ClinicalTrials.gov Resources

Resources accessible at **https://hso.research.uiowa.edu/clinicaltrialsgov**

GETTING STARTED–CLINICALTRIALS.GOV CHECKLIST

The ClinicalTrials.gov Checklist is an easy to use tool that allows investigators to prepare for registration and results reporting. The document easily lays out expectations and considerations, as well as provides links to useful materials such as planning templates.

HAWKACT DETERMINATION FORM

This optional ACT checklist has been revised for the purposes of UI investigators. The form may be completed by investigators to communicate to the IRB regarding the ACT determination made on a study. Investigators can also use the form to receive guidance on this determination prior to the IRB's determination of an ACT.

ICMJE DATA SHARING STATEMENT GUIDANCE

This guide will assist you in complying with the ICMJE Data Sharing policy.

PRS REVIEW CHECKLIST

The PRS Review Checklist provides a check before the record is submitted for review. It a incorporates common errors identified by reviewers so that these pitfalls may be avoided when submitting a record for review.

CLINICALTRIALS.GOV REDACTION GUIDE

Understanding which information, if any, to redact is important when uploading required documents into ClinicalTrials.gov. This guide indicates when it is appropriate to redact, and when it should be avoided.

ICTS ACADEMY FOR RESEARCH PROFESSIONALS PRESENTATION—HOW TO REGISTER AND MAINTAIN A RECORD

This presentation is presented at the ICTS Academy for Research Professionals annually. It may be accessed at anytime as a resource for new PRS users, or as an education tool for existing users.

CLINICALTRIALS.GOV OFFICE HOURS

ClinicalTrials.gov Office Hours are held every Wednesday from 11:00 am – 12:00 pm in Hardin Library for the Health Sciences (HLHS) room 101.

CLINICALTRIALS.GOV REGULATIONS AND POLICIES

ClinicalTrials.gov is a public database containing information about federally and privately supported clinical trials for an array of diseases and conditions. A service of the U.S. National Library of Medicine (NLM) at the National Institutes of Health (NIH), and in collaboration with the Food and Drug Administration (FDA). Background information regarding history, policies, and laws can be found on ClinicalTrials.gov Section 801 of the Food and Drug Administration Act (FDAAA 801) specifies registration and results reporting requirements for clinical trials, but other registration and reporting policies can apply. Investigators wishing to publish on ClinicalTrials.gov must do so in the Protocol Registration and Results System (PRS) at register.clinicaltrials.gov.

CLINICALTRIALS.GOV COMPLIANCE PROGRAM

The Human Subjects Office | 600 Newton Rd. Suite 105 | Iowa City, IA 52242 | 319-384-4623

THE UNIVERSITY OF IOWA

UNIVERSITY OF IOWA HEALTH CARE

DATA ELEMENT	**DEADLINE FOR UPDATING** (i.e., not later than the Specified Date)
Study Start Date	30 calendar days after the first subject is enrolled
Overall Recruitment Status	30 calendar days after a change in overall recruitment status
IRB Approval Status	30 calendar days after a change in status
Primary Completion Date	30 calendar days after the clinical trial reaches its actual primary completion date
Enrollment	At the time the primary completion date is changed to "actual," the actual number of participants enrolled must be submitted
Study Completion Date	30 calendar days after the clinical trial reaches its actual study completion date
Responsible Party, by Official Title	30 calendar days after a change in the Responsible Party or the official title of the Responsible Party
Responsible Party Contact Information	30 calendar days after a change in the Responsible Party or the contact information for the Responsible Party
Device Product not Approved or Cleared by US FDA	15 calendar days after a change in approval or clearance status has occurred
Record Verification Date	Any time the record is updated for accuracy and not less than every 12 months, even if no other updated information is submitted at that time.

DATA ELEMENT	FINAL RULE	NIH POLICY	ICMJE POLICY
Scope/Applicability	Applicable clinical trials of FDA-regulated drug, biological, and device products and pediatric post-market surveillance studies of devices required by the FDA under the FD&C Act. Does not apply to phase 1 feasibility studies.	All clinical trials funded wholly or partially by NIH. Clinical trial is defined as an evaluation of a drug, device, or behavioral outcome on a biomedical or health-related outcome. Includes phase 1 clinical trials and trials that do not involve any FDA regulated product such as trials involving only behavioral interventions.	All clinical trials wishing to publish in an ICMJE or affiliated journal must register prior to enrolling the first subject. Manuscripts submitted to ICMJE journals must contain a data sharing statement and, if applicable, a data sharing plan. Clinical trial is defined as an evaluation of a drug, device, or behavioral outcome on a biomedical or health-related outcome.
Timeframe for registration on ClinicalTrials.gov	Not later than 21 days after enrollment of the first participant.	Not later than 21 days after enrollment of the first participant.	Prior to enrollment of first subject.
Timeframe for results information submissions to ClinicalTrials.gov	Not later than 12 months after primary completion date: possible delay of up to an additional 2 years for reasonable cause.	Not later than 12 months after primary completion date: possible delay of up to an additional 2 years for reasonable cause.	No results reporting mandated by policy.
Potential Consequences of Non-compliance	Civil monetary penalties of up to $11,805 per day Potential withholding of existing funding, possible denial of future funding Notice of non-compliance in public record Criminal penalties	Suspension or termination of grant or contract funding Denial of future funding	Inability to publish in ICMJE or affiliated journal