**IRB-HSBS Clinical Trials and PI Responsibilities**

**START**

**Is the research**

**NIH funded?**

**But does meet definition of a “clinical trial”\* and PI plans to publish in ICMJE journal**

 **“Clinical Trial Indicator” on PAF is “YES”**

**N**

**Y**

**Y**

**N**

**N**

**COMPLETE APPLICATION SECTIONS AS NOTED:**

**1-2.7** is “yes”; selects “other” rather than a “phase” and provides simple description in text box

**7-1.8** is “yes” & 17 Placebo is completed **- only if have control group**

**7-1.10** is “yes” & 32 DSMP is completed **- only if required by sponsor**

**10-1** Consent states that study is registeredat ClinicalTrials.gov(see IRB-HSBS consent template for text) **- only if PI plans to publish in ICMJE journal**

**Others as determined by nature of the protocol**

**(e.g., multi-site non-exempt protocol)**

**PI RESPONSIBLE FOR**

**(IRB does not track):**

**1.** Registering at ClinicalTrials.gov

**2.** If other federal funding, must upload a copy of the approved consent(s) to a public website, per the New Common Rule

**And does not meet definition of a “clinical trial”\***

**NIH and ICMJE Policies Do Not Apply**

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**COMPLETE APPLICATION SECTIONS AS NOTED:**

**Face of application:** NCT # appears here (assigned after PI registers at ClinicalTrials.gov)

**1-2.7** is “yes”; selects “other” rather than a “phase” and provides simple description in text box

**5.1** stand-alone protocol uploaded either using the NIH Social Behavioral Protocol Template OR using your own. If using your own, you must include the exact information from section 3 (pages 9-11) of the NIH Social Behavioral Protocol template

**7-1.8** is “yes” & 17 Placebo is completed **- only if have control group**

**7-1.10** is “yes” & 32 DSMP is completed

**10-1** Consent states that study is registered at ClinicalTrials.gov (see IRB-HSBS consent template for required text)

**Others as determined by nature of the protocol**

**(e.g., multi-site non-exempt protocol)**

**PI RESPONSIBLE FOR (IRB does not track):**

**1.** Registering the research at ClinicalTrials.gov\*\* w/in 21 days after enroll first subject

**2.** Submitting summary results at ClinicalTrials.gov

**3.** Updating at least once per year (if changes) at ClinicalTrials.gov

**4.** Ensuring that they and all study team members who are involved in the conduct, oversight, or management of the research complete and document GCP training

**5.** Uploading a copy of the approved consent to a public website, per the New Common Rule

**\*** To determine if your research meets the definition of a Clinical Trial, see page 2.

**\*\*** BESH studies may register/report on alternative portals (instead of ClinicalTrials.gov).

**Does your Research Meet the Definition of a Clinical Trial?**

**Does the research:**

**Not a Clinical trial**

**Involve one or more human subjects?**

**N**

**Not a Clinical trial**

**Y**

**N**

**Involve the use of one or more interventions?**

**Y**

**Not a Clinical trial**

**Prospectively assign human subjects to an intervention?**

**Y**

**N**

**N**

**Not a Clinical trial**

**Y**

**Have a health-related biomedical or behavioral outcome?**

**Your research meets the definition of a Clinical Trial**