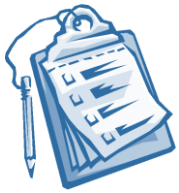
File Checklist for Human Subject/Clinical Trial Form



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 inputted data, sections 1.1, 2.1& 2.2 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**. If you are considered a use of Human Subject project you only have to complete sections 1-3, Clinical Trial proposals also have to complete sections 4 & 5.

	File Type	Comments	Page Limits
	Item 2.4: Inclusion of Women, Minorities and Children	These are now all uploaded together	No limit
	Item 2.5: Recruitment and Retention Plan	This is new with the E Forms	No limit
	Item 2.7: Study Timeline	This is new with the E Forms	No limit
	Item 3.1: Protection of Human Subjects*		No limit
	Item 3.2: Single IRB Plan	New Mandatory if this is a domestic multi-site study	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 4.4: Statistical Design and Power	Mandatory for CT projects unless otherwise noted in the FA	No limit
	Item 4.5: 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
	Data Entry Fields	**Comments**	**Character Limit**
	Item 2.1 Conditions or Focus of Study	A list of keywords (search criteria) that describe the study	None

	Item 2.2 Eligibility Criteria	Inclusion and exclusion conditions	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	
	Item 2.6 Recruitment Status	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 Subject	You need to enter both a date and whether that is an actual or anticipated target	
	Inclusion Enrollment Report	This needs to be activated and completed	

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.