

VII.B.1 and CT.Gov Related Changes

The Human Subjects Office (HSO) is excited to inform you of the newest enhancement eliminating content duplication in the eResearch (HawkIRB) application and the [ClinicalTrials.Gov registration process](#). Beginning in August 2020, research submitted under IRB-01 that is required or opts to register on [ClinicalTrials.Gov \(CT.Gov\)](#) is eligible for the HawkIRB system to generate a CT.Gov record on your behalf. There is a new question for researchers to “push” IRB approved responses from the HawkIRB application initiating a new CT.Gov record. This option applies to research with a developed protocol initiated by a UI Investigator where the UI PI would be named as the [Responsible Party](#) in the Protocol Registration and Results System (PRS) for a CT.Gov record. To launch, we made a few changes to how you answer questions in HawkIRB. The first change is to question **VII.B.1** which currently has eight options:

- Registry
- Repository
- Expanded Access
- Clinical (or Treatment) Trial
- Physiology Intervention/study
- Behavioral Intervention/study
- Diagnostic Trial
- Other


The **revised** VII.B.1 question will categorize the responses consistent with the CT.Gov study design fields.

- **Interventional** (prior interventional study type options will now be combined as a sub question if interventional is selected)
- **Observational** – **NEW Option!**
- Expanded Access
- Registry
- Repository
- Other

If **Interventional** is selected in VII.B.1, the following subcategory options will now appear:

Does this project involve any of the following (Check all that apply):

Interventional – Includes **Clinical (or Treatment) trial, Physiology intervention/study, Behavioral intervention/study, Diagnostic Trial.**

 **Clinical (or Treatment) trial** – A prospective biomedical or behavioral research study of new treatments, new drug or combinations of drugs, new devices, or new approaches to surgery or radiation therapy. (NIH and [ClinicalTrials.gov](#) & [FDA](#))

Physiology intervention/study – A pharmacologic or measurement study aimed at understanding basic mechanisms of disease and/or of normal human physiology, often without any therapeutic intent (though a clinical trial could include such components, often labeled as “translational” or “basic science” aims.) Measurements in such studies could include, but are not limited to, a blood draw, EKG, EEG, MRI, auditory or sensory testing, checking vital signs, DEXA scans, eye tracking, specimen collection, exercise, fasting, special diets, etc.

Behavioral intervention/study – May be used to refer to studies of individual or group behavior. This option does not include drugs, biologics, or devices but could include psychotherapy, lifestyle counseling, behavior modification, etc.

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Diagnostic trial – Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition ([ClinicalTrials.gov](https://clinicaltrials.gov) & [FDA](https://www.fda.gov))

If **Expanded Access** is selected, the following subcategory options will now appear:

Expanded Access – A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Examples of expanded access include non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access to investigational drug, and parallel track ([ClinicalTrials.gov](https://clinicaltrials.gov) & [FDA](https://www.fda.gov)).

Availability of an experimental drug or device outside of a clinical trial protocol:

- Not Applicable**
- Individual Patients**
- Intermediate-size Population**
- Treatment IND/Protocol**

All existing and new IRB applications will see the changes to question VII.B.1. For all existing studies, HawkIRB will automatically select the most appropriate option based on your prior selection.

Studies eligible to push information from HawkIRB into a CT.Gov record will be required to have a full developed protocol submitted by a UI PI. A new question will appear if **VII.B.12** indicates the “**UI Investigator**” is who initiated\provided the protocol. The new question is under **VII.B.12.c**

VII.B.12

Who initiated/provided the protocol?

- Sponsor
- UI Investigator
- Other

NEW! *The IRB will determine if this study is an Applicable Clinical Trial (ACT), which requires registration and results reporting on [ClinicalTrials.gov](https://clinicaltrials.gov). Studies which do not meet this definition may still choose to register for other reasons, such as meeting publication requirements for some journals. Contact ct-gov@uiowa.edu if you have questions on the CT.Gov registration process. [Iowa ACT Checklist](#)*

VII.B.12.c Would you like to use information from this IRB application to have a [ClinicalTrials.gov](https://clinicaltrials.gov) record started on your behalf?

- Yes
- No

All “yes” selections will pull information from the IRB approved application and initiate a CT.Gov record on the UI PI’s behalf. If the UI PI is not registered in the PRS system, the CT.Gov Administrator will

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register the PI using their HawkID and UI directory information. Upon registration, an email will be sent with login information.

The wording of question **VII.B.18** has been revised to be consistent with FDA and CT.Gov regulatory language. The bold content is new:

“Does this project involve **the evaluation or testing**, of the safety and/or efficacy of a medical device?”

If VII.B.18 is answered yes, **VII.B.18.a** is a **new question** that will appear. It asks for additional details to clarify what evaluation or testing may occur with the medical device. This addition is directly relevant to fields in the CT.Gov record.

VII.B.18.a

Indicate evaluation type (select all that apply):

- Efficacy of the device
- Safety of the device
- Feasibility of the device
- Pediatric Post-Market Surveillance


After the IRB has approved the project, the CT.Gov Administrator in the HSO will initiate the “push” of information from HawkIRB to the newly created CT.Gov record. The table below represent a summary of which HawkIRB questions\responses auto populate fields in the new CT.Gov record:

HAWKIRB QUESTION\RESPONSE	CT.GOV FIELD
IRB ID #	Unique Protocol ID
I.3 Short Title (optional)	Brief Title
I.2 Project Title	Official Title
II.1 Principal Investigator	Responsible Party
II.1 Principal Investigator	Record Owner
V.8 Investigational Drugs Used In Study, VII.B.25 Is there an IDE	U.S. FDA IND/IDE, IND/IDE Number
IRB Approval Status	Human Subjects Protection Review : Board Status
VII.B.1 Clinical Intervention	Study Design : Study Type
VI.1, VI.6 Number of adult / minor subjects	Study Design : Enrollment
VI.4, VI.5, VI.9, VI.10 Percentage Subjects Male / Female	Eligibility : Sex
VI.2, VI.3, VI.7, VI.8 Min/Max Age Adults, Min/Max Age Minors	Eligibility: Minimum Age, Maximum Age
II.1 Principal Investigator	Overall Contacts : Central Contact Person
Applicable Clinical Trial (as determined by the IRB per 42 CFR Part 11)	Oversight : FDA Regulated Intervention, Section 801 Clinical Trial


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An IRB application associated with a CT.Gov record will now have several new sections on the Project Summary level. Under the FDA Regulated section, there will be an “Applicable Clinical Trial” listing with a Yes/No response as shown below.

FDA Regulated	
IND Numbers	N/A
IDE Number	N/A
HDE Number	N/A
Non-Significant Risk Device	N/A
Emergency Use	N/A
Applicable Clinical Trial	Yes



For any studies indicating “Yes” to an Applicable Clinical Trial, there will also be a **new** corresponding ClinicalTrials.gov tab. Selecting this tab will show information specific to the CT.Gov record associated with the IRB approved application.



Summary	<u>Project Details</u>	<u>Attachments</u>	<u>Research Team</u>	<u>Funding</u>	<u>REFs</u>	<u>Approval</u>	<u>Monitoring</u>	ClinicalTrials.gov
IRB	IRB-01							Create Form Modification/Update Form Continuing Review Form Modification/Update + Continuing Review Form Reportable Event Form Project Close Form
IRB ID #	202001022							
Title	Clinical Trial ACT							
Short Title								
PI	Michele Countryman							
Status	Approved							

After selecting the ClinicalTrials.Gov tab, the user will see basic PRS information as collected in the ClinicalTrials.Gov record such as the:

- NCT Number,
- Record Status,
- Name of the Record Owner,
- Primary Completion Date,
- Study End Date,
- Whether or not the study appears on a [Problem Report](#),
- Last update pushed from CT.Gov to the HawkIRB record and
- A link to the full clinicaltrials.gov data

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Automated reminder emails will be sent from HawkIRB after 30 and 44 days for any incomplete CT.Gov records initiated on the PI's behalf. [All records must be completed](#) in line with either FDAAA regulations, NIH policy, or ICJME requirements.

The project closure notices for any Applicable Clinical Trials (ACT) will have an additional question on the closure form asking a yes/no response to the question, **“Have Results been submitted to ClinicalTrials.gov?”** If no, the HSO will request this action be complete prior to finalizing the closure form.