THE UNIVERSITY OF VERMONT
RESEARCH DEVELOPMENT

PHS Human Subjects and Clinical Trials Information Form - CHECKLIST

(NIH Forms F effective: May 25, 2020)

Required? *	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)
Section 2 – Study Population Characteristics		
CT HS	2.3a Inclusion of Individuals Across the Lifespan	
CT HS	2.4 Inclusion of Women and Minorities	
CT HS	2.5 Recruitment and Retention Plan	
CT HS	2.7 Study Timeline	
CT HS	2.9 Inclusion Enrollment Report(s)	• Planned Enrollment Report (i.e., projected), and/or • Cumulative Enrollment Report (i.e., actual from existing dataset)
Section 3 – Protection and Monitoring Plans		
CT HS	3.1 Protection of Human Subjects	
CT	3.3 Data and Safety Monitoring Plan	
CT	3.5 Overall Structure of the Study Team	
Section 4 – Protocol Synopsis		
CT	4.1a Study Design – Detailed Description	• 32,000 char limit (~ 6.5 pages)
CT	4.2 Outcome Measures	
CT	4.3 Statistical Design and Power	
CT	4.5a FDA-regulated Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) Status	(if applicable)
CT	4.7 Dissemination Plan	
Section 5 – Other Clinical Trial-related Attachments		
CT	5. Other Clinical Trial-related Attachments	• **ONLY** if specifically requested by RFA

***** required for CT = Clinical Trial applications; HS = Human Subjects applications