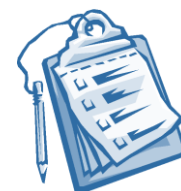


# File Checklist for Human Subject/Clinical Trial Form



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. <b>As of 1/25/2019 you need to include Inclusion Across Lifespan</b> ( <a href="https://grants.nih.gov/grants/funding/lifespan/lifespan.htm">https://grants.nih.gov/grants/funding/lifespan/lifespan.htm</a> )	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
<b>Data Entry Fields</b>	<b>Comments</b>	<b>Character Limit</b>

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 as one of the options from 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 allowed 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](mailto:SOMCAA@stonybrookmedicine.edu), if you have any questions on what is required for a complete submission.