File Checklist for Human Subject/Clinical Trial Form

Needed for each study related to the project. This information is now located on new Human Subject & Clinical Trials Information form. *This form is a mixture of uploads and entered data, (sections 1.1, 2.1& 2.2, 4.1, 4.2a&c, 4.3 among others)*. **Questions 1.4 A-D will determine if your project is considered a Clinical Trial, if you answer no to just one of these four questions your project is not considered a Clinical Trial**. Note it you say yes to human subject question 1.4A will default to yes. If you considered a use of Human Subject project and not deemed a clinical trial, you only have to complete sections 1-3, Clinical Trial proposals also have to complete sections 4 & 5.

	File Type	Comments	Page Limits
	Item 2.3: Inclusion of Individuals Across the Lifespan	With Forms F this is now a separate upload. Note this is the new name for inclusion of Children	No limit
	Item 2.4: Inclusion of Women, Minorities	Required unless study is exempt 4	No limit
	Item 2.5: Recruitment and Retention Plan	Required unless study is exemption 4, 1.4a is not or otherwise noted in the funding opportunity	No limit
	Item 2.6 Recruitment Status	Required unless study is exemption 4, 1.4a is not or otherwise noted in the funding opportunity	No limit
	Item 2.7: Study Timeline	Required unless study is exemption 4, 1.4a is not or otherwise noted in the funding opportunity	No limit
	Item 2.9: Inclusion Enrollment Report (s)	Required unless study is exemption 4, 1.4a is not or otherwise noted in the funding opportunity. New with Forms F you now need to provide a unique title for each enrollment report added	Up to 20 different reports can be added
	Item 3.1: Protection of Human Subjects*	Required	No limit
	Item 3.2: Single IRB Plan	Not required if yes but recommended	No limit
	Item 3.3: Data & Safety Monitoring Plan	Mandatory for CT projects, optional for HS only submissions	No limit
	Item 3.5: Overall structure of the study team	Optional	No limit
	Item 4.3: Statistical Design and Power	Mandatory for CT projects unless otherwise noted in the FA	No limit

	Item 4.4: Subject Participation Duration	Mandatory for CT projects unless otherwise noted in the FA	No limit
	Item 4.7: Dissemination Plan	Mandatory for CT projects unless otherwise noted in the FA	No limit You can use the same dissemination plan for each study if there are multiple studies as long as they have different file names.
	Item 5.1 Other Clinical Trial Related Attachments	Supports up to 10 attachments. Only allowed for CT studies. Only include those attachments requested in the funding opportunity	
	Data Entry Fields	**Comments**	**Character Limit/Notes**
	Item 2.1: Conditions or Focus of Study	A list of keywords or phrases (search criteria) that describe the study Required unless study is exemption 4,	Up to 20 conditions at 255 character each allowed
	Item 2.2: Eligibility Criteria	Inclusion and exclusion conditions Required unless study is exemption 4, or otherwise noted in the funding opportunity	15,000 Characters
	Item 2.3: Age Limits (Minimum and Maximum)	Need to include age an one of the options form a drop down that include: years, months, weeks, days, hours, minutes . Required unless study is exemption 4, or otherwise noted in the funding opportunity	
	Item 2.6: Recruitment Status	Enter or select from a drop down	Choices include but are not limited to: not yet recruiting, recruiting, completed, enrolling by invitation and active
	Item 2.8: Enrollment of first Participant	You need to enter both a date and whether that is an actual or anticipated target. Required unless study is exemption 4, 1.4a is no or otherwise noted in the funding opportunity	
	Inclusion Enrollment Report	This needs to be activated and completed	If doing a secondary data analysis figure need to be entered in the actual and not planned section
	Item 4.1a: Detailed Description	Describe your plans for assignment of participants and delivery of interventions. You will also need to show that your methods for sample size and data analysis are appropriate given those plans. For trials that randomize groups or deliver interventions to groups, special methods are required.	Limited to 32,000 Characters
	Item 4.1b: Primary Purpose	Enter or select from the dropdown menu a single "Primary Purpose" that best describes the clinical trial	Choices include: Treatment, Prevention, Diagnostics, Screening, Basic Science, and Device Feasibility
	Item 4.1c: Interventions	Complete fields for each intervention to be used in your proposed protocol. If an arm of the study to which subjects will be assigned (as discussed in 4.1.a. Detailed Description) includes more than one intervention (e.g., drug plus educational intervention), complete this section for each intervention.	You can add up to 20 interventions. You must choose an intervention, and a unique name, limited to 200 characters, and enter a description of up to 1,000 characters
	Item 4.1d: Study Phase	Enter or choose from a drop down menu	Choices range from Early Phase 1 (or Phase 0) to Phase 4

	Item 4.1e: Intervention Model	Enter or choose from a drop down menu	Choices include: Single Group, Parallel, Factorial, and Sequential
	Item 4.1f Masking	Check box choices Yes/No if yes need to select a secondary choice between Participant/Care Provider /Investigator/Outcome Assessor	
	Item 4.1g: Allocation	Dropdown list: N/A, Randomized and Non-Randomized	
	Item 4.2 Outcome Measures - Primary, Secondary and other important measures	Needs to be completed for each outcome: • primary (the outcome measures specified in your protocol that are of greatest importance to your study), • secondary (measures specified in your protocol that are of lesser importance to your study than your primary outcomes), and • other important measures (additional key outcome measures used to evaluate the intervention to be collected during your proposed clinical trial.). 1. Time Frame: Indicate when a measure will be collected for analysis (e.g., baseline, post-treatment). 2. Brief Description: Describe the metric used to characterize the outcome measure if the metric is not already included in the outcome measure name. 3. Your description is additional key outcome measures used to evaluate the intervention.	Note: You may have more than one primary outcome measure, and you can add up to 50 unique outcome measures The Description is limited to limited to 999 characters. The Time Frame and Outcome Measure is limted to 255 Characters
	Item 4.5: FDA Regulated Intervention	Yes/No answer required. If yes you need to upload an attachment stating availability of Investigational Product (IP) and Investigational New Drug (IND) exemption status	
	Item 4.6 Applicable Clinical Trial under FDAAA	Yes or No answer required	

Note: You should always read the specific FA to see if it deviates from the standard requirements. You should also see if any other files or appendix material are allow or required. If it is not specified these items should not be included. Contact The Office of Clinical Award Administration 8-4490/SOMCAA@stonybrookmedicine.edu, if you have any questions on what is required for a complete submission.