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

CHECKLIST

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

	If YES to Human Subjects	
	Other Requested Information	(if applicable, per FOA)
	Study Record – or – Delayed Onset Study Record	Must attach either: Delayed Onset Justification Full Study Record
STUDY RECORD Section 1 – Basic Information		
	Basic Information	(data entry)
STUDY RECORD Section 2 – Study Population Characteristics		
	Inclusion of Women, Minorities, and Children	
	Recruitment and Retention Plan	
	Study Timeline	
	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		**Degree of Significant Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption**
	Protection of Human Subjects	

	(IDE) Status	**(if applicable)**
	Dissemination Plan	
STUDY RECORD Section 5 – Other Clinical Trial-related Attachments		