Institutional Review Board (IRB)
Human Subjects Review Form

IRB-00002563

For new projects involving human subjects

Date: _____ IRB # _____

Principal Investigator: _____Phone # _____

Address to which notice of approval should be sent: _____

Institution:_____Department: _____

Research Coordinator(s):_____Phone #_____

Proposed project dates, beginning date: _____ Completion Date:_____

E-mail address:_____

Project Title:

Funding Agencies (if applicable):

Type of Project: ☐ New Project ☐ Dissertation /Thesis Research/Independent Study
☐ Student Research Project ☐ include Genetic Research

Dissertation/Thesis Advisor, or Student Advisor: _____

This study will involve: Check all that apply, or check here if N/A ☐

- ☐ New Drugs (IND) IND # _____ Attached Approval
- ☐ Non-Approved Use of Drug(s)
- ☐ Investigational Device Exemption (IDE) # _____ Attached Approval
- ☐ Deception (attach waiver or alteration of Informed consent requirements)
- ☐ Other: _____

If your project involves any human tissue, body fluids, pathological specimens, donated organs, fetal material, stem cells, discarded tissue or placental materials, check here: ☐

If any of your subjects fall in any of the following classifications, please indicate the classification:

- ☐ Children (< 18 years) ☐ Students ☐ Pregnant Women/Fetuses
- ☐ Cognitively impaired persons or persons unable to consent
- ☐ Prisoners ☐ Control Group ☐ Other: _____

☐ **Expedited** Review requested under item _____ (number) of HHS Regulations (see attached explanation)

☐ **Exempt** Review requested under item _____ (number) of HHS Regulations (see attached explanation)

If your project has been/will be submitted to another Institutional Review Board(s), please list name of Board(s): If you affiliated to UND we will need a copy of your proposal.

Status of submission to another IRB: ◯Submitted: date_____; ◯Approved: date _____; ◯Pending

Any additional information should be documented on a separate sheet of paper.

Completed by: _____

Attachment Necessary: Copies of all instruments (such as: survey/interview questions, data collections forms completed by subjects, etc. must be attached to this proposal. PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal including data collection instruments when applicable.

1. **ABSTRACT:** *Please provide a brief explanation of the rationale and purpose of the study (limit to 200 words or less) and include justification or necessity for using human subjects Attach additional sheet if necessary.*

2. **BENEFITS:** *Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.)*

3. **RISKS:** *Clearly describe the anticipated risks to the subject/others including any physical, emotional and financial risks that might result from this study.*

   a) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms and if so, what the justification is for having that link:

   b) Provide a description of the data monitoring plan for all research that involves greater than minimal risk:

   c) Describe procedures you will take to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants:

4. **PROTOCOL:** *Please provide a thorough description of the procedures to be used by addressing the instructions under the following categories:*

   1. **Subject Selection:**

      a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc.., that will be used to recruit subject:

      b) Describe your subject selection procedures and criteria, as well as your exclusion criteria:

      c) Describe the estimated number of subjects that will participate:

   2. **Description of Methodology:**

      a) Describe the procedures used to obtain informed consent:

      b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding and space available to conduct this research:

      c) Indicate who will carry out the research procedure:

      d) Describe audio/visual procedures and proper disposal of tapes:

      e) Describe compensation procedures (payment or class credit for the subjects, etc.):

5. **CONSENT FORM:** *A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject must be attached to this proposal. If no CONSENT FORM is to be used, document the procedures to be used to protect human subject.* ***Please Note:*** *All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided.*

   Waiver: If you are waiving consent or its documentation, please justify how your study meets the federally mandated criteria.

Describe who will be obtaining consent, where signed consent forms will be kept, and for what period of time.

6. For **FULL IRB REVIEW,** forward the signed original and 15 copies of this completed form and, when applicable, 15 copies of the proposed consent form, survey, interview questions, etc., and any supporting documentation (such as signed student consent to release of Education Record Form (for students only) to: (see below)

For **EXEMPT or EXPEDITED REVIEW,** forward a signed original with the consent form, survey, interview questions, etc., and any supporting documentation (such as signed student consent to release of Education Record Form (for students only); to:

Marie-Laure Reese - IRB Reliance Specialist (Telephone 701-780-6161)
IRB Office - Altru 860 Columbia
860 South Columbia Road
Grand Forks ND 58201

Prior to receiving an IRB approval, the Principal Investigator, research nurse, research coordinator and any key personnel of a research team must complete the required IRB human subjects' education. Please go to https://acrpnet.org/ethics choose "Pricing without contact hours" then "check out". You will need to register and to create an account. You will get a confirmation number when you are done with it. Finally, you will receive an email to let you know how to launch your course (if already completed an IRB education, please submit a copy to the IRB Office or email at: mreese@altru.org).

The policies and procedures on Use of Human Subjects in Altru Health System Institutions apply to all activities involving use of Human Subjects performed by personnel conducting such activities. No activities are to be initiated without prior review and approval of the Altru Health System Institutional Review Board (IRB). It is the intent of the Altru Health System (IRB) to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards.

I certify that the information provided on this form is accurate and that this research will be conducted in accordance with Federal Regulations and Altru Health System policies for the protection of the right of human subjects engaged in research. I also understand that if I want to make changes to the research protocol after IRB approval, I must submit a protocol amendment to the IRB for review prior to implement the changes.

Signatures:

Principal Investigator: _____ Date: _____

Research Coordinator: _____ Date: _____

New Study Investigator Questionnaire

1. Does the investigator or sub-investigator have a conflict of interest: ◯ **No** ◯ **Yes,** explain below:

2. Who will be doing the recruiting of patients or reviewing the patients' record?

3. Will advertisements be used to recruit patients: ◯ **No** ◯ **Yes,** explain:

4. Does the study involve vulnerable patients or minors: ◯ **No** ◯ **Yes,** explain:

5. Are there any increased costs to the patient exceeding those that would occur with the standard of care?
   ◯ **No** ◯ **Yes,** explain:

6. Are the study participants provided reimbursement or gifts for participation in the trial?
   ◯ **No** ◯ **Yes,** explain:

7. Are pregnancy protection measures required for study participants? ..... ◯ **Yes** ◯ **No**

8. Does the study have a DSMB assigned to review the safety of this trial?..... ◯ **Yes** ◯ **No**

9. Does the study involve Genetic Testing?..... ◯ **Yes** ◯ **No**

10. Does the study involve the storage of tissue for future research? ..... ◯ **Yes** ◯ **No**

11. Will the patients be informed of Incidental Findings from Test Results?..... ◯ **Yes** ◯ **No**

12. What measures are in place to protect the privacy of patient data, genetic test results, and stored tissue samples?
    ☐ Data encrypted ☐ Password protected ☐ Coded ☐ Anonymous
    ☐ Other, explain: