**Human Subjects Template for WVCTSI Funded Projects**

* 1. Study Title:

1.2 Is this study exempt from federal regulations? (y/n)

1.3 If Yes- Exemption number?

*An intervention is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.  Examples include:  drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.*

1.4.a Does this study involve human participants (y/n)?

1.4.b Are the participants prospectively assigned to an intervention (y/n)?

1.4.c Is the study designed to evaluate the effect of the *intervention* on the participants (y/n)?

1.4.d Is the effect that will be evaluated a health-related biomedical or behavioral outcome (y/n)?

**If the answers to 1.4.a-1.4.d are all yes- this study qualifies as a clinical trial**.

1.5 Provide the ClinicalTrials.gov Identifier if applicable:

**ALL Human Subjects projects (including non-clinical trials) MUST complete sections**

**2.1 to 3.2**

2.1 Conditions or Focus of Study:

Enter up to 1500 characters

2.2 Eligibility Criteria

Enter up to 1500 characters

2.3 Age limits- minimum age: maximum age:

2.4 Inclusion of women, minorities, and children:

Enter up to 5000 characters

2.5 Recruitment and Retention Plan

Enter up to 5000 characters

2.6 Recruitment Status (Not yet recruiting, recruiting, enrolling by invitation, active but not recruiting, completed, suspended, terminated, withdrawn):

2.7 Study Timeline:

2.8 Enrollment of first subject (anticipated or actual) date:

3.1 Protection of human subjects: Please follow the instructions in the attached comments. The bolded headers MUST all be answered.

Enter up to 5000 characters

**1. Risk to Human Subjects**

**a. Human Subjects Involvement, Characteristics, and Design**

**b. Study Procedures, Materials, and Potential Risks**

**2. Adequacy of Protection Against Risks**

**a. Informed Consent and Assent**

**b. Protections Against Risk**

**c. Vulnerable Subjects, if relevant to your stud**y

**3. Potential Benefits of the Proposed Research to Research Participants and Others**

**4. Importance of the Knowledge to be Gained**

3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site (y/n)? If yes, describe the single IRB plan.

**Sections 3.3 to 4.7 are for clinical trials ONLY. ALL sections MUST be answered.**

3.3 Data safety monitoring pan

Enter up to 3000 characters

3.4 Will a data safety monitoring board be appointed for this study (y/n)?

If yes, please describe:

3.5 Overall structure of the study team?

Enter up to 3000 characters

4.1 Brief Summary

Enter up to 5000 characters

4.2 Study Design

4.2a. Narrative Study Description

Enter up to 3000 characters

4.2.b Primary purpose (treatment, prevention, diagnostics, supportive care, screening, health services research, basic science, device feasibility, other):

4.2.c Interventions (For each intervention fill out the following)

|  |  |  |
| --- | --- | --- |
| Intervention Type | Name | Description |
|  |  |  |
|  |  |  |

Intervention Types: Drug (including placebo), Device, Biological/Vaccine, Procedure/Surgery, Radiation, Behavioral, Genetic (including gene transfer, stem cell, and recombinant DNA), Dietary Supplement, Combination Product, Diagnostic Test, Other

4.2.d Study Phase (Early Phase 1 or 0, Phase 1, Phase ½, Phase 2, Phase 2/3, Phase 3, Phase 4, Other):

4.2.e Intervention model (single group, parallel, cross-over, factorial, sequential, other):

4.2.f Masking (y/n)

If yes mark all that apply (participant, care provider, investigator, outcomes assessor)

4.2.g Allocation (N/A, randomized, non-randomized)

4.3 Outcomes measures (for each please describe):

|  |  |  |  |
| --- | --- | --- | --- |
| Type | Name | Time Frame | Brief Description |
|  |  |  |  |
|  |  |  |  |

Outcome Types: Primary, Secondary, Other

4.4 Statistical design and power

Enter up to 3000 characters

* 1. Subject Participation Duration:
  2. Will the study use an FDA-regulated intervention (y/n)?

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status:

Enter up to 5000 characters

* 1. Dissemination Plan

Enter up to 5000 characters