NIH Human Subjects and Clinical Trial Information

TRANSCEND RESEARCH DESIGN, COMPLIANCE AND DATA MANAGEMENT CORE (RDCDC)

Methods to Complete

ASSIST

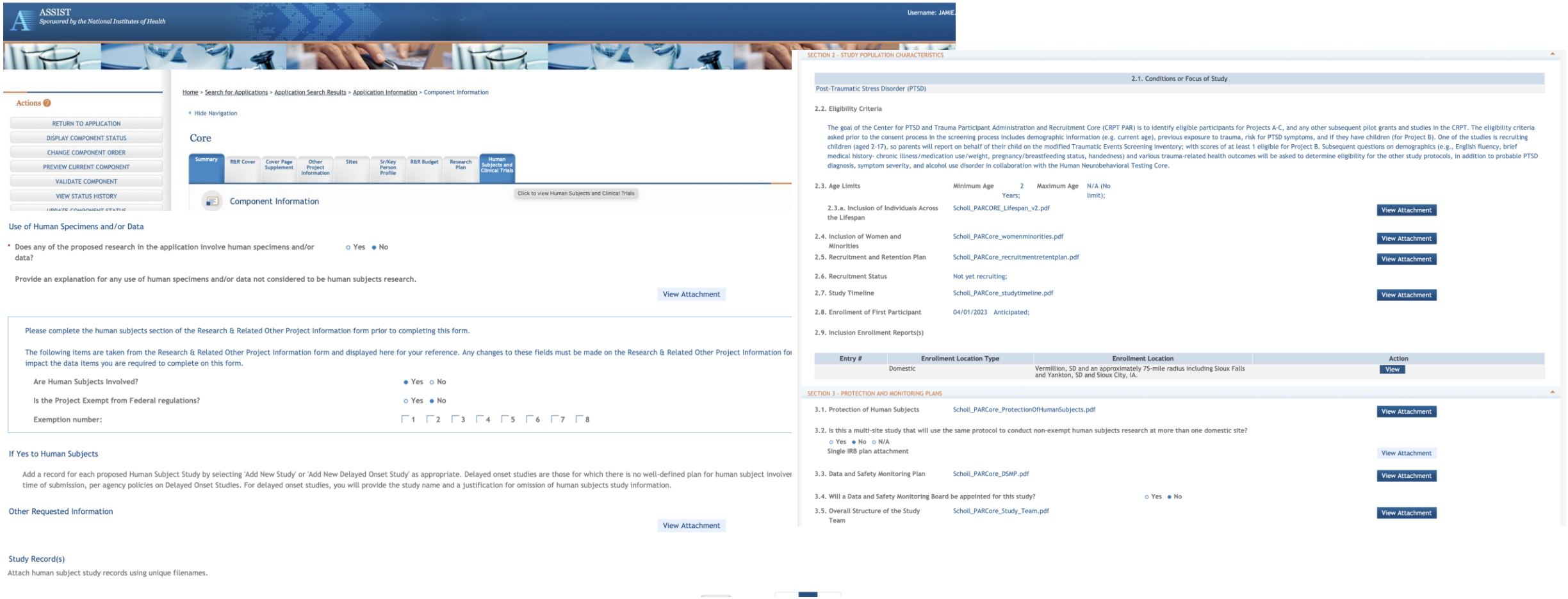
Institutional Solutions (System-to-System, S2S)

Grants.gov Workspace

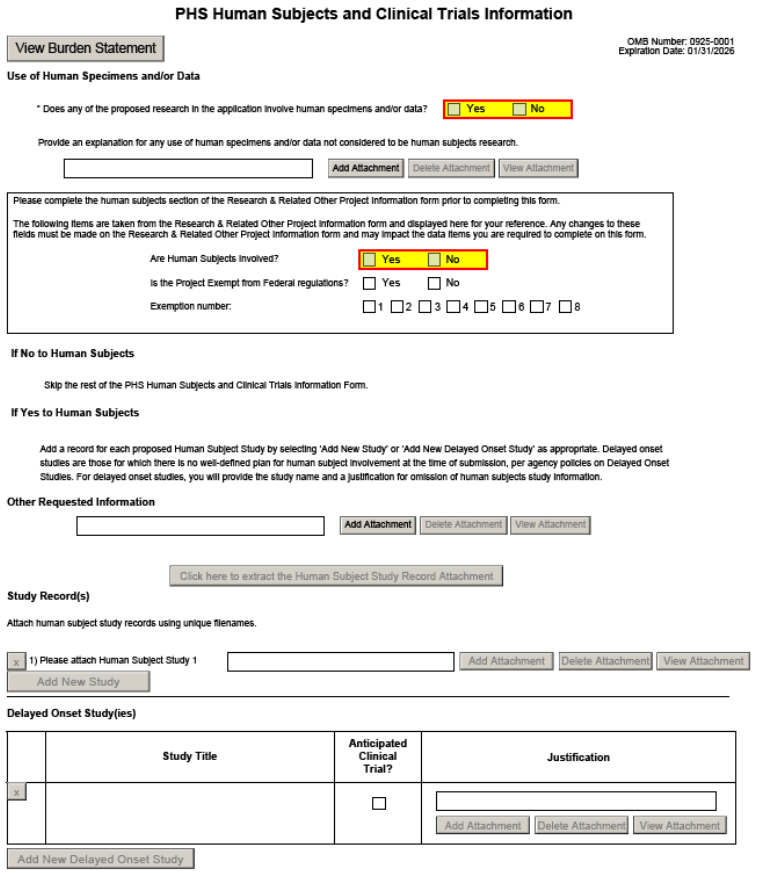
PDF Paper Submission – Transcend's Process

Institutional Processes (Cayuse, Novelution, etc)

Electronic Version



PDF Version



PHS Human Subjects and Clinical Trials Information

View Burden Statement

OMB Number: 0925-0001
Expiration Date: 01/31/2026

Use of Human Specimens and/or Data

* Does any of the proposed research in the application involve human specimens and/or data? ☐ Yes ☐ No

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Add Attachment | Delete Attachment | View Attachment

Please complete the human subjects section of the Research & Related Other Project information form prior to completing this form.

The following items are taken from the Research & Related Other Project information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? ☐ Yes ☐ No

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

Exemption number: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

If No to Human Subjects

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Add Attachment | Delete Attachment | View Attachment

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

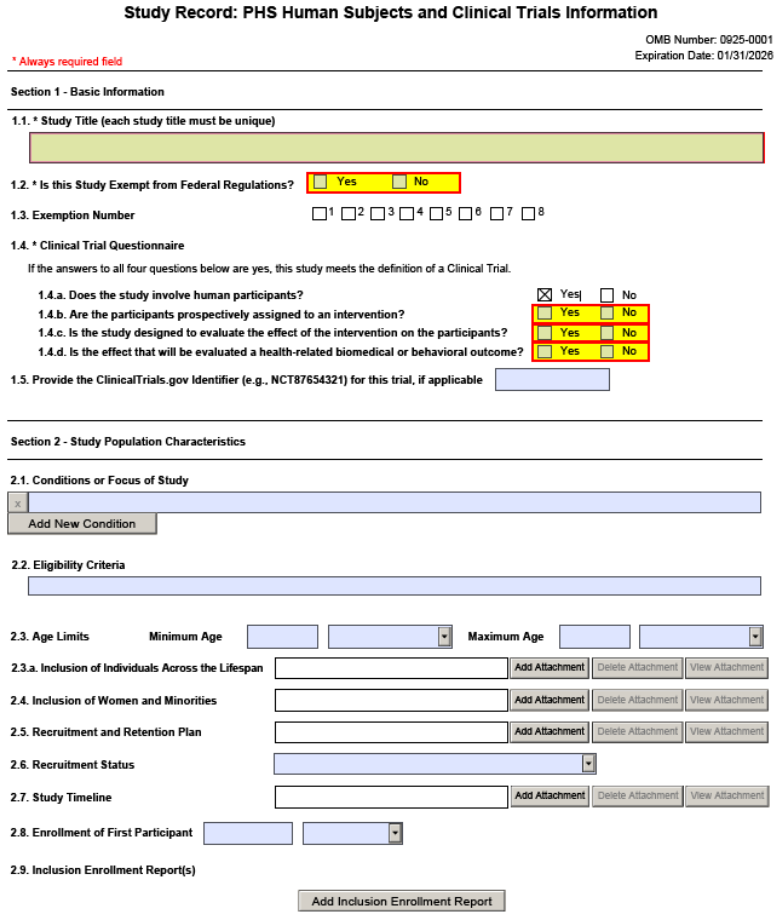
x 1) Please attach Human Subject Study 1 Add Attachment | Delete Attachment | View Attachment

Add New Study

Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
x		☐	Add Attachment | Delete Attachment | View Attachment

Add New Delayed Onset Study



Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 01/31/2026

* Always required field

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)

1.2. * Is this Study Exempt from Federal Regulations? ☐ Yes ☐ No

1.3. Exemption Number ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

1.4. * Clinical Trial Questionnaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants? ☒ Yes ☐ No

1.4.b. Are the participants prospectively assigned to an intervention? ☐ Yes ☐ No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? ☐ Yes ☐ No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? ☐ Yes ☐ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

x

Add New Condition

2.2. Eligibility Criteria

2.3. Age Limits **Minimum Age** **Maximum Age**

2.3.a. Inclusion of Individuals Across the Lifespan Add Attachment | Delete Attachment | View Attachment

2.4. Inclusion of Women and Minorities Add Attachment | Delete Attachment | View Attachment

2.5. Recruitment and Retention Plan Add Attachment | Delete Attachment | View Attachment

2.6. Recruitment Status

2.7. Study Timeline Add Attachment | Delete Attachment | View Attachment

2.8. Enrollment of First Participant

2.9. Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report

What to Consider

Timing – when this is due compared to other project components
- IRB Approval

Drafting – how to gather the information included in the paperwork

Does your project involve human subjects

Is your project an Applicable Clinical Trial (ACT) or not

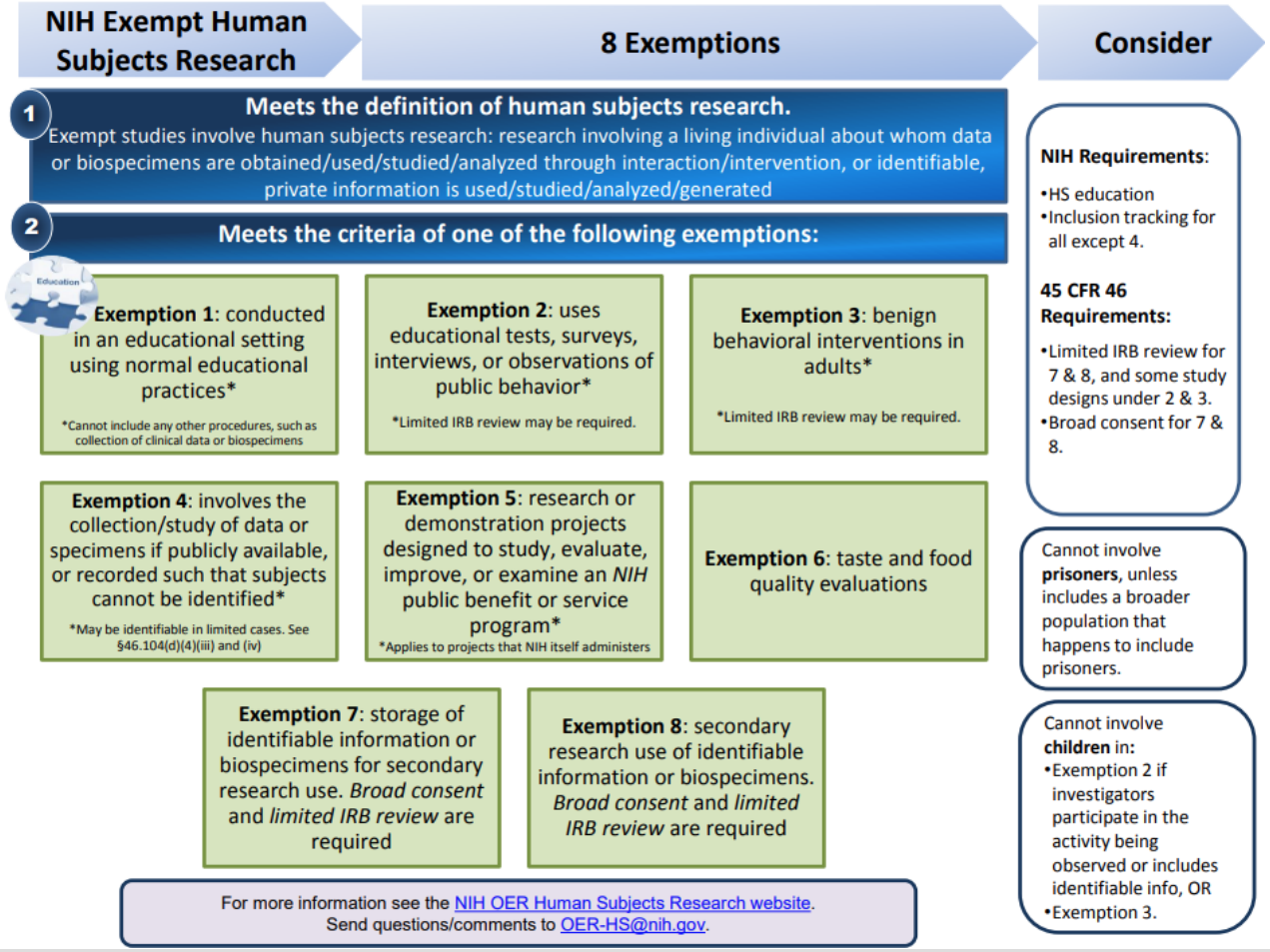
Does your project have any exemptions

Who is listed on your grant application vs study team

Is your project multi-site
- If yes, additional attachment documents are needed

If an ACT – additional questions may be requested (IP, IND, IDE)

Exemptions


NIH Exempt Human Subjects Research
8 Exemptions
Consider
1
Meets the definition of human subjects research.
Exempt studies involve human subjects research: research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated
2
Meets the criteria of one of the following exemptions:
Education
Exemption 1: conducted in an educational setting using normal educational practices*
*Cannot include any other procedures, such as collection of clinical data or biospecimens
Exemption 2: uses educational tests, surveys, interviews, or observations of public behavior*
*Limited IRB review may be required.
Exemption 3: benign behavioral interventions in adults*
*Limited IRB review may be required.
Exemption 4: involves the collection/study of data or specimens if publicly available, or recorded such that subjects cannot be identified*
*May be identifiable in limited cases. See §46.104(d)(4)(iii) and (iv)
Exemption 5: research or demonstration projects designed to study, evaluate, improve, or examine an NIH public benefit or service program*
*Applies to projects that NIH itself administers
Exemption 6: taste and food quality evaluations
Exemption 7: storage of identifiable information or biospecimens for secondary research use. Broad consent and limited IRB review are required
Exemption 8: secondary research use of identifiable information or biospecimens. Broad consent and limited IRB review are required
For more information see the NIH OER Human Subjects Research website.
Send questions/comments to OER-HS@nih.gov.
NIH Requirements:
•HS education
•Inclusion tracking for all except 4.
45 CFR 46 Requirements:
•Limited IRB review for 7 & 8, and some study designs under 2 & 3.
•Broad consent for 7 & 8.
Cannot involve prisoners, unless includes a broader population that happens to include prisoners.
Cannot involve children in:
•Exemption 2 if investigators participate in the activity being observed or includes identifiable info, OR
•Exemption 3.

Inclusion Enrollment Reports

Planned

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	0	0	0	0	0

Cumulative (Actual)

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

< Previous Report | Report 1 of 1 | Next Report >

|<< First Report | Delete Report | Last Report >>|

Attachments (Typically Needed)

1. Inclusion of Individuals Across the Lifespan
2. Inclusion of Women and Minorities
3. Recruitment and Retention Plan
4. Study Timeline
5. Protection of Human Subjects
6. Data and Safety Monitoring Plan
7. Overall Structure of Study Team

Inclusion of Individuals Across the Lifespan

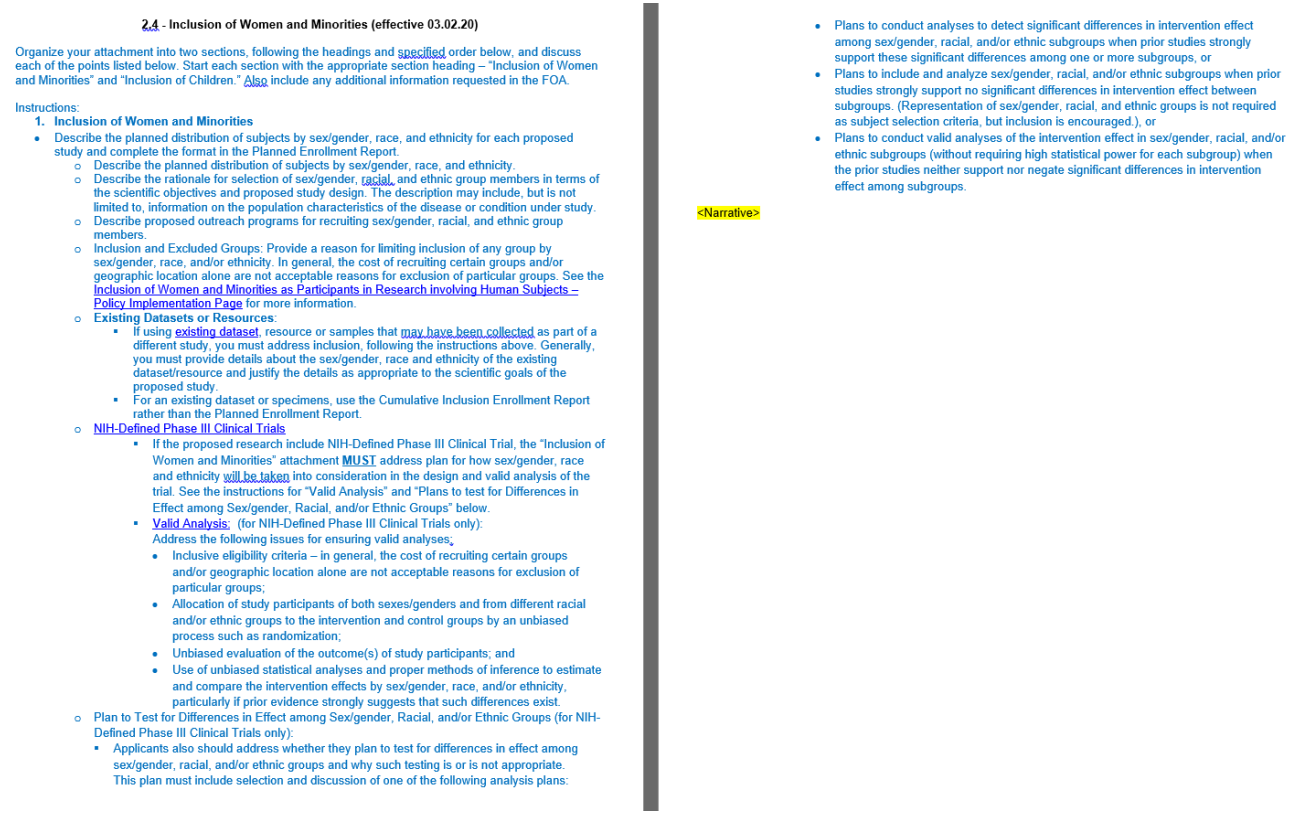
- Discuss the age group of individuals are included in the study. If a population is not included (ex children) describe why this population is not included. This can be a short description

2.3.a Inclusion of Individuals Across the Lifespan

Children (less than 18 years old) are not included in this study due to their very low prevalence of a cancer diagnosis that meets the inclusion criteria. All other ages (18 and older) are being included.

Inclusion of Women and Minorities

- Think of why women or men would not be included, as well as considerations for race, ethnicity or gender, and age.
- Why you are including certain groups or excluding other groups



2.4 - Inclusion of Women and Minorities (effective 03.02.20)

Organize your attachment into two sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – "Inclusion of Women and Minorities" and "Inclusion of Children." Also include any additional information requested in the FOA.

Instructions:

1. **Inclusion of Women and Minorities**

- Describe the planned distribution of subjects by sex/gender, race, and ethnicity for each proposed study and complete the format in the Planned Enrollment Report.
  - Describe the planned distribution of subjects by sex/gender, race, and ethnicity.
  - Describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
  - Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members.
  - Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups. See the Inclusion of Women and Minorities as Participants in Research involving Human Subjects – Policy Implementation Page for more information.
  - **Existing Datasets or Resources**:
    - If using existing dataset, resource or samples that may have been collected as part of a different study, you must address inclusion, following the instructions above. Generally, you must provide details about the sex/gender, race and ethnicity of the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study.
    - For an existing dataset or specimens, use the Cumulative Inclusion Enrollment Report rather than the Planned Enrollment Report.
  - NIH-Defined Phase III Clinical Trials
    - If the proposed research include NIH-Defined Phase III Clinical Trial, the "Inclusion of Women and Minorities" attachment **MUST** address plan for how sex/gender, race and ethnicity will be taken into consideration in the design and valid analysis of the trial. See the instructions for "Valid Analysis" and "Plans to test for Differences in Effect among Sex/gender, Racial, and/or Ethnic Groups" below.
    - Valid Analysis: (for NIH-Defined Phase III Clinical Trials only):
      Address the following issues for ensuring valid analyses:
      - Inclusive eligibility criteria – in general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups;
      - Allocation of study participants of both sexes/genders and from different racial and/or ethnic groups to the intervention and control groups by an unbiased process such as randomization;
      - Unbiased evaluation of the outcome(s) of study participants; and
      - Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects by sex/gender, race, and/or ethnicity, particularly if prior evidence strongly suggests that such differences exist.
  - Plan to Test for Differences in Effect among Sex/gender, Racial, and/or Ethnic Groups (for NIH-Defined Phase III Clinical Trials only):
    - Applicants also should address whether they plan to test for differences in effect among sex/gender, racial, and/or ethnic groups and why such testing is or is not appropriate. This plan must include selection and discussion of one of the following analysis plans:
      - Plans to conduct analyses to detect significant differences in intervention effect among sex/gender, racial, and/or ethnic subgroups when prior studies strongly support these significant differences among one or more subgroups, or
      - Plans to include and analyze sex/gender, racial, and/or ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender, racial, and ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), or
      - Plans to conduct valid analyses of the intervention effect in sex/gender, racial, and/or ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect among subgroups.

<Narrative>

Recruitment and Retention Plan

Detailing how you are going to find and recruit your participants (ex fliers, hospital schedules, phone calls, etc)

Including details if you think you'll have issues recruiting and how you'll address those

Discuss how you will make every effort to keep participants involved with the project

2.5 Recruitment and Retention Plan

Participants and Recruitment Plan

Participants will be recruited from the medical record and clinic schedule. A member of the study team will approach potential participants either ahead of or during a regularly scheduled clinic visit. The potential participant can consent for the study any time prior to their surgery scheduled for their cancer treatment.

Retention Plan

All reasonable efforts must be made to locate participants to determine and report their ongoing status. This includes follow-up with persons authorized by the participant. Lost to follow-up is defined by the inability to reach the participant after a minimum of three documented phone calls or emails as well as lack of response by participant to one registered mail letter. All attempts should be documented in the participant's study record. Should the participant continue to be unreachable, she will be considered to have withdrawn from the study.

2.5 - Recruitment and Retention Plan (effective 03.02.20)

This attachment is required unless the following applies to your study:

- You selected only Exemption 4 and no other exemptions on the"1.3 Exemption Number" question.

Instructions:
Describe how you will recruit and retain participants in your study. You should address both planned recruitment activities as well as proposed engagement strategies for retention.

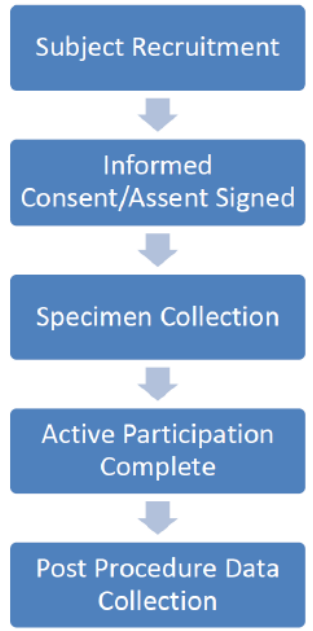
<Narrative>

Study Timeline

- Think of reasonable timeframes to complete milestones of your project
- Format is not as important as having reasonable timelines & expectations
- Simple can be better

2.7 - Study Timeline

1.2 Schema



STUDY TIMELINE

It is expected that data collection will occur in each of the five years of grant funding. At the end of Year 2 and years 3-4, analysis of collected data and building of machine classifiers is expected to occur. In the final year, bioinformatics will be completed, and the model for a multimodal screening tool will be finalized and tested for diagnostic capacity. Preparation of future investigator-related grants for submission based on the collected data will begin in years 4-5. Dissemination of research findings will occur as the results become available.

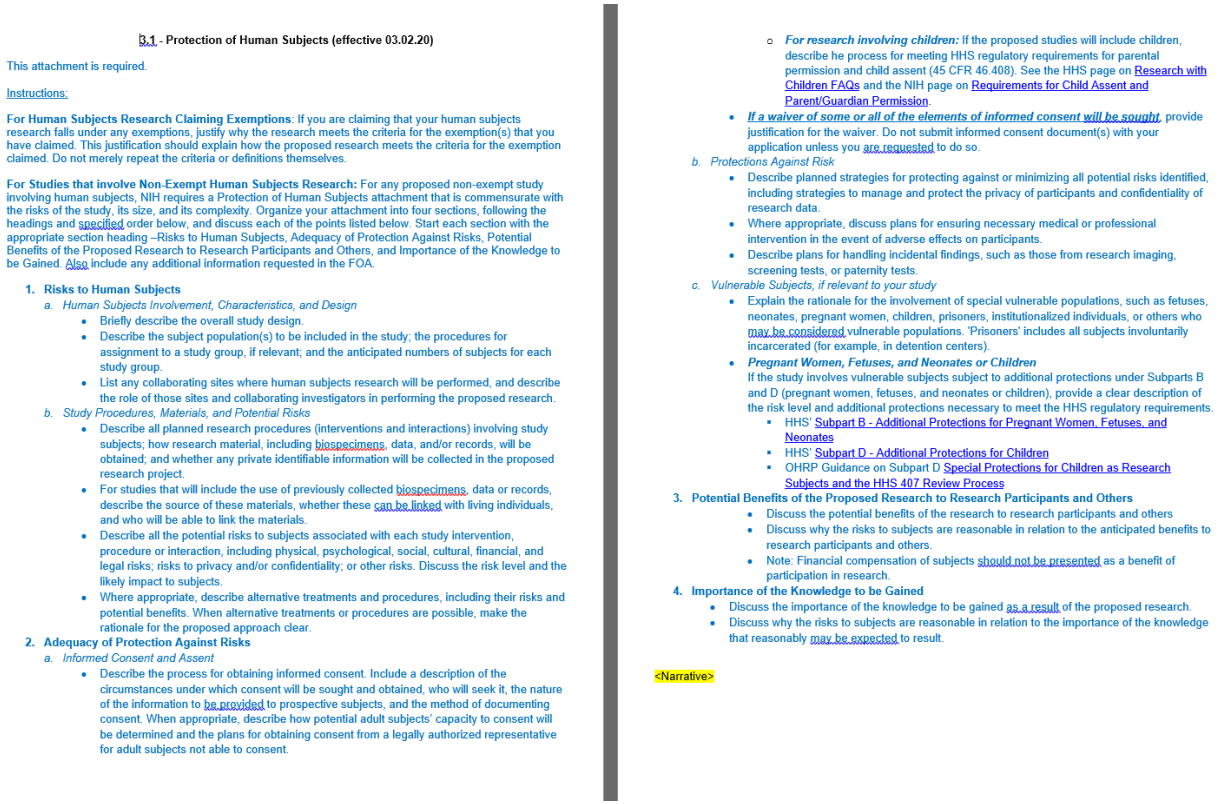
Study Timeline										
Milestone	Year 1		Year 2		Year 3		Year 4		Year 5	
	Mid	End	Mid	End	Mid	End	Mid	End	Mid	End
Obtain all relevant IRB Approvals	X									
Begin Enrollment of Participants	X									
Data Collection	X	X	X	X	X	X	X	X	X	
Data Analysis		X	X	X	X	X	X	X	X	X
Create multimodal screening tool				X	X	X	X	X		
Dissemination of Results				X	X	X	X	X	X	
Analysis of Whole Data Set									X	X
Preparation of Future Grants								X	X	X
Data made available via data sharing										X

2.7 - Study Timeline

1. Notice of Award
2. Enrollment of participants upon notice of award
3. Subject participation: Participation will begin prior to treatment (after diagnosis and prior to treatment – treatment usually occurs as soon as possible after diagnosis) and continue until 5-6 months status post-treatment completion. The length of time will differ depending on the clinical diagnosis and treatment trajectory.
4. Enrollment timeframe: It is anticipated that it will take 12 months to enroll all participants.
5. Last visit last subject: 18 months after start of enrollment
6. Analysis of data: 12 months after last visit last subject

Protection of Human Subjects

- Consider the study design and procedures
- Consider participant risks and how those will be alleviated
- Compensation Involvement
- Consider participant and societal benefits Consider study populations that may be vulnerable
- Consider all data being recorded, collected and stored (if using for future research)
- Consider consent/assent methods, timing, location, non-English speakers, if consent is withdrawn
- Consider important/significance of the study



3.1 - Protection of Human Subjects (effective 03.02.20)

This attachment is required.

Instructions:

For Human Subjects Research Claiming Exemptions: If you are claiming that your human subjects research falls under any exemptions, justify why the research meets the criteria for the exemption(s) that you have claimed. This justification should explain how the proposed research meets the criteria for the exemption claimed. Do not merely repeat the criteria or definitions themselves.

For Studies that involve Non-Exempt Human Subjects Research: For any proposed non-exempt study involving human subjects, NIH requires a Protection of Human Subjects attachment that is commensurate with the risks of the study, its size, and its complexity. Organize your attachment into four sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading –Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to Research Participants and Others, and Importance of the Knowledge to be Gained. Also include any additional information requested in the FOA.

1. **Risks to Human Subjects**
   a. *Human Subjects Involvement, Characteristics, and Design*
      - Briefly describe the overall study design.
      - Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group.
      - List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research.

   b. *Study Procedures, Materials, and Potential Risks*
      - Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project.
      - For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.
      - Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects.
      - Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.

2. **Adequacy of Protection Against Risks**
   a. *Informed Consent and Assent*
      - Describe the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent.
        - ***For research involving children:*** If the proposed studies will include children, describe he process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/Guardian Permission.
      - ***If a waiver of some or all of the elements of informed consent will be sought***, provide justification for the waiver. Do not submit informed consent document(s) with your application unless you are requested to do so.

   b. *Protections Against Risk*
      - Describe planned strategies for protecting against or minimizing all potential risks identified, including strategies to manage and protect the privacy of participants and confidentiality of research data.
      - Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects on participants.
      - Describe plans for handling incidental findings, such as those from research imaging, screening tests, or paternity tests.

   c. *Vulnerable Subjects, if relevant to your study*
      - Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers).
      - ***Pregnant Women, Fetuses, and Neonates or Children***
        If the study involves vulnerable subjects subject to additional protections under Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.
        - HHS' Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates
        - HHS' Subpart D - Additional Protections for Children
        - OHRP Guidance on Subpart D Special Protections for Children as Research Subjects and the HHS 407 Review Process

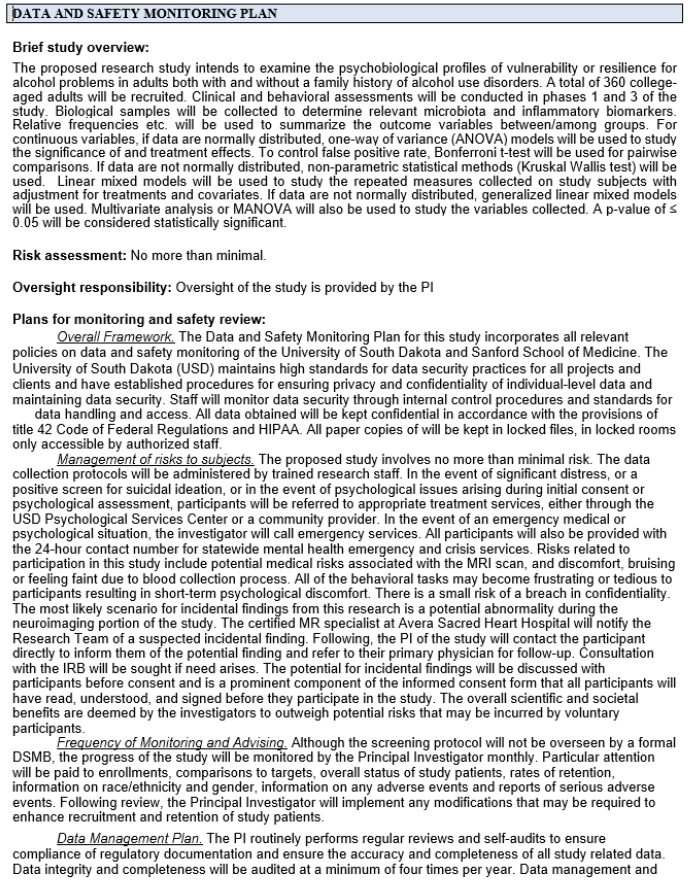
3. **Potential Benefits of the Proposed Research to Research Participants and Others**
   - Discuss the potential benefits of the research to research participants and others
   - Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.
   - Note: Financial compensation of subjects should not be presented as a benefit of participation in research.

4. **Importance of the Knowledge to be Gained**
   - Discuss the importance of the knowledge to 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 reasonably may be expected to result.

<Narrative>

Data and Safety Monitoring

- Is a formal Data and Safety Monitoring Plan (DSM) required for your project or a formal Data and Safety Monitoring Board (DSMB)
- Are there any safety concerns that could arise during your project and how you are addressing/reducing the risk of those (AEs/SAEs)
- How are you ensuring the safety of the data
- Is PHI involved



DATA AND SAFETY MONITORING PLAN

Brief study overview:

The proposed research study intends to examine the psychobiological profiles of vulnerability or resilience for alcohol problems in adults both with and without a family history of alcohol use disorders. A total of 360 college-aged adults will be recruited. Clinical and behavioral assessments will be conducted in phases 1 and 3 of the study. Biological samples will be collected to determine relevant microbiota and inflammatory biomarkers. Relative frequencies etc. will be used to summarize the outcome variables between/among groups. For continuous variables, if data are normally distributed, one-way of variance (ANOVA) models will be used to study the significance of and treatment effects. To control false positive rate, Bonferroni t-test will be used for pairwise comparisons. If data are not normally distributed, non-parametric statistical methods (Kruskal Wallis test) will be used. Linear mixed models will be used to study the repeated measures collected on study subjects with adjustment for treatments and covariates. If data are not normally distributed, generalized linear mixed models will be used. Multivariate analysis or MANOVA will also be used to study the variables collected. A p-value of ≤ 0.05 will be considered statistically significant.

Risk assessment: No more than minimal.

Oversight responsibility: Oversight of the study is provided by the PI

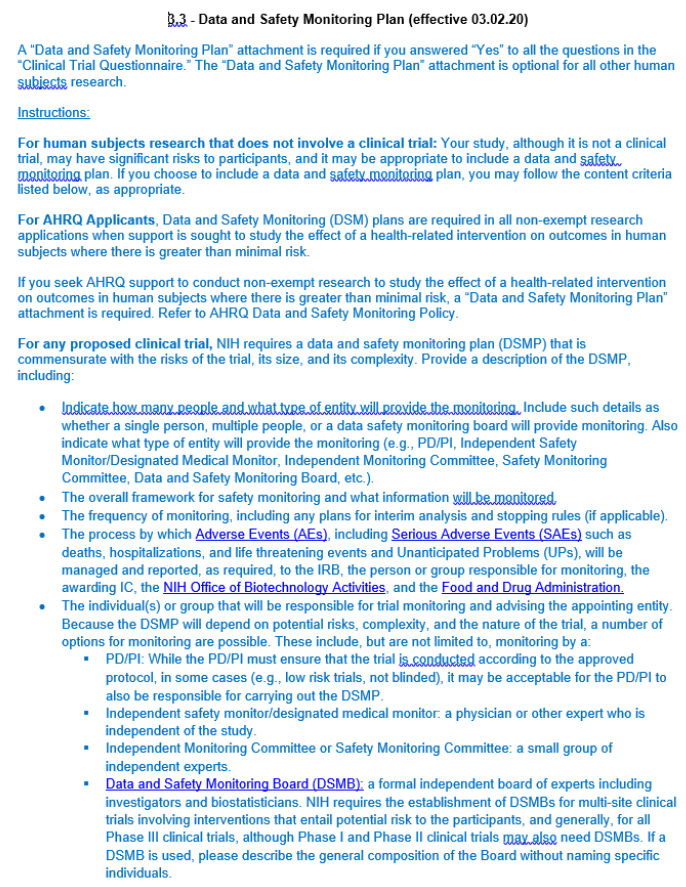
Plans for monitoring and safety review:

Overall Framework. The Data and Safety Monitoring Plan for this study incorporates all relevant policies on data and safety monitoring of the University of South Dakota and Sanford School of Medicine. The University of South Dakota (USD) maintains high standards for data security practices for all projects and clients and have established procedures for ensuring privacy and confidentiality of individual-level data and maintaining data security. Staff will monitor data security through internal control procedures and standards for data handling and access. All data obtained will be kept confidential in accordance with the provisions of title 42 Code of Federal Regulations and HIPAA. All paper copies of will be kept in locked files, in locked rooms only accessible by authorized staff.

Management of risks to subjects. The proposed study involves no more than minimal risk. The data collection protocols will be administered by trained research staff. In the event of significant distress, or a positive screen for suicidal ideation, or in the event of psychological issues arising during initial consent or psychological assessment, participants will be referred to appropriate treatment services, either through the USD Psychological Services Center or a community provider. In the event of an emergency medical or psychological situation, the investigator will call emergency services. All participants will also be provided with the 24-hour contact number for statewide mental health emergency and crisis services. Risks related to participation in this study include potential medical risks associated with the MRI scan, and discomfort, bruising or feeling faint due to blood collection process. All of the behavioral tasks may become frustrating or tedious to participants resulting in short-term psychological discomfort. There is a small risk of a breach in confidentiality. The most likely scenario for incidental findings from this research is a potential abnormality during the neuroimaging portion of the study. The certified MR specialist at Avera Sacred Heart Hospital will notify the Research Team of a suspected incidental finding. Following, the PI of the study will contact the participant directly to inform them of the potential finding and refer to their primary physician for follow-up. Consultation with the IRB will be sought if need arises. The potential for incidental findings will be discussed with participants before consent and is a prominent component of the informed consent form that all participants will have read, understood, and signed before they participate in the study. The overall scientific and societal benefits are deemed by the investigators to outweigh potential risks that may be incurred by voluntary participants.

Frequency of Monitoring and Advising. Although the screening protocol will not be overseen by a formal DSMB, the progress of the study will be monitored by the Principal Investigator monthly. Particular attention will be paid to enrollments, comparisons to targets, overall status of study patients, rates of retention, information on race/ethnicity and gender, information on any adverse events and reports of serious adverse events. Following review, the Principal Investigator will implement any modifications that may be required to enhance recruitment and retention of study patients.

Data Management Plan. The PI routinely performs regular reviews and self-audits to ensure compliance of regulatory documentation and ensure the accuracy and completeness of all study related data. Data integrity and completeness will be audited at a minimum of four times per year. Data management and



3.3 - Data and Safety Monitoring Plan (effective 03.02.20)

A "Data and Safety Monitoring Plan" attachment is required if you answered "Yes" to all the questions in the "Clinical Trial Questionnaire." The "Data and Safety Monitoring Plan" attachment is optional for all other human subjects research.

Instructions:

For human subjects research that does not involve a clinical trial: Your study, although it is not a clinical trial, may have significant risks to participants, and it may be appropriate to include a data and safety monitoring plan. If you choose to include a data and safety monitoring plan, you may follow the content criteria listed below, as appropriate.

For AHRQ Applicants, Data and Safety Monitoring (DSM) plans are required in all non-exempt research applications when support is sought to study the effect of a health-related intervention on outcomes in human subjects where there is greater than minimal risk.

If you seek AHRQ support to conduct non-exempt research to study the effect of a health-related intervention on outcomes in human subjects where there is greater than minimal risk, a "Data and Safety Monitoring Plan" attachment is required. Refer to AHRQ Data and Safety Monitoring Policy.

For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity. Provide a description of the DSMP, including:

- Indicate how many people and what type of entity will provide the monitoring. Include such details as whether a single person, multiple people, or a data safety monitoring board will provide monitoring. Also indicate what type of entity will provide the monitoring (e.g., PD/PI, Independent Safety Monitor/Designated Medical Monitor, Independent Monitoring Committee, Safety Monitoring Committee, Data and Safety Monitoring Board, etc.).
- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC, the NIH Office of Biotechnology Activities, and the Food and Drug Administration.
- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the DSMP will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:
  - PD/PI: While the PD/PI must ensure that the trial is conducted according to the approved protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
  - Independent safety monitor/designated medical monitor: a physician or other expert who is independent of the study.
  - Independent Monitoring Committee or Safety Monitoring Committee: a small group of independent experts.
  - Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all Phase III clinical trials, although Phase I and Phase II clinical trials may also need DSMBs. If a DSMB is used, please describe the general composition of the Board without naming specific individuals.

Overall Structure of the Study Team

- Who is listed as a key personnel on the grant application
- What will their involvement/contributions be on the project
- What is their background, training, qualifications to be on the study team and for their contributions

3.5 - Overall Structure of the Study Team (effective 03.02.20)

Instructions:

Provide a brief overview of the organizational/administrative structure and function of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers. The attachment may include information on study team composition and key roles (e.g., medical monitor, data coordinating center), the governance of the study, and a description of how study decisions and progress are communicated and reported.

Note: Do not include study team members' individual professional experiences (i.e., biosketch information)

<Narrative>

Section 4 – Protocol Synopsis

- This section needs to be completed if your project is an Applicable Clinical Trial (ACT)
- Intervention – need to include a table for each intervention (different doses, different timeframe, etc.), each arm of the study including the control
- Consider the phase of the study, the model, is it blinded or open, randomized
- Is the intervention FDA regulated or an ACT under FDAAA
- Additional Attachments: Statistical Design and Power, IP/IND/IDE, Dissemination Plan

Resources

- Transcend Contacts
  - Miranda Leitheiser, Miranda.Leitheiser@sanfordhealth.org
  - Jamie Scholl, Jamie.Scholl@usd.edu
- Human Subjects and Clinical Trial Information Form
- PHS Human Subjects and Clinical Trial Information
- Transcend Website


QUESTIONS