Clinical Research Office: Services

From

To

of a Clinical Research Study

NIH Definition of Clinical Research

- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes:
    a. Mechanisms of human disease,
    b. Therapeutic interventions,
    c. Clinical trials, or
    d. Development of new technologies.
- Epidemiologic and behavioral studies
- Outcomes research and health services research

NIH definition of Clinical trials

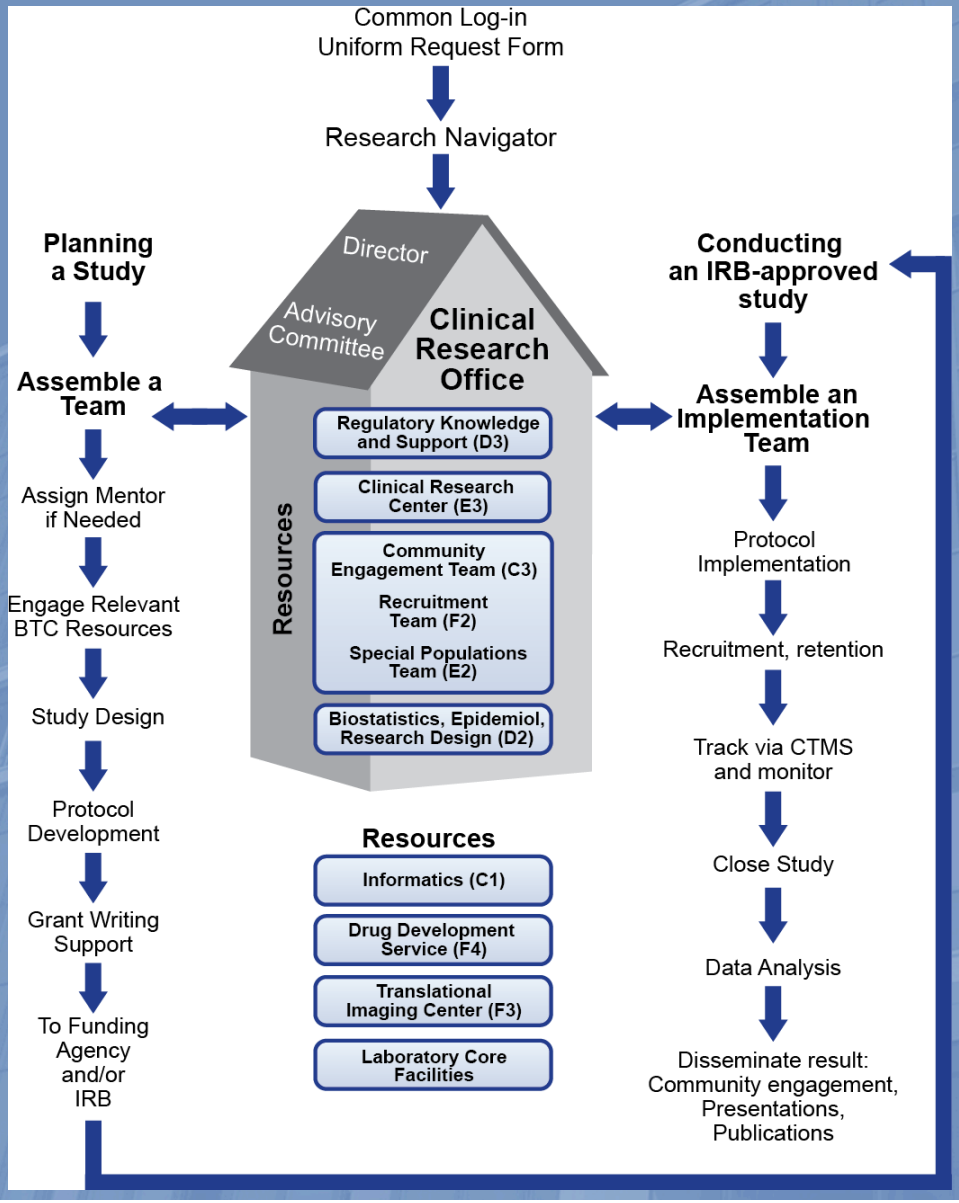
- A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Clinical Research Office March 8, 2016

Clinical Research Office Staff

Function	Number of Staff Assigned
Oversee Operations (RNs)	2
Contract negotiation	2
Budget design and negotiation	2
Coverage analysis	2
Regulatory review and support	2*
IRB pre review (clinical research facilitators)	2*
Accounts receivable/accounts payable	2
Research coordinators	7
CTMS “Super Users” trained	5
IT, data entry, data “extraction” support	2*

*Supported by CTSA


Common Log-in
Uniform Request Form
Research Navigator
Director
Advisory Committee
Clinical Research Office
Planning a Study
Assemble a Team
Assign Mentor if Needed
Engage Relevant BTC Resources
Study Design
Protocol Development
Grant Writing Support
To Funding Agency and/or IRB
Resources
Regulatory Knowledge and Support (D3)
Clinical Research Center (E3)
Community Engagement Team (C3)
Recruitment Team (F2)
Special Populations Team (E2)
Biostatistics, Epidemiol, Research Design (D2)
Resources
Informatics (C1)
Drug Development Service (F4)
Translational Imaging Center (F3)
Laboratory Core Facilities
Conducting an IRB-approved study
Assemble an Implementation Team
Protocol Implementation
Recruitment, retention
Track via CTMS and monitor
Close Study
Data Analysis
Disseminate result: Community engagement, Presentations, Publications

CRO: Initiatives

- Developing new workflows incorporating
  - Study Registration
  - Departmental/School Scientific Review
  - Research facilitator
- Policies and Procedures (Investigator Handbook/Website redo)
- CTMS (OnCore) Implementation
- Collection of metrics
- Central IRB for multi-site Clinical Trials
- Accelerated Confidential Disclosure Agreements (ACDA)
- Accelerated Clinical Trial Agreements (ACTA)
- SUNY Integrated Clinical Trial Infrastructure

Scientific Review

- Not a Top Down approach
- Recognize diversity of Clinical Research
  - Biomedical research
  - Social and Behavioral research
- Two working groups
- Initial drafts (policy and form) substantially modified based on input from working groups
- Currently working on integration into CLICK

Scientific Review: Final Products

Departmental Scientific Review Committee Policy

Purpose: The purpose of the scientific review is to ensure that proposals reflect an acceptable level of scientific rigor and merit prior to ethical (IRB) review. Ensuring scientific merit is a key component in protecting the rights and welfare of our human research participants. Through the scientific review process we ensure that the study is well designed and has adequate resources so that we do not expose research subjects to unnecessary harms.

Specifically, accreditation standards require the scientific review shall confirm the following:

a) the research uses procedures consistent with sound research design, which do not unnecessarily expose subjects to risk;
b) the research is likely to answer the proposed question; and
c) the knowledge reasonably expected to result from the research has scientific importance.

Scientific review committees should insure that the evaluation of the scientific merit of protocols does not conflict with principles of academic freedom.

This policy is designed to allow the IRB to focus its efforts primarily on ethics issues regarding human subject protections. While the IRB will continue to review issues of scientific design and subject safety as needed in the context of subject protection, the scientific review policy will enable those with the most relevant scientific expertise to be responsible for assessing scientific merit.

Purview: Projects that will undergo departmental scientific review prior to IRB review will include research protocols that are:

- investigator initiated and have not undergone peer review (e.g., pilot studies, unfunded research projects);
- sponsored by industry, but not under an IND or IDE application (e.g., single site clinical trials);
- supported by national or local funding agencies which do not have a robust peer review process.

Research proposals that have undergone equivalent or greater scientific review by another body will not require departmental/school scientific review prior to submission to the IRB. Such research proposals include those that are/have:

- undergone peer review and is under consideration for funding by federal agencies (e.g., including but not necessarily limited to NIH, NSF);
- supported by national or local funding agencies with robust peer-review processes (e.g., including but not necessarily limited to American Heart Association, American Cancer Society, Alzheimer's Association);
- sponsored by industry AND being conducted under an IND or IDE application (e.g., multi-site clinical trials);

Departmental or School Scientific Review of Human Subjects Research Protocol Documentation

Department/School name	
Title of research protocol	
Principal Investigator:	

Fill out **either** Section A **or** B

A. This protocol does not require Departmental/School scientific review because:

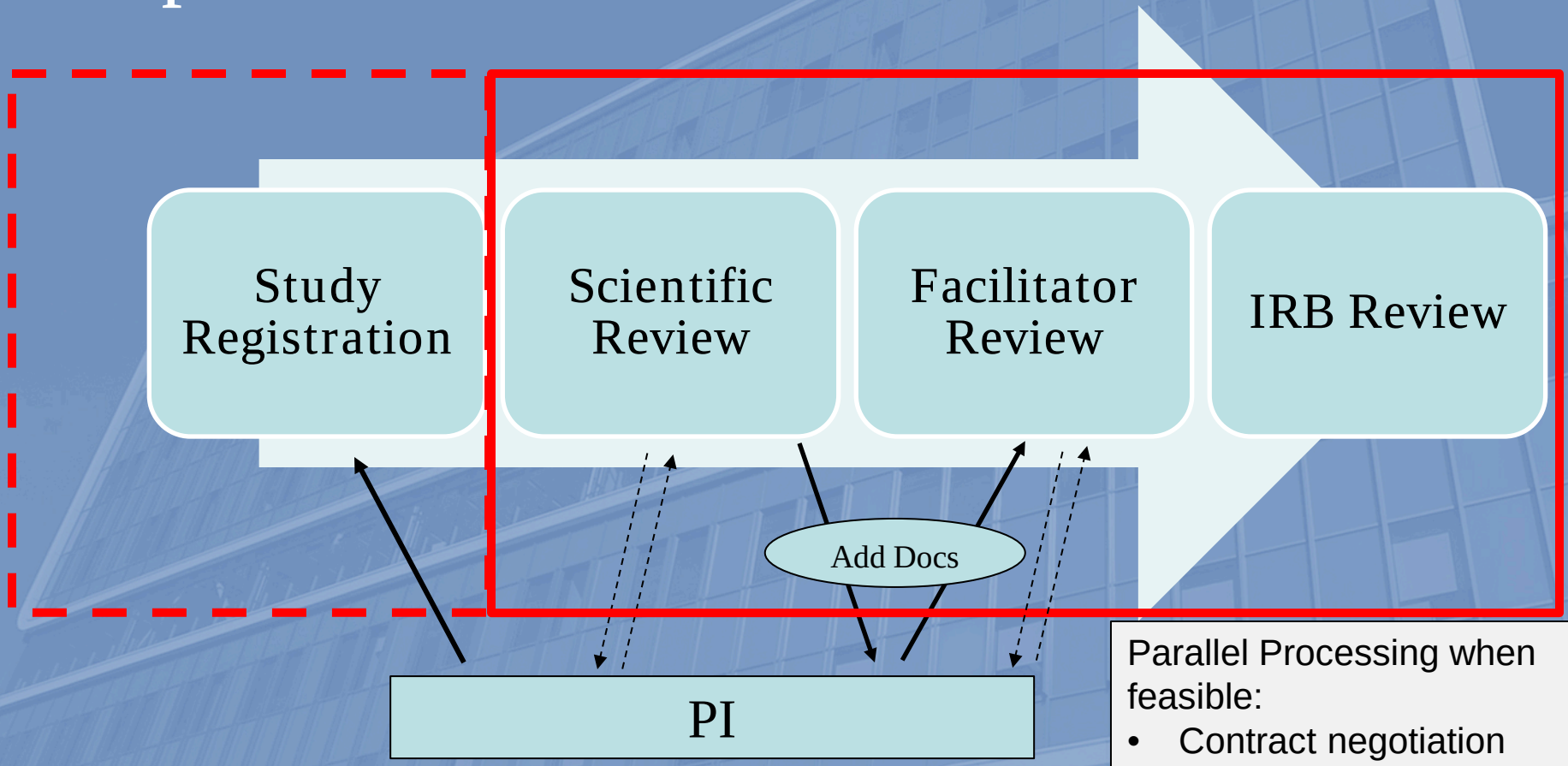
- ☐ It is funded by a federal agency. Please specify _____.
- ☐ It is supported by a national or local funding agency with robust peer-review processes Please specify _____.
- ☐ It is sponsored by industry and being conducted under an IND or IDE application. Please specify _____.
- ☐ It is a student research project that has been approved by a formal advisory committee (e.g., thesis or dissertation research). Please specify _____.
- ☐ It is a study that would be regarded as 'Exempt' from IRB approval.

B. The Scientific Review committee of our department/school has evaluated the above-named research protocol and has found the following:

Criteria	Comments (optional)
1. The rationale for the study is clearly stated and the rationale is scientifically sound.	
2. The aims and/or corresponding hypothesis are clearly stated.	
3. The primary outcome (and secondary outcomes, as appropriate) is clearly defined.	
4. There are adequate preliminary data in the literature (or from the investigator) to justify the proposed research. An adequate literature review has been done to support this study.	
5. The question or hypothesis being tested is providing important knowledge to the field.	
6. The design of the study is appropriate for the questions posed.	
7. All measures are of appropriate quality and applicability for the proposed study	
8. The proposed subject population is appropriate.	

Please submit this form as part of the 'Other Study Documents' with the IRB application in Click.

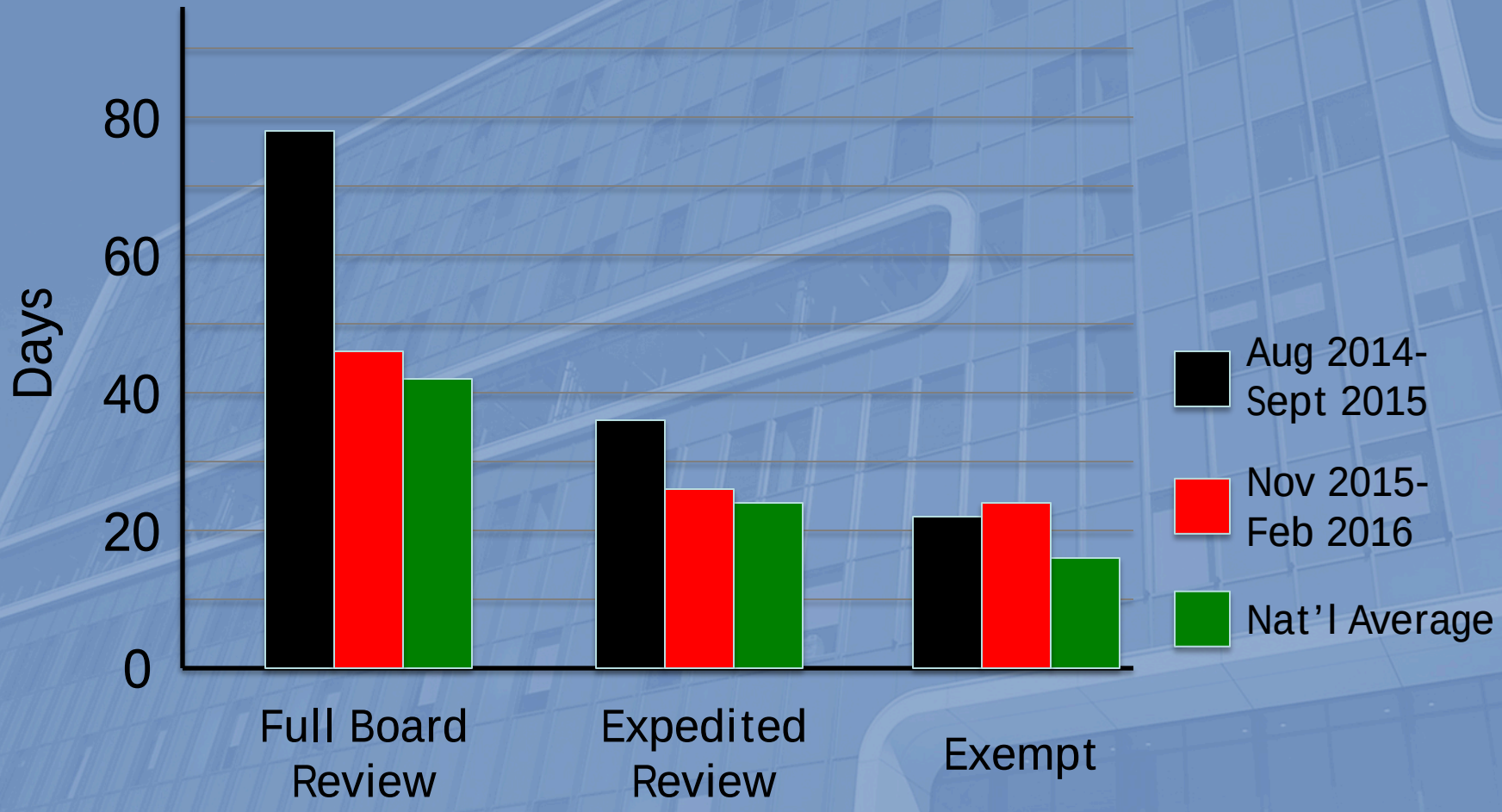
Proposed Workflow



Parallel Processing when feasible:

- Contract negotiation
- Budget negotiation
- Affiliate agreements
- Conflict of interest
- Coverage analysis

IRB Turnaround Time



One year goals: Clinical Study Activation

Reduce IRB turnaround time

- Implement scientific review
- Fully implement pre review by facilitators
- Multi center industry sponsored trials to be reviewed by centralized IRBs
- Follow metrics in real time and be responsive

Sign and use IRBrely Master Common Reciprocal IRB Authorization Agreement

Reduce time for contracts, budgets and coverage analysis.

Adopt and use Accelerated Clinical Trials Agreement (ACTA)