Guidelines for ClinicalTrials.gov Registration of Clinical Trials

This guidance offers support to researchers who must register and report clinical research trials to ClinicalTrials.gov, a database of clinical research trials conducted in the United States and around the world.

Who are the University of Arizona ClinicalTrials.gov Administrators?
Non-cancer studies contact:

- UAHS Research Administration Regulatory Team: regulatory@email.arizona.edu

Cancer studies contact:

- UACC National Clinical Trials Network Team: UACC-NCTN@uacc.arizona.edu

Which Clinical Trials Are Required to Be Registered?
The University of Arizona (UA) ClinicalTrials.gov administrators recommend that all clinical trials conducted at the University of Arizona are registered with ClinicalTrials.gov. Registration is required for many trials.

The FDA Amendments Act of 2007 (FDAAA or U.S. Public Law 110-85) and Final Rule for Clinical Trials Registration and Results Information Submission ("Final Rule" or 42 CFR Part 11) require a "responsible party" to register "applicable clinical trials" involving drugs, biologics, or devices that are subject to FDA regulations. Some study sponsors have additional reporting requirements – for instance, all NIH-funded clinical trials require registration, even if they are not considered "applicable clinical trials".

In addition, investigators or sponsors must register clinical trials in the Protocol Registration System (PRS) of ClinicalTrials.gov to comply with the International Committee of Medical Journal Editors (ICMJE) Initiative, which requires prior entry of clinical trials in a public registry as a condition for publication.

If you are unsure about whether your trial requires registration, please review the UA ClinicalTrials.gov Registration and Results Requirements Decision Tree. You may also reach out to the University of Arizona ClinicalTrials.gov administrators for assistance in determining if your study should be registered.

Why Should You Register Your Clinical Trial?
Non-reporting of applicable clinical trials may result in the following:

- Potential monetary penalties
- Withholding or recovery of grants
- Unregistered trials will not be considered for publication in journals that adhere to the ICMJE standards.

How Do I Register a Trial at ClinicalTrials.gov?
You will need a user account in order to access the Protocol Registration System (PRS). Send an e-mail to the University of Arizona ClinicalTrials.gov Administrators at regulatory@arizona.edu.

Once the Principal Investigator (PI) and/or the PI's designee receives their user account and logs onto the ClinicalTrials.gov Registration System, they will be guided to enter specific information about the study.

- Under FDAAA, an applicable trial must be registered **no later than 21 days** after the enrollment of the first subject.
- A study is considered registered once the responsible party releases the record to PRS for review.

- The National Clinical Trial (NCT) number is generated after the central ClinicalTrials.gov PRS staff has completed their initial review and approved the record to be published on the public site. During this process, the PRS staff may have comments or corrections that the study team must respond to.

Who Is Responsible for Registering the Trial?
The "responsible party" is responsible for registering the trial on ClinicalTrials.gov.

ClinicalTrials.gov defines the "responsible party" as:

- The sponsor of the clinical trial, as defined in 21 CFR 50.3; or
- The principal investigator (PI) of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the PI is:
    - Responsible for conducting the trial
    - Has access to and control over the data from the clinical trial
    - Has the right to publish the results of the trial, and
    - Has the ability to meet all of the requirements for the submission of clinical trial information

UA policy is that the PI should be designated as the Responsible Party for all non-cancer studies registered through the University of Arizona, as long as the above criteria are met. Please contact the UA ClinicalTrials.gov administrators for questions about the appropriate "responsible party" for your study.

What Are My Reporting Responsibilities?
The Principal Investigator of the study is responsible for maintaining the accuracy of the information on the registered trials.

Timeline for Entering Information into ClinicalTrials.gov

Event	**Timeline requirements**	**Notes**
Registration	No later than 21 days after the first subject is enrolled Registration is required to be complete prior to first subject enrollment.	A study is considered registered once the responsible party releases the record to PRS for review.
Actively enrolling studies	Update/verification every six months	The record must be verified even if no changes need to be made.
Studies closed to enrollment or pending results	Update/verification annually	The record must be verified even if no changes need to be made.
Change in study status	Within 30 days of status change	For more information on the Primary Completion Date and/or Study Completion Date, please refer to Protocol Registration Data Element Definitions—Study Status.
Posting of IRB-approved informed consent	After the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject	Required for all federally-funded clinical trials. Alternately, the consent may be uploaded to Regulations.gov Docket ID: HHS-OPHS-2018-0021.

Event	Timeline requirements	Notes
Results submission	No later than 1 year after the primary completion date	Delayed submission of results is permitted in certain circumstances. See ClinicalTrials.gov guidance on results deadlines for details.

What Happens When the Study Is Completed?
The sponsor/investigator of a clinical trial is responsible for posting basic study results at the conclusion of the study. The following items must be posted on the ClinicalTrials.gov site:

- Demographic and Baseline characteristics of patient sample
- Adverse Events/Serious Adverse Events
- Primary and Secondary Outcomes results measures
- Point of Contact

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Additional Information and Resources

- ClinicalTrials.gov public view
- ClinicalTrials.gov Protocol Registration System
- PRS User's Guide
- PRS Guided Tutorials
- Submit Studies to ClinicalTrials.gov PRS
- FDAAA 801 and the Final Rule
- UAHS RA Regulatory ClinicalTrials.gov help page
- UA ClinicalTrials.gov Registration and Results Requirements Decision Tree
- UA IRB Clinical Trials Guidance
- U.S. Public Law 110-85, Food and Drug Administration Amendments Act of 2007
- 21 CFR 11, Clinical Trials Registration and Results Information Submission
- Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov
- ICMJE Clinical Trial Registration