ClinicalTrials.gov workshop

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Disclosure

- The information herein is not intended to replace any in-depth personal review of the Code of Federal Regulations, ICH GCP Guidelines, or any other applicable IRB, federal, state, or local rules, laws, or guidelines applicable to the conduct of clinical research at this site.
ClinicalTrials.gov

Food & Drug Modernization Act
Enacted November 21, 1997

- To establish, maintain, and operate a data bank of information on clinical trials for drugs to treat serious or life-threatening diseases and conditions
What is ClinicalTrials.gov?

Web-based registry that provides regularly updated information about federally and privately supported clinical trials

First version publicly available Feb 2000
September 2004

Required entry of clinical trials in a public registry prior to subject enrollment as a condition of consideration for publication of the trial results

Registration prior to enrollment of first subject for studies that had not enrolled by July 1, 2005
Which studies are required to be registered? (ICMJE)

- Studies that prospectively assign human subjects to intervention & at least one concurrent control or comparison groups.
- Studies the cause-and-effect relationship between a medical intervention & a health outcome.
- Medical intervention includes any intervention used to modify a health outcome, including drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, etc.
Public Law 110-85 Title VIII, Section 801 (*FDAAA)

- September 27, 2007
- Expansion of the data bank
- To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials
- Added some required information sections
Which studies are required to be registered? (FDA)

The trials that must be registered are called “applicable clinical trials.” (Section 801)

- Include:
  - Trials of **Drugs and Biologics**: Controlled, clinical investigations (other than Phase 1 investigations) of a product subject to FDA regulation
  - Trials of **Devices**: Controlled trials with health outcomes (other than small feasibility studies) and pediatric post-market surveillance
  - NIH encourages registration of **ALL** trials whether required under the law or not.
Who is responsible for Registering?

- For **Investigator-initiated** trials, the lead PI responsible for conducting and coordinating the overall clinical trial takes responsibility for registration.

- For **Sponsor-initiated** trials, the Sponsor takes responsibility for registration.

- Trials sponsored by the federal government (e.g. NIH) should be registered by the grantee (PI).
Who is Responsible for Registering?

Trials involving Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications with the U.S. FDA should be registered by the IND/IDE Holder.
When must trial be registered?

- All trials should be registered prior to subject enrollment
- Must be registered within 21 days of the first subject enrollment date
Penalties for failing to Register an “applicable clinical trial”

- For responsible parties who fail to register, or provide false or misleading information in connection with, applicable clinical trials, the penalties are significant and may include civil monetary penalties and, for federally-funded trials, the withholding or recovery of grant funds.
When can trial be registered?

- At UC Davis, it is required to be IRB approved prior to entry into the Protocol Registry System (PRS)

- Should be registered prior to enrollment of first subject
How do I register a trial?

- There are 2 types of accounts:
  - Organization Account
  - Individual Account
How do I register a trial?

- UC Davis has an Organizational Acct
- UCD ClinicalTrials.gov Protocol Registration System (PRS) Administrator
- Assigns/controls access for all users for all UCD studies registered
How do I register a trial?

- Establish an account
- UCD - Send an e-mail request to Denise Owensby (Lotus Notes)
- The subject line should state “ClinicalTrials.gov Protocol Registration”
- Include the name, telephone number, and email address of the individual who will be completing the listing
- Within 2 business days, you will receive an e-mail message from ClinicalTrials.gov containing your login name and temporary password
Register the Trial

- Go to the ClinicalTrials.gov registration website [https://register.clinicaltrials.gov/] This link will be on the email from ct.gov

- Complete the login fields
Each Record Lists:

- Title, PI, lay & detailed description
- Requirements for participation
- Disease or condition and experimental treatments studied
- Locations where the study is available
- Contact information
- Links to relevant information at other health Web sites, such MedlinePlus and PubMed
Each Record Lists:

- Study Design
- Interventions
- Eligibility Criteria
  - Inclusion Criteria
  - Exclusion Criteria
- Start Date & End Dates
- Outcome Measures
Before you are finished...

- Check for:
  - ERROR messages - which indicate serious problems that need to be addressed
  - ALERT messages - which indicate problems that need to be addressed
  - i-NOTE messages - which indicate potential problems that should be reviewed & corrected as needed
What happens next?

- Click [Complete] in the Record Status area of the Edit Protocol screen
- This generates automatic e-mail notification to the CT.gov Administrator that the record is complete
- Your CT.gov Administrator will review the record. Approved records are released to ClinicalTrials.gov.
Responsibilities once Trial is Registered

- Ensuring that the information is complete, accurate and updated
- Every 6 months or as changes occur
  - Review listing & update as necessary
  - Active trials / Recruitment Status
  - Closed to Enrollment
  - Holds
Additional Responsibility

- Enter some specified study RESULTS data into the Basic Results System
Basic Results Data Entry System

August 2008

Basic Results Data Entry System
Basic Results Data Entry System

- Basic Results Data are required to be entered 1 year following the Primary Completion Date.

- “Primary Completion Date” – the date that the final subject was examined, or received an intervention for the purposes of final collection of data, for the Primary Outcome.
Basic Results Data Entry

- Pay special attention to study Arms/Groups and Outcome Measures, including time frame, as they are used to pre-fill the Results section.
Basic Results Data Entry

- Key information relevant to the recruitment process
- Significant events & approaches for the overall study
- Participant Flow: # subjects started & # subjects completed study
- Distribution of subjects within reporting groups
Basic Results Data Entry

- Outcome Measures
- Adverse Events/Serious Adverse Events
- Statistical Analysis for Outcome Measures
- Publication of Results
Contact Me

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