent. The majority of studies will require documentation of consent. Option 1 is not applicable to FDA regulated studies.</p>   |
| <p>Note: The majority of studies will require documentation of consent. The IRB will make the final determination as to whether consent must be documented.</p>  |   |
| <p>Option 1 for waiver of the requirement to document consent. <b>Direction:</b> Option 1 is not applicable to FDA regulated studies. If option 1 is requested, the subject must still be given the option of signing and dating a consent form and the subject's wishes prevail. Therefore, a consent form must still be submitted for review and approval by the IRB. In order for option 1 to be acceptable the answer to both 9.1 and 9.2 must be yes.</p> |   |
| 9.1  | <p>Would the consent form be the only record linking the subject to the research study? <b>Direction:</b> If requesting this type of waiver, provide a yes or no response.</p>  |
| 9.2  | <p>Is the principal risk that of potential harm caused if there were a breach of confidentiality? <b>Direction:</b> If requesting this type of waiver, provide a yes or no response. If yes, describe the potential harm caused due to a breach of confidentiality.</p>   |
| <p>Option 2 for waiver of the requirement to document consent. <b>Direction:</b> In order for option 2 to be acceptable the answer to both 9.3 and 9.4 must be no. The IRB may require that subjects be provided with a summary of the research and that summary must be reviewed by the IRB.</p>  |   |
| 9.3  | <p>Does the research present more than minimal risk? If no, explain the rationale for this assessment. <b>Direction:</b> If requesting this type of waiver, provide a yes or no response and the reason that the study is of no more than minimal risk.</p>   |
| 9.4  | <p>Does the research involve any procedures for which written consent is normally required outside of the research context? <b>Direction:</b> If requesting this type of waiver, provide a yes or no response.</p>  |
| <p><b>SECTION 10– PROTECTION OF PRIVACY OF SUBJECTS &amp; CONFIDENTIALITY OF DATA (45 CFR 46.111(A)(7) &amp; HIPAA)</b></p>  |   |
| 10.0   | <p>How will the privacy interest of subjects be maintained throughout the conduct of the study? <b>Direction:</b> Describe the procedures in place to ensure that the subject's privacy is maintained throughout the conduct of the study. For example, for initial and return visits subject's in waiting rooms will be called by first name only. All discussions and procedures will occur in the private office of ..... etc. Privacy refers to the individual not to the data collected from the individual.</p>   |
| 10.1   | <p>What information, if any, will be sought from the subject about other living individuals? <b>Direction:</b> Provide the specific information that will be obtained from the subject about others. Note, if private identifiable information is being gathered from the subject about others the IRB may require that additional consent, or permission to waive the requirement of consent, from those individuals be obtained. If no information is being collected from the subject about other individuals provide a statement to that effect.</p>  |

10.2 Describe the procedures to protect the confidentiality of data during the conduct of the study by addressing each element noted below.

Who will house the data? **Direction:** Indicate who, e.g. HT or a sponsor, will house the data and / or samples collected for the study. If data are shared describe those circumstances. Note: For student projects that data must ultimately reside with the principal investigator, not the student.

Describe plans for storage and security of information on hard copy, including how research records will be labeled and if applicable, how information will be protected during transportation from external sites to HT. **Direction:** Medical records and research records must be kept in secured locations. Describe the physical location where hard copy data are to be stored and the security measures in place, e.g. "all data will be maintained in the private office of the PI which is locked when not occupied. Within the office the data will be kept in a locked filing cabinet. The secured research records will be labeled with the subjects' first name and first three letters of the last name." Note: You do not have to use the method in the sample – but you must accurately describe the method that you will use for labeling research records. If data will be collected off-site and brought back to HT plans should include how that data will be protected during transport.

Will lab results be posted to medical records or research records? **Direction:** Indicate medical record or research record. To prevent labs from being posted to the medical record, contact the manager in the dept. of lab medicine. Within a given study, lab results cannot be split between the medical record or the research record. If the study does not involve any lab tests provide a statement to that effect. The consent form must also indicate where information will be stored.

Will other study related information, e.g. the informed consent document, survey tools, be posted to the medical record or research record? **Direction:** Indicate medical record, research record or both if applicable. If both describe what information will be posted to the medical record vs. the research record. The consent form must also indicate where information will be stored.

Describe plans for storage and security of identifiable/coded samples. **Direction:** Provide an accurate description of the plan for storage of samples. For example, describe who will have access to samples, how the samples are labeled, and if coded where the list that links the code to an individual will be kept, and who will have access to the code.

Describe plans for storage and security of electronic data. **Direction:** All electronic files (e.g., databases, spreadsheets, etc.) containing identifiable patient information must be password protected. Any computer hosting such files should also have a BIOS password to prevent access by un-authorized users. Furthermore, for systems not running Windows 2000/XP, a password-protected screen saver should be installed and configured to activate no more than ten minutes after the computer has been idle. PGP software is an option for data encryption. Information Technology should be contacted for assistance with data security elements.

Describe the security measures that are in place for the equipment that houses identifiable data. **Direction:** Describe the security measure in place for equipment, e.g. "all personal computers are within an office that is locked when not occupied"

Who will have access to hardcopy, samples and / or electronic data? **Direction:** Indicate who (by name or role) will have access to the data.

How will access be managed? **Direction:** Describe the procedures in place to manage access, e.g. indicate who has keys to locked offices or locked cabinets; indicate who knows passwords to secure files, indicate how access is removed if someone leaves the research team etc.

Describe the plans for storage or destruction of identifiable data for screened failures **Direction:** If identifiable information is obtained during the screening process, describe the plan in place for dealing with the information when a subject does not qualify for the study.

10.3 Describe procedures to continue to protect confidentiality **after** study closure by addressing each element noted below. **Direction:** Provide the requested information.

How long will information be stored? **Direction:** Describe the length of time for which records will be maintained after study closure. The minimum requirement for retention after closure/completion is three years. If the information will be retained for a longer period of time, e.g. due to sponsor requirement, regulations etc., describe the information here. Note: HIPAA Authorizations that do not have an expiration date must be retained indefinitely.

Describe plans for on-going storage of hard copy data. **Direction:** Describe the physical location where hard copy data are to be stored and the security measures in place. If the storage procedure after closure is the same as when the study is active you may use the statement "same as above". If storage after completion will be different, describe the procedure, e.g. "all data will be archived off-site with a HT approved vendor (e.g. Iron Mountain or Cardone).

Describe plans for on-going storage of identifiable samples. **Direction:** Provide an accurate description of the plan for storage of samples. For example, describe the location where the samples will be stored and the security

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| measures in place. Note: Samples for genetic studies must be coded without any direct link, e.g. medical record number, to the subject's identity. If samples will not be stored beyond the completion of the study provide a statement to that effect.   |
| Describe plans for on-going storage of electronic records? <b>Direction:</b> If the storage procedure for electronic files after closure is the same as when the study is active you may use the statement "same as above". If electronic storage after completion will be different describe the procedure, e.g. "all data will be archived to disk and the disk will be maintained in the locked office of the PI etc." |
| Who will have access to hardcopy, samples, and/or electronic data? <b>Direction:</b> Describe the procedures in place to manage access, e.g. indicate who has keys to locked offices or locked cabinets; indicate who knows passwords to secure files, indicate how access is removed if someone leaves the research team etc.  |
| How will access be managed? <b>Direction:</b> Describe the procedures in place to manage access, e.g. indicate who has keys to locked offices or locked cabinets; indicate who knows passwords to secure files, indicate how access is removed if someone leaves UCHC. If the procedures as the same as for when the study is active you may use the statement "same as above".   |
| Describe the plans for the destruction of identifiable data. <b>Direction:</b> Describe the plans accordingly, for example describe plans for destroying video or audio tapes, for shredding documents etc. If documents will be permanently retained provide a statement to that effect.   |

**SECTION 11 –SAFETY MONITORING (45 CFR 46.111(A)(6))**

11.0 Have you requested exempt or expedited status for a non-HT RSC&IRB supported, non-NIH funded study? If yes, skip to section 11.3. If no answer all questions in this section.

11.1 Place an X after the entity responsible for safety monitoring of the study and after the type(s) of safety monitoring in place for this study. **Direction:** If monitoring is internal to UCHC append the completed template for creating a DSMP/B available in Appendix B. For multi-center trials, or trials with external monitoring submit the monitoring plan; and when applicable the DSMB charter, describing details of membership, frequency of meeting etc., and summaries of DSMB meetings or findings that have already occurred if available. Provide the requested information providing details for any "other" entities and/or mechanisms used for monitoring. Studies of moderate or high risk are generally required to have a Board in place. If a Board is not feasible, e.g. due to the short length of the study or the small number of subjects to be enrolled, other provisions must be in place and described in the application and in the protocol. All minimal risk studies and studies with a slight increase over minimal risk supported by the HT RSC&IRB or NIH funds are required to have at least a plan in place. The IRB may require a plan for other minimal risk studies and generally requires at least a plan for studies above minimal risk that are non-RSC&IRB, non-NIH supported, investigator initiated studies. Guidelines for assessing risk are available on the HSPO / IRB web site at [http://resadm.uchc.edu/hspo/irb/files/risk\\_guidelines.doc](http://resadm.uchc.edu/hspo/irb/files/risk_guidelines.doc). Note: these are guidelines and the IRB makes the final determination of risk levels and may require additional monitoring mechanisms for a study.

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| <b>Entity responsible for monitoring</b> |  | If applicable, describe other entities below. |
| Monitoring internal to HT                |  |   |
| Monitoring by sponsor                    |  |   |
| Monitoring by other entity (describe)    |  |   |

|                              |  |                     |  |  |
|------------------------------|--|---------------------|--|--|
| <b>Mechanism(s) in Place</b> |  |                     |  |  |
| Data Safety Plan             |  | Independent Monitor |  | If applicable describe other mechanisms below: |
| Data Safety Board            |  | Other (describe)    |  |  |

11.2 Describe the plans for communicating significant findings to subjects, in particular those findings that may impact the subject's willingness to continue to participate or that relate to the safety or medical care of the subjects. **Direction:** Plans should be appropriate to the nature of the study. The IRB requires that subjects be re-consented if there have been developments, e.g. adverse events, which may affect a subject's willingness to continue to participate. The investigator must submit a request for modification to the Informed Consent Form to the IRB and then, after obtaining approval, re-consent the subjects at the next regularly scheduled visit. Re-consenting a subject will serve to demonstrate that s/he has been informed of the additional information and that s/he willingly consents to continued participation. If the consent document has not yet been approved by the IRB at the time of the visit a verbal explanation of the information must be provided to the subject and documentation of the explanation must be noted in the research or medical record as appropriate to the study.

The investigator or IRB may also determine that subjects need to be contacted immediately depending on the nature of the information and the level of risk it presents to subjects. This may occur prior to the consent document being approved. For example, if a life threatening adverse event occurs, the PI will determine the best way to communicate the information to the subjects in the study. Consideration must be given to the subject's underlying condition, available support systems, and the nature of the information being conveyed. The PI must document the contact with the subjects

If the investigator's opinion is that no such plan is needed because of the minimal risk associated with a study, i.e. that no such events

11.3 Provide a brief description of the resources available to conduct this study, including the accessibility/availability of such resources. **Direction:** Describe the resources available for a study. If a resource is not needed indicate why, e.g. bed space not needed because this is a survey study.

| Resource  | Description of available resource  | Accessibility /Availability  |
|---|--|--|
| Financial resources: (internal and external):<br><b>Direction:</b> Provide the dollar amount of funding available for this study. If the study is unfunded indicate that.   | Example: \$100,000 NIH grant   | Example: Funded through 5/31/2014  |
| Staff: <b>Direction:</b> Provide a description of available staff available, including and in addition to the research team, and for interventional studies, discuss plans for ensuring staff are available for necessary medical or professional intervention in the event of adverse effects to the subjects, | Example: In addition to the research team the XX center has research nurses, biostatisticians and administrative support staff. All interventions occur during the day when a cardiologist is available." If staff is not a concern note that no additional staffing resources beyond the study team are needed and explain why, e.g. study is non-interventional. | Example: clinic staffed 24 / 7; each subject provided with pager # of PI and number for the clinic           |
| Equipment and Resources for Subject Safety ( <b>Direction:</b> Describe accordingly or explain why the resource is not applicable, e.g. N.A. survey study only.   | Example: The XX center provides for crash carts and resuscitation equipment  | Example: Procedures are only done during the day and the equipment is always accessible during the procedure |
| Medical Supplies: <b>Direction:</b> Describe accordingly or explain why the resource is not applicable, e.g. N.A. survey study only.  |  |  |
| Laboratory space: <b>Direction:</b> Describe accordingly or explain why the resource is not applicable, e.g. N.A. survey study only.  |  |  |
| Bed space: <b>Direction:</b> Describe accordingly or explain why the resource is not applicable e.g. N.A. survey study only.  |  |  |
| Services (e.g. counseling, ancillary care):<br><b>Direction:</b> Describe accordingly or indicate that it is not applicable, e.g. a social worker will be present as the survey is administered in case the subject becomes upset due to the sensitive nature of the survey questions.                          |  |  |
| Other Resources: <b>Direction:</b> If applicable, describe any other resources available for the conduct of the study.  |  |  |
| General Comments: <b>Direction:</b> Optional area for clarification/comments regarding resources  |  |  |

|   |  |  |
|---|--|--|
| for the conduct of the study.   |  |  |
| <b>SECTION 12– KNOWLEDGE OF LOCAL RESEARCH CONTEXT (REQUIREMENT PER OHRP GUIDANCE DOCUMENT)</b> |  |  |
| 12.0  | Will the study, in whole or in part, be conducted off of UCHC grounds? If yes answer 12.1 – 12. 4. If no, skip to section 13. <b>Direction:</b> Provide the location where your research will be conducted. For studies conducted on UCHC premises indicate HT (including multi-center trials in which HT is participating and collaborating studies for which IRB approval is obtained at each site).   |  |
| 12.1  | Provide the location(s) where the research will be conducted: <b>Direction:</b> Provide the requested information. If the research will be conducted at external locations provide the name of the facility and a description of the area in which the research will be conducted.   |  |
| 12.2  | For study locations within the U.S. that are off of HT grounds, describe who granted permission to conduct the research on the premises of the facility and their authority to do so. Attach proof of permission. <b>Direction:</b> Provide the requested information. When applicable, attach proof of permission to conduct the study at external agencies, companies or clinics that have granted access to their files or premises. The letter should state confirmation of knowledge and purpose of the project and in what capacity the individual is authorized to provide permission (e.g. studies conducted in school settings with permission of principal or superintendent). If the research is not conducted within the U.S. indicate NA. |  |
| 12.3  | If the study is conducted outside of the U.S., describe who granted permission for the study to be conducted at the foreign site and provide an explanation of the of the local experts authority to grant such approval. Attach proof of review and approval by the local equivalent of an IRB or local experts or community leaders and provide their credentials. <b>Direction:</b> Provide the requested information. If the study is conducted within the U.S. indicate NA  |  |
| 12.4  | If the study is conducted outside of the U.S., describe the investigators knowledge of the culture and language of the area: <b>Direction:</b> Describe accordingly. If the study is conducted with the U.S. indicate NA.  |  |
| <b>SECTION 13– ADDITIONAL INFORMATION PERTAINING TO GENETIC RESEARCH</b>                        |  |  |
| 13.0  | Does the study involve genetic research? <b>Direction:</b> Provide a yes or no response. If no skip to section 14. If yes, respond to the remaining questions in this section.   |  |
| 13.1  | Will findings related to the study be disclosed to the subject? <b>Direction:</b> Provide a yes or no statement. If yes, answer 13. 1 – 13.7. If no, skip to 13.8. Note that if the researchers plan to release findings the subjects must also be given the opportunity to decline receiving information.   |  |
| 13.2  | Describe what information will be provided: <b>Direction:</b> Describe accordingly   |  |
| 13.3  | Describe who will provide the information to the subject. <b>Direction:</b> Describe accordingly.  |  |
| 13.4  | Describe at what point in the study the information will be provided: <b>Direction:</b> Describe accordingly   |  |
| 13.5  | Describe by what means it will be provided: <b>Direction:</b> Describe accordingly:  |  |
| 13.6  | Describe the reliability of information provided: <b>Direction:</b> Describe accordingly   |  |
| 13.7  | Explain the basis upon which the disclosure decision was made. <b>Direction:</b> In determining whether to disclose findings factors to consider include the magnitude of the threat posed to the subject, the accuracy with which the data predict that the threat will be realized and the possibility that action can be taken to avoid or ameliorate the potential injury.   |  |
| 13.8  | Will unexpected and/or unrelated findings be disclosed? <b>Direction:</b> If yes, describe the basis for this decision and the plans for such disclosure. Note that subjects must also be given the opportunity to decline receiving information. Unexpected or unrelated findings that do not relate to the subject’s health, e.g. issues of maternity or paternity should not be disclosed.  |  |
| 13.9  | If findings will be published explain how the subject’s confidentiality will be ensured. <b>Direction:</b> Genetic studies, in particular pedigree studies, often deal with a small number of subjects. If findings will be published explain how the subject’s confidentiality will be ensured. For example, in a pedigree study, indicate whether it would be possible to alter or delete identifying data such as gender without changing the validity of the study.  |  |
| <b>SECTION 14 – SIGNATURE OF PRINCIPAL INVESTIGATOR AND DATE</b>                                |  |  |
| 14.0  | Indicate if this protocol, or one similar to it, has previously been denied approval by any IRB panel. <b>Direction:</b> Provide a statement indicate that the protocol has or has not been previously denied approval. If it has also provide details regarding the IRB that denied approval, for what reasons approval was denied, when it was denied and how the concerns have been addressed.  |  |
| 14.1  | Signature of Principal Investigator. The undersigned assures that all key study personnel 1) have completed the required human subjects training, 2) are knowledgeable of the protocol and the institutions policy for reporting unanticipated problems, non-compliance (protocol deviations/violations) and adverse events, 3) commit to conducting the study in accordance with the protocol as approved by the IRB, state law, federal regulations, Health Center policies and with the ethical principles of respect for persons, beneficence and justice as set forth in the Belmont Report. The undersigned also accepts primary responsibility for all aspects of the management of this study.   |  |

For continuing review the undersigned also believe that the information presented on this form and the addendum for continuing approval are accurate and support on-going approval of the research.

Signature..... Date.....

Reminder: If applying to the RSC&IRB for support you must submit this form and all supporting document to Jaya Soni (jksoni@htu.edu) for RSC&IRB review and approval. Refer the submission instruction to determine which documents to submit to the RSC&IRB electronically and which to submit in hard copy.