Managing Clinical Trials

ClinicalTrials.gov Registry

Required Registration

Registration is required for trials that meet the FDAAA 801 definition of an "applicable clinical trial" that include the following:

- **Trials of drugs and biologics**. Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation
- **Trials of devices**.
  - Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and
  - pediatric post-market surveillance required by FDA

"Applicable clinical trials" generally include interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices that meet one of the following conditions:

- The trial has one or more sites in the United States
- The trial is conducted under an FDA investigational new drug application or investigational device exemption
- The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research

For complete statutory definitions and more on the meaning of "applicable clinical trial," see Elaboration of Definitions of Responsible Party and Applicable Clinical Trial.

Please keep in mind that FDAAA801 regulations apply to “applicable clinical trials” regardless of the funding source or lack thereof.

As a part of the IRB review, the ClinicalTrials.gov identifier (NCT number) will be requested for applicable studies.

Can I register a study after it has started?

Yes, you can register a study on ClinicalTrials.gov after it has started, but initial registration must occur prior to closing subject accrual. Please note that, in general, Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) requires Applicable Clinical Trials to be registered within 21 days of enrollment of the first participant. The International Committee of Medical Journal Editors and many journals also require registration of clinical trials *prior* to enrollment of the first participant.

Who is responsible for submitting my study to Clinicaltrials.gov?

Whoever is listed as the sponsor/investigator for the study has the responsibility for registering the study with ClinicalTrials.gov. If you need access to ClinicalTrials.gov, have questions, or require assistance with the submission, the Office of Regulatory Affairs can assist you. Call 402-559-6463 with questions.

Epic One Chart

Epic One Chart is used in many ways for clinical trials.

Building a study

Only those designated as Clinical Research Specialists can build and activate studies. Research coordinators must submit a completed Clinical Trial Master Matrix and an IRB number to a Clinical Research Specialist. To reach a Clinical Research Specialist contact the Clinical Research Center or phone: 402-552-2983.

Enrolling subjects

Research Coordinators can enroll patients in active studies using One Chart. The patient's name must be linked to the study to enroll them. Step by step instructions are available in the EPIC Research Quick Start Guide.

Training

Training is provided through the OneChart User Resource Center at Nebraska Medicine.

Advertising a Study

General Guidelines

The IRB has specific requirements for information that can be included in advertisements. See HRPP Policy #3.5 for information.

The following items are appropriate to include in an ad:

- Name and address of the PI and associated institution
- A clear statement that the activity is research
- Purpose of the research
- Eligibility criteria (in shortened form)
- A brief list of potential benefits to the subject, if any
- Time or other commitments required from the subject
- Location of the research, contact person, and phone number for further information
- IRB number

If applicable, you may mention that compensation is available but you may not provide the dollar amount. Avoid words such as "new," "improved," and "better."

The layout of the advertisements must conform to UNMC's requirements regarding the use of logos and brands. Templates are available on the brand platform website, "Brand Wise".

Industry-sponsored research also requires sponsor approval of any advertisement or promotional pieces in addition to UNMC IRB and campus approvals.

Where to Advertise a Study

You are encouraged to post your IRB approved study on the UNMC Clinical Trials database, an online, searchable directory of UNMC based clinical trials. To post a study, follow the instructions listed in the Clinical Trials Database Guide.

Translating Study Materials

Translation services are available through Nebraska Medicine Interpretive Services Office. Staff interpreters translate Nebraska Medicine documents, pamphlets, consent forms, and patient education materials, including site translation of discharge forms. Research documents including IRB consent forms are translated on a first come first served basis as time allows. To request services, visit the Interpretive Services Request form on the Nebraska Medicine intranet.

The Center for Reducing Health Disparities offers translation services of IRB approved research related documents for a fee. 402-559-2095

Translation services are available at Children's Hospital & Medical Center. More information is available on their website or by calling 402-955-5418.

Recruiting Underrepresented Minorities

Assistance and consultation for recruitment of underrepresented populations may be available through the Research Branch of the Center for Reducing Health Disparities. The CRHD provides services to facilitate health disparities/health equity research including promotion and enrollment in

research studies.

For additional information on this and other services provided by the Center for Reducing Health Disparities, visit their website or get in touch with their office.

Phone: 402-559-9660
Email: crhd@unmc.edu

Overnight Monitoring

If a study requires overnight monitoring but your study staff are only working during the day, you may contact the CRC Manager to assist you in determining how best to arrange coverage for your study. CRC staff may be available to address personnel needs outside of business hours.

Revision #3
Created Mon, Sep 16, 2019 8:01 PM by James Geiger
Updated Thu, Oct 24, 2019 9:06 PM by James Geiger