PHS Human Subjects and Clinical Trials Information
Decision Tree

Is R&R Other Project Info Form complete?

No

STOP
Complete R&R Other Project Info Form before continuing

Yes

Continue to Human Subjects and Clinical Trials (HS/CT) Info Form

Are human subjects involved?
(Pre-populated from R&R Other Project Info form)

No

Complete “If NO to Human Subjects” section

Yes

Complete “If YES to Human Subjects” section

Research involves humans specimens and/or data?

No

STOP
Skip the rest of HS/CT form

Yes

ATTACH justification re: NOT human subjects

Renewal? Multi-project? Special instructions in FOA?

Yes

ATTACH “Other Requested Information”

No

ATTACH Delayed Onset justification
Enter: Study Title? Anticipated Clinical Trial

ATTACH HS Study Record (at least 1, up to 150 records)

Go to Study Record form decision tree

Source: Jeralyn Haraldsen, PhD, Grant Proposal Manager
University of Vermont, Office of the Vice President for Research
ALL Studies involving Human Subjects: complete Section 1 – Basic Information

Section 1.4 Clinical Trial Questionnaire responses

NO to ANY questions? this study meets the definition of HUMAN SUBJECTS

YES to ALL questions? this study meets the definition of a CLINICAL TRIAL

Section 2 – Study Population Characteristics

Section 3 – Protection and Monitoring Plans

Section 4 – Protocol Synopsis

Section 5 Required by FOA?

Yes

Section 5 – Other Clinical Trial-Related Attachments

Follow detailed instructions for the completion of these sections

NIH Forms E
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