PHS Human Subjects and Clinical Trials Information Form (effective: Jan. 25, 2018)

CHECKLIST

	If NO to Human Subjects	Notes/Status
CT HS	Justification	If proposed research involves human specimens and/or data, upload justification

	If YES to Human Subjects	
CT HS	Other Requested Information	(if applicable, per FOA)
CT HS	Study Record – or – Delayed Onset Study Record	Must attach either: • Delayed Onset Justification • Full Study Record
	STUDY RECORD **Section 1 – Basic Information**	
CT HS	Basic Information	(data entry)
	STUDY RECORD **Section 2 – Study Population Characteristics**	
CT HS	Inclusion of Women, Minorities, and Children	
CT HS	Recruitment and Retention Plan	
CT HS	Study Timeline	
CT HS	Inclusion Enrollment Report(s)	• Planned Enrollment Report (i.e., projected), and/or • Cumulative Enrollment Report (i.e., actual from existing dataset)
	STUDY RECORD **Section 3 – Protection and Monitoring Plans**	
CT HS	Protection of Human Subjects	
CT HS	Single IRB Plan	(if applicable)
CT	Data and Safety Monitoring Plan	
CT	Overall Structure of the Study Team	
	STUDY RECORD **Section 4 – Protocol Synopsis**	
CT	Brief Summary	• 5000 char limit (~ 1 page)
CT	Narrative Study Description	• 32,000 char limit (~ 6.5 pages)
CT	Statistical Design and Power	
CT	FDA-regulated Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) Status	(if applicable)
CT	Dissemination Plan	
	STUDY RECORD **Section 5 – Other Clinical Trial-related Attachments**	
CT	RFA may indicate additional required documents	• Only if specifically requested by RFA