(HawkACT) Applicable Clinical Trial Checklist

Study Title (required): _____

This form is optional. Investigators using drugs, devices, or biologics in research may complete this form to:

1) Provide direct input to the IRB regarding the determination of an Applicable Clinical Trial (ACT), or
2) Receive an informal ACT determination (only the IRB may make a formal determination)

Provide additional detail where applicable in the 'Points for discussion' section. If unsure whether one of the criteria below apply, select 'Maybe' and be sure to elaborate on this selection in the Points for Discussion. **Submit this form using the link below**. For IRB considerations, attach this form in HawkIRB under the 'miscellaneous' attachment category after obtaining a ClinicalTrials.gov Departmental Liaison signature. *Determinations will be provided within 10 business days. *Note - This checklist evaluates the applicability of the Federal registration requirements laid out in FDAAA 801 and 42 CFR 11. This form does not evaluate NIH policy requirements for registering a clinical trial, nor does it evaluate journal requirements for publication.*

*Click on the text 'Applicable Clinical Trial' below to be taken to the full ACT checklist

HawkIRB Question	**Checklist Question**			
The sections below provide the most likely Hawkirb section corresponding to the ACT checklist question	**Applicable Clinical Trial (ACT)** – If questions 1-4 below are all answered 'Yes' the study is considered an ACT.	☐ **Yes**	☐ **No**	☐ **NA**
VII.B.1/VII.E.6	1. Is the study Interventional (a clinical trial)? *Prospective enrollment of subjects to a group or groups to evaluate the effect of the intervention on subjects*	☐ Yes	☐ No	☐ Maybe
VII.A.1, V.8, &\or VII.B.18	2. Do ANY of the following apply (is the answer "Yes" to at least one of the following sub-questions: 2a, 2b, OR 2c)? *a. Is at least one study facility located in the United States or a U.S. territory?* *Facility Location – Country data element is "United States," "American Samoa,"* *"Guam," "Northern Mariana Islands,"* *"Puerto Rico," "U.S. Virgin Islands," or other U.S. territory.* *b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)? U.S. Food and Drug Administration IND or IDE Number data element is "Yes."*	☐ Yes	☐ No	☐ Maybe

	C.Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country? Product Manufactured in and Exported from the U.S. data element is "Yes."			
V.1 – V.8/VII.B.18	3.Does the study Evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)? Studies a U.S. FDA-regulated Device Product data element is "Yes" and/or Studies a U.S. FDA-regulated Drug Product data element is "Yes."	☐ Yes	☐ No	☐ Maybe
VII.B.1. or VII.B.1.a	4. Is the study other than a Phase 1 trial of a drug and/or biological product or is the study other than an early device feasibility study? For drug product trials, Study Phase data element is NOT "Phase 1" and for device product trials, Primary Purpose is NOT "Device Feasibility."	☐ Yes	☐ No	☐ Maybe

Points for discussion:

Submitting to the IRB

To submit the HawkACT Checklist to the IRB for consideration, this form must be approved and signed by a ClinicalTrials.gov Departmental Liaison. Forms attached without an approval signature will not be considered. To request review and approval of this checklist, complete this form.

Resources

Need help with ClinicalTrials.gov? Contact your ClinicalTrials.gov Departmental Liaison by filling out this form, or by contacting ct-gov@uiowa.edu

Visit https://hso.research.uiowa.edu/clinicaltrialsgov for additional resources.

_____ _____

(ClinicalTrials.gov Departmental Liaison signature) (Date)

_____ _____

(Investigator Signature) (Investigator Printed Name)