**North Texas Regional Institutional Review Board (IRB)**

**Site-Specific Protocol Information (Required for Sponsored Clinical Trials)**

***Protocol Title***

*Sponsor*

1. **CRITERIA FOR THE INCLUSION/EXCLUSION OF SUBJECTS**

* *Indicate age range of subjects to be recruited* ***at this site****. For studies only involving an adult population, include a statement justifying why children are not being included in the study – e.g., investigator’s patient population is adult only; condition is primarily found only in older individuals; safety and effectiveness in children have not been confirmed, this study may help provide sufficient data to make that determination. Indicate any site-specific exclusionary parameters.*

**II. SITE-SPECIFIC RECRUITMENT OF SUBJECTS**

* *Briefly describe where subjects will be recruited from: e.g., investigator’s existing subject population, physician referrals, etc. Explain in detail (and attach supplemental materials as necessary) if subjects will be recruited via telephone script, in the emergency room [thus, potentially making subjects more vulnerable to coercion], etc. All materials (e.g., flyers, ads, emails, letters, postings, handouts, etc.) to be used for recruiting subjects must be submitted to the IRB for review. Please do not include sponsor recruitment methods that will* ***not*** *be used at this site (e.g. sponsor website recruitment, etc.).*
* *NOTE: If other institutional review boards (IRBs) or approvals are required, note them by name, affiliation and contact person. Also, be aware that the approval of other institutions’ IRBs must be obtained before initiation of the project (but are not essential for this IRB review to begin).*

**III.** **PROCEDURES**

***Drug Studies: Provide copy of FDA Investigational New Drug (IND) Determination Letter for all studies involving a drug that has not been approved by the FDA (or has not been approved by the FDA for the indication being studied).***

***Device Studies:******Include copy of Investigational Device Exemption (IDE) Letter or Sponsor Declaration of Significant vs Non-Significant Risk****. Describe and address issues associated with a device presenting “Significant Risk” or “Non-Significant Risk” or if the device is classified as 510(k) Exempt.*

* *Indicate number of subjects to be enrolled/randomized* ***at this site****. Indicate estimated total duration of subject participation and total amount of blood to be collected over the course of the study (including blood being collected as part of an optional or mandatory substudy, as applicable).*
* *Briefly describe study procedures and randomization (method, ratio, groups).*
* *List and briefly describe all optional and mandatory substudies and whether they will be* ***performed at this site.***
* *Provide details regarding other study components (photographs, recordings, questionnaires, etc.) and their disposition. Storage (location, duration and destruction) of biospecimens such as blood, urine, sputum, etc. must be described, as well as any optional or mandatory sub-studies. Future research (as applicable) must also be discussed, including sample storage details. If genetic testing will be performed on biospecimens address who results will be provided to (if any) and how confidentiality of results will be maintained.*
* *Data Storage and Confidentiality – Describe where the research data will be stored; length of time data will be stored and how the data will be secured. The investigator must take necessary steps to maintain confidentiality of data. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to data. Indicate who will have access to the data.*
* *Other areas to address, as applicable: federal Certificate of Confidentiality (CoC); Apps and Web-Based Recruitment Tools (describe data security features [encrypted? HIPAA compliant?]; background data collection such as location tracking or usage; roaming charges, etc. as applicable).*

**IV. COMPENSATION FOR TIME AND TRAVEL**

* *Describe any financial payments to subjects for participation (e.g. compensation for time and travel). Indicate any partial payment schedule for less than complete study participation. Consider that payments cannot be perceived as coercive (overpayment for time and effort). Remember: payments are NOT benefits.*

**V. COSTS TO SUBJECTS**

* *Describe costs to subjects. If none, state that there are no costs to subjects.*

**VI. SPECIAL PRECAUTIONS**

* *Describe the procedures for protecting against or minimizing potential risks (e.g., confidentiality, reputational injury, direct injury or harm to subject, etc.).*

* *Describe diagnostic procedures used to exclude or protect vulnerable subjects and/or to monitor existing subjects; subject discontinuation parameters; Data and Safety Monitoring Boards (DSMBs), etc.*
* *Pay special attention to reproductive risks (both female and male) and outline the contingency plan for pregnancy. List abstinence (refraining from all sexual activity when it is in line with the subject’s preferred and usual lifestyle) as a birth control measure.*

**VII. KEY PERSONNEL**

* *List all individuals directly involved in the conduct, design or reporting of the research, including identifying anyone who may be consenting subjects. This list will include the Principal Investigator, Co-Investigators, collaborating investigators, study coordinators, etc.*

**VIII. LOCATION OF RESEARCH ACTIVITIES**

* *List all locations where study procedures will be performed (clinics, hospitals, etc.), including the location(s) of contracted services to be performed as part of the protocol.*

**IX. RISK / BENEFIT ASSESSMENT**

* *Describe the level of risk and describe how this research holds the prospect of a direct benefit for the subjects. If there is NO direct benefit to subjects, state such in protocol and in the consent documents.*
* *Describe how the anticipated benefit(s) justifies the risk. Describe how the anticipated benefit(s) of this research is at least as favorable to the subjects as that to be received by available alternative approaches.*

**INFORMED CONSENT GUIDANCE**

Attach copies of all consent/assent forms. Translations of consent forms should be submitted after initial IRB approval of documents. All translations submitted for IRB review and approval must be accompanied by a notarized statement from the individual translating the document affirming that it is a true and correct translation of the English language version of the document(s) IRB approved on (date).

The following “standard clauses” must be incorporated into **all** sponsor consent forms:

**UNTHSC:**

* If you are a student or employee at the University of North Texas Health Science Center your participation (or non-participation) will in no way affect your employment status.
* We, at the University of North Texas Health Science Center at Fort Worth, have not set aside any money for financial compensation or for costs of medical treatment should you be injured as a result of your participation in this research. If required, medical care will be made available to you in the case of injury, but you (or your insurance provider) will be responsible for the expense of any medical care, including hospitalization, that is needed.

You should know that by signing this form, you are neither waiving any of your legal rights against nor releasing the sponsor, the Principal Investigator, the University of North Texas Health Science Center at Fort Worth, nor any of their respective agents from liability for negligence with respect to the conduct of this study.

* If you have any questions about your rights as a research participant, or you would like to obtain information or offer input, or you wish to speak with someone **not** directly involved with the research study, you may contact the Chair, North Texas Regional IRB UNTHSC Office of Research Compliance 3500 Camp Bowie Blvd. Fort Worth, TX 76107 or at (817) 735-0409 during regular business hours. An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject’s rights and welfare in mind. The IRB has reviewed and approved the research study described in this Consent and Authorization Form.

**JPS**:

* If you are an employee at John Peter Smith Health Network your participation (or non-participation) will in no way affect your employment status.
* We, at the John Peter Smith Health Network and Acclaim, have not set aside any money for financial compensation or for costs of medical treatment should you be injured as a result of your participation in this research. If required, medical care will be made available to you in the case of injury, but you (or your insurance provider) will be responsible for the expense of any medical care, including hospitalization, that is needed.

You should know that by signing this form, you are neither waiving any of your legal rights against nor releasing the sponsor, the Principal Investigator, the John Peter Smith Health Network, Acclaim, nor any of their respective agents from liability for negligence with respect to the conduct of this study.

* If you have any questions about your rights as a research participant, or you would like to obtain information or offer input, or you wish to speak with someone **not** directly involved with the research study, you may contact the Chair, North Texas Regional IRB UNTHSC Office of Research Compliance 3500 Camp Bowie Blvd. Fort Worth, TX 76107 or at (817) 735-0409 during regular business hours. An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject’s rights and welfare in mind. The IRB has reviewed and approved the research study described in this Consent and Authorization Form.

**Conflict of Interest Disclosure (as applicable):** Subjects must be apprised in the Informed Consent when the investigator has a financial relationship (such as stock ownership equal to or greater than 5%, honoraria exceeding $5,000 annually, etc.) with the sponsor.