

## Information Required for a Clinical Trial Registration

Please answer the following questions.

1. **Clinical Trial:** Please answer as appropriate

“This protocol involves:

- a. one or more human subjects,  YES  NO;
- b. who are prospectively assigned according to a protocol,  YES  NO;
- c. to one or more interventions (or no intervention, which may include placebo or other control),  YES  NO;
- d. to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes  YES  NO.

*If all answers are Yes, then this study is considered a Clinical Trial.*

2. **Responsible party (RP):** the individual identified to submit information to ClinicalTrials.gov, usually the PI

- a. Is NIH Responsible party?  YES  NO
- b. If No, who is named as the Responsible Party \_\_\_\_\_  
Who is the PI? \_\_\_\_\_

3. **What is the Primary Completion Date:** The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated

4. **Submission of results required *not later than 1 year after the primary completion date.***

**NIH Policy:** NIH expects registration and results submission to ClinicalTrials.gov for all NIH Clinical Trials regardless of phase, type of intervention, whether they are subject to FDAAA or not.

I, \_\_\_\_\_, as the Responsible Party for \_\_\_\_\_, acknowledge my obligation to post results of this study to ClinicalTrials.gov within one year of reaching the Primary Completion date or study termination for any reason. This date may be subject to change, and I will notify OPS should this occur. Nevertheless, I am aware that results reporting are still required no later than 1 year after reaching a final completion date.

Compliance Agreement NIH IRP

Furthermore, should I leave NIH prior to posting results, it is my responsibility to (1) facilitate submission of results by making myself available to the designated NIH staff or (2) transfer the responsibility to another investigator, who must also submit a compliance agreement specifically for this study.

*Signature* \_\_\_\_\_

*Date Sent to Clinical Director and IC Point of Contact* \_\_\_\_\_

**Note:** **BE ADVISED THAT RESULTS POSTING SHOULD BEGIN WELL BEFORE THE ONE YEAR DEADLINE.** Delaying completion until after the deadline increases the chance of incurring penalties. Assistance with data entry can be obtained through

- Your IC representative, (listing available on the Sourcebook)
- BTRIS Team, contact Sachi Rath,
- ClinicalTrials.gov is piloting a process to provide one-on-one assistance to investigators throughout the results submission process. As part of the process, a member of the ClinicalTrials.gov results team would be assigned to help prepare you for results submission, orient you to the PRS (protocol registration and results system), and walk you through the data entry process. If you would like to take advantage of this assistance, please send a request to [register@clinicaltrials.gov](mailto:register@clinicaltrials.gov) that includes some available dates/times (including time zone) for an introductory call and the best phone number to reach you.