ClinicalTrials.Gov Overview
&
UCSF Clinical Research Resource *HUB*

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Office of Ethics and Compliance
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UCSF
University of California
San Francisco

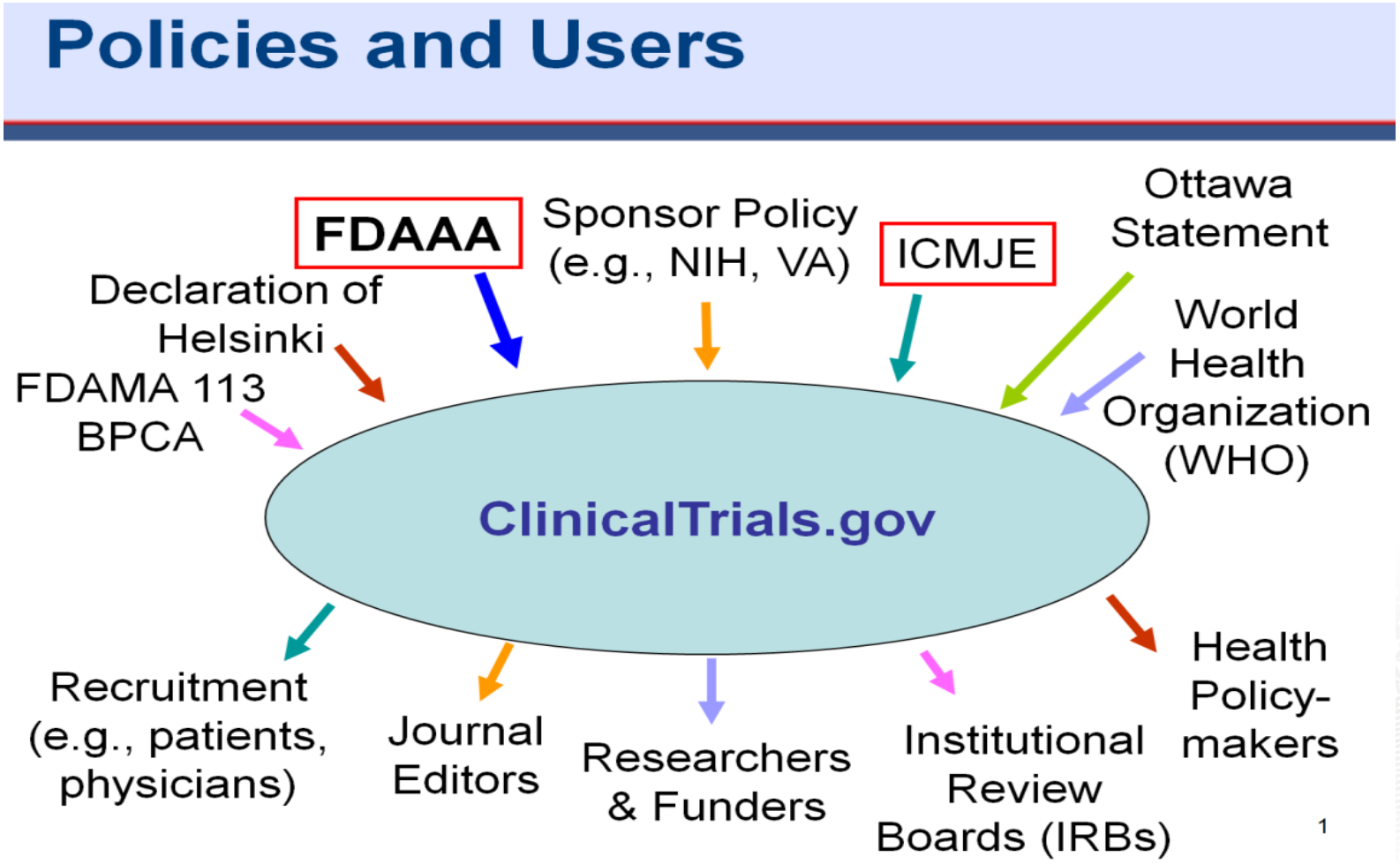
Discussion Points

- ClinicalTrials.Gov
  - Overview
  - Registration
  - Results (may not be applicable for UC Merced)
- UCSF Clinical Research Resource HUB
- Q & A

Be aware that…

- Any PowerPoint presentation is only an introduction to a topic
- This subject is complex – this will point you to other resources – and our office is happy to assist you further
- PowerPoint bullets are neither the law nor regulations
- Information here may be superseded
  - (For example) November 2014:
    NIH Draft Policy on Registration and Results

ClinicalTrials.gov is a registry and results database of clinical studies of human participants



Is registration required for my study?*

- "Scientific, ethical and moral responsibility"
  - Every research study involving human subjects (WMA)
  - All interventional trials (WHO)
- As a condition of consideration for publication (ICMJE)
  - Studies of cause-and-effect between study intervention and biomedical or health outcome
- Applicable Clinical Trials, by U.S. Public Law (FDAAA 2007)
  - Most studies involving a drug, biologic or device subject to FDA regulation, or conducted under an IND or IDE
- Billing insurance for routine costs of care (CMS)
  - Report NCT# on billing claims related to a qualifying clinical trial
  - PRS reviewers assign NCT# after a study passes QA review

** Investigator-initiated studies (most industry studies will be registered by the sponsor or central site)*

Study types

- STUDY TYPE Describes the nature of a clinical study. Study types include Interventional Studies (or Clinical Trials), Observational Studies, and Expanded Access. (See also Study Type data element on http://ClinicalTrials.govClinicalTrials.gov.)

- INTERVENTIONAL STUDY (or Clinical Trial) A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

- OBSERVATIONAL STUDY A clinical study in which participants identified as belonging to study groups are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to specific interventions (as in an interventional study).

Results Reporting for ClinicalTrials.gov

- Required for Applicable Clinical Trials (FDAAA 2007)
  - Within 12 months of primary data collection
- A complex process, similar to preparing a manuscript for publication
  - Requires close involvement of individual(s) familiar with the study design and data analysis (clinical investigator &/or study statistician)
  - Accurately summarize results information in a tabular format required by law
  - Ensure consistency with review criteria
- New ISTs should budget for PI/CRC/PPM/statistician time needed to comply

OMB Burden Statement

OMB NO: 0925-0586
EXPIRATION DATE: 08/31/2015
Burden Statement

- Public reporting burden for this collection of information is estimated to average –
  - 7.0 hours per response for initial registration
  - 2.0 hours each for 8 updates to registration during the course of the trial
  - 25.0 hours per response for initial results submission
  - 8.0 hours for two substantive updates to the results information
  - These estimates include the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information.

HOW to register a study?

- Protocol Registration and Results System (PRS)
  - https://register.clinicaltrials.gov
  - Data entry system for registering a clinical study and submitting results at the conclusion of a registered study
- PRS User: Individual given login credentials to access PRS
  - Enter information about a study, ensuring that the information is correct and updated in a timely manner over the life of the study
  - Currently at UCSF, PRS user accounts are given only to principal investigators of investigator-initiated studies
- PRS Reviewers: NIH/NLM team that reviews PRS submissions
  - Review for logic, completeness and consistency prior to public posting
  - Provide feedback (stipulations) via “QA Comments”

PRS: “New Record”

- Starts a series of data entry modules
  - Not very intuitive ☹
  - Detailed information at these various links (don’t assume):
  - **Help** – read the Help link at the start of each module to understand the requirements
  - **Protocol Data Element Definitions** - Read the definition before entering each field to ensure the correct information is entered
  - **Help > Protocol Review Criteria** – To avoid delays in registration, check your entries against the review criteria before submitting a new or updated record
  - Check the HUB or contact a PRS Administrator at UCSF (Elaine, Marlene) for specific questions about registering a study

Compliance through the study life cycle

- Registration – prior to enrollment
  - Allow time for data entry and QA review
- Keep records up to date – at least every 6 months
  - Accuracy and timeliness of public information is extremely important to patients and health care professionals
  - Recruiting status – update within 30 days
  - Start date, Site status, Recruiting status, Completion date
- Resolve “Problem Records” in the PRS user account
- Submit Results
  - Within 12 months of final data collection for primary outcome

Problem Records

- Not Completed
- Ready for Review and Approval
- Update Not Released

- Not Recently Updated – Not Recruiting
- Not Recently Updated

- Pending PRS Review Comments
  - See “Review Comments” link in study summary record

- Late Results – per FDAAA

ClinicalTrials.Gov

Where this information can be found on the HUB

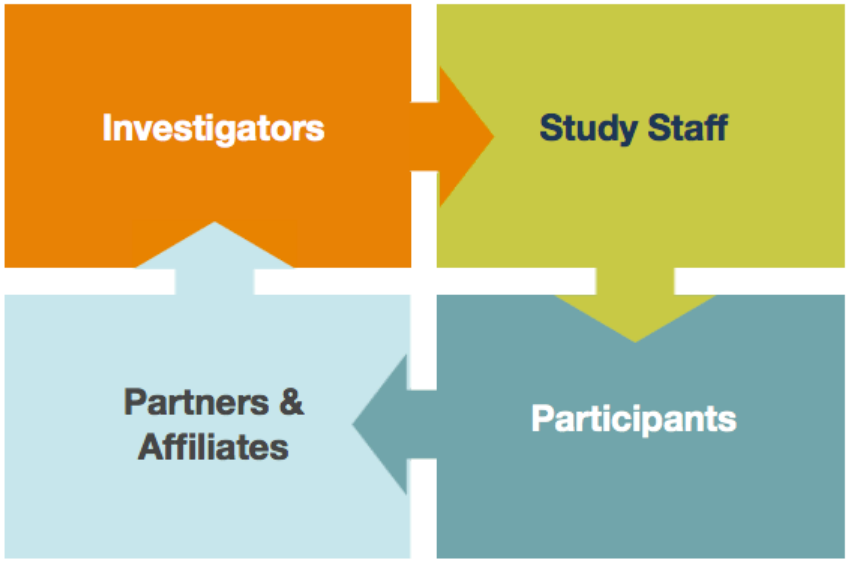
http://hub.ucsf.edu/

Clinical Research Resource HUB

tools, templates, guidance and go-to ...

The *HUB* provides a single portal to resources, expertise, and best practices for investigators, study staff, participants and partners/affiliates.

Click Below to Get Started!



WHO YOU ARE

- Investigators
- Study Staff
- Participants
- Partners & Affiliates

TRIAL MANAGEMENT

- Budgeting & Billing
- Consent Development
- Data & Safety Monitoring
- Data Management
- Feasibility & Review
- Protocol Development
- Recruitment Strategy
- Regulatory Binder
- Safety Reporting
- Study Management

REGULATORY

- 21 CFR Part 11 Compliance
- ClinicalTrials.Gov
- FDA & OHRP Inspections
- FDA Alerts
- IDE Development Process
- IND Development Process
- SOPs

TRAINING

- APex / STOR / UCare
- Clinical Trial Budgeting
- Good Clinical Practice
- Human Subjects
- iMedRIS / CHR
- Investigator Resources
- OnCore
- Research Coordinator
- Safety Courses

UCSF QUICK REFERENCE

- Contracts & Grants
- Cores Search
- Ethics & Compliance
- Glossary
- Human Subjects Protection
- ICH GCP Guidelines
- Industry Contracts
- Med Center Research Policies
- MyAccess
- UCSF Profiles

ABOUT THE HUB

- Contact Us
- HUB Vision & Goals
- Who We Are

The HUB is a collaborative effort of the Office of Research, the Office of Ethics and Compliance and the Clinical & Translational Science Institute (CTSI).

Not finding what you need? Contact Us | HUB@ucsf.edu | 415.476.9371 | 415.476.9429

Clinical Research Resource *HUB*

tools, templates, guidance and go-to ...

Search

Clinical Research

- Design Study
- Set Up Study
- Conduct Study
- Close Out Study

Trial Management

- Budgeting & Billing
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Regulatory

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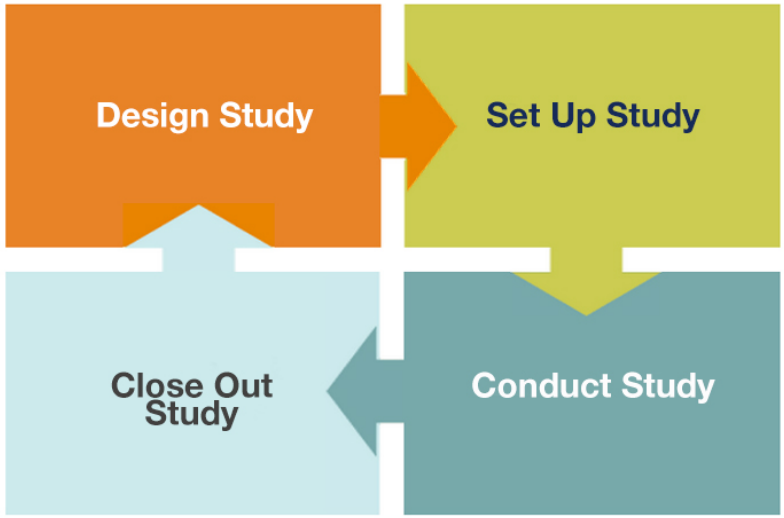

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Training

- APeX / STOR / UCare
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- Clinical Trial Budgeting
- Good Clinical Practice
- Human Subjects
- iRIS / CHR
- Investigator Resources
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- New Investigators
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UCSF Quick Reference

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Cancer Center | Clinical & Translational Science Institute | Contracts & Grants | Core Search | CTSI Clinical Research Services
Environmental Health & Safety | Global Health Research | Human Research Protection Program | Industry Contacts

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Design Study

LEARN ABOUT FEASIBILITY & REGULATORY REQUIREMENTS

Evaluate Study Feasibility
IRB Approval
Regulatory Support, Resources, and QuickLinks
Assistance with an FDA Device (IDE) Submission
Assistance with an FDA Drug or Biologics (IND) Submission

EXPLORE FUNDING OPPORTUNITIES & BUDGET PREPARATION

Identify Funding Opportunities
Proposal Preparation and Submission
Assistance with Informatics/IT Support Section of Your Proposal
Set Up Research Budgets & Participant Billing
Overview of Coverage Analysis, Budget and Billing Process
Support for Research Participant Billing
Billing Codes and Research Pricing Information

SEEK STUDY DESIGN ASSISTANCE & RESOURCES

Identify a Patient Cohort for Reseach
Request a CTSI Ethics Consultation
Research Data Management Best Practices (Consultation)
Review Project for HIPAA, Privacy & IT Security Requirements
Clinical Informatics - Information and Consultation
Biostatistics - Information and Consultation
Study Design - Information and Consultation
Clinical Data Related to Research - Electronic Health Record
Clinical Research Services (CRS)
Research Data Management Tools
Find a Collaborator or Mentor

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Set Up Study

PROPOSAL, FUNDING, BUDGET & BILLING

- Identify Funding Opportunities
- Proposal Preparation and Submission
- Assistance with Informatics/IT Support Section of Your Proposal
- Set Up Research Budgets
- Participant Billing
- Overview of Coverage Analysis, Budget and Billing Process
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INITIATE REGULATORY TASKS

- Submit CHR Application for Human Subjects & Stem Cell Research
- Submit IACUC Application for Animal Subjects Research
- Submit Applications for Studies Requiring Biosafety & Radiation Approvals
- Prepare Regulatory Binder

COMPLETE THESE TASKS BEFORE ENROLLING STUDY PARTICIPANTS

- Register Study on ClinicalTrials.Gov
- Investigational New Drug (IND) Submission to FDA
- Investigational Device Exemption (IDE) Submission to FDA

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configure edit menu

edit the menu that defines this block

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Conduct Study

MANAGE BUDGET & BILLING

- Manage Budgeting & Billing-Overview of Services
- Resources for Budgeting & Billing
- Support for Research Participant Billing

REQUESTING HELP WITH ENROLLMENT, ETHICS & MORE

- Access Electronic Health Records
- Request a Consultation - Ethics (Bedside)
- Request a Consultation - Ethics (Benchside)

REVIEW REGULATORY & COMPLIANCE DOCUMENTS

- Regulatory and Compliance - Support Services, Resources, and QuickLinks
- Medical Center Policies
- Standard Operating Procedures
- Review Regulatory Binder Requirements

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Close-Out Study

STUDY COMPLETION TASKS

- Study Closeout Reports
- UCSF Document Management and Storage
- UCOP Record Retention Relating to Research
- Update Results on ClinicalTrials.Gov

GET ADVICE ON MEDIA OUTREACH (BEFORE AND AFTER PUBLICATION)

- Media Coverage at UCSF
- News & Media Services
- Media Coverage Guidelines
- Publishing & Open Access

PUBLISH YOUR STUDY – REQUIREMENTS!

- Comply with NIH Public Access Policy
- Acknowledge Grant Support - Wording for Manuscipts
- Submit Manuscript to PubMed Central and Report PMCID
- Publishing & Open Access

Questions?

For questions about clinical trial registration,

please visit the HUB or

contact a PRS Administrator

Elaine.Cooperstein@ucsf.edu 415-502-3212

Marlene.Berro@ucsf.edu 415-476-9429