BU Clinical & Translational Science Institute (CTSI)

Research Professionals Network Workshop Series

STUDY START-UP TIMELINE

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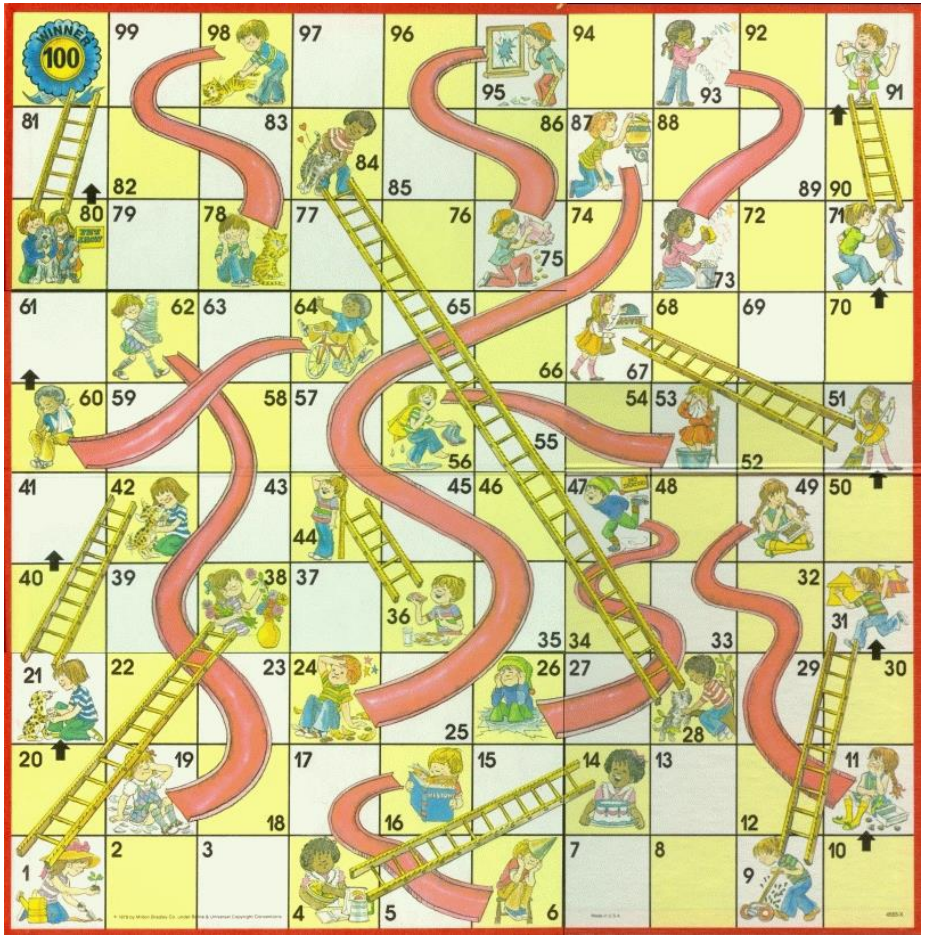
Objectives

- Identify the activities associated with starting a research study at BU/BMC
- Describe the various parties involved in starting a new research study at BU/BMC
- Compare the differences in study start up plans and timelines for drug v. socio-behavioral studies
- Create a mock study start-up plan and timeline for a “new” research study using case studies

Study Start-Up in a Nutshell

Study Start-up



Start Here

Where do we begin?

At the beginning,
of course!

Who is involved?

- Principal Investigator
- Sub-investigators
- Research Coordinator(s) & other research staff
- Sponsor (Industry? NIH? Etc?)
- IRB / IBC
- Pharmacy
- OSP (BU) / Grants (BMC)
- Clinical Trial Office (BMC)
- Infrastructure Services
- GCRU
- Departmental Support?
  - Laboratory Medicine
  - Radiology?
  - Pulmonary?
  - Orthopedics?
  - Psychiatry?
  - Emergency Room?
  - Etc?

Site Assessment/Selection

Questionnaire		
#	**Evaluation of eligibility criteria**	**Answer**
1.	(a) How many adults aged 18 to 65 years (inclusive) patients with PAH* Group I (etiology: idiopathic, heritable, CTD, corrected simple congenital heart disease, drug/toxin induced) are actively followed at the site? (b) How many adults aged > 65 Years are followed at the site? **PAH must have been confirmed by RHC using the standard definition from Dana Point 2008 (resting mPAP>25 mmHg, PCWP≤15 mmHg, PVR>240 dyne.m.sec-5 or 3 Woods Units)*	
For the questions below please provide actual number of patients rather than %		
2.	Among patients referred to in **Question 1a**, how many are in modified NYH/WHO FC I-III?	
3.	Among patients referred to in Question 2, how many are able to walk ≥165 meters during a 6MWT?	
4.	Among patients referred to in Question 2: (a) how many have at least one of the following co-morbidities: - Severe coronary heart disease - Unstable angina - Decompensated cardiac failure not under close supervision	

The CDA

CDA stands for Confidentiality Disclosure Agreement (also known as a non-disclosure agreement, or NDA)**.**

- Needs to be completed in order to receive basic study documents from the study sponsor or coordinating center.
- Can help the investigator decide if they feel that this study is something they would want to participate in.
- But why?
  - You would want to use this form if you want to share confidential information such as study design, drug or device information.
  - Protect intellectual property

Documents Needed Prior to Start-up

Contract

Budget

IRB Approval

PSF, CTA, MCA, VELOS, & More

BU – CDA and PSF to OSP

MCA/Velos Determination Checklist
http://internal.bmc.org/grants/MCA_Velos_Determination_Checklist_Form.htm

- Once submitted, an automatic email alert is sent to the BMC CTO inbox.

CTO staff will review the checklist.

- If BMC clinical infrastructure is utilized, the study will be assigned to a Financial Analyst who will reach out to the study team.
- If BMC clinical infrastructure is not utilized, CTO staff will notify the study team, with a cc to BU OSP, that the study does not need to be reviewed by the CTO.

The Budget

"Spare a dollar for some lab consumables, buddy?"

Image credit © Eoin O'Sullivan : http://www.ifm.eng.cam.ac.uk/research/grant-writers-handbook/cartoons/

Essential Regulatory Documents

- Signed CDA/NDA
- Signed protocol (and amendments if applicable)
- CTA (Clinical Trial Agreement) or Contract
- Budget agreement (sometimes part of the contract)
- FDA1572
- FDA1571 (if needed) – Do you need an IND?
- CV's for key personnel (those listed on 1572)
- Licenses (MD, PA, NP, RN, etc)
- Trainings (GCP, HIPAA, Human Subjects Protections, others)
- Clinicaltrials.gov registration

Establishing the Study Team

- Principal Investigator
- Sub-investigators
- Research Coordinator(s) & other research staff
- Sponsor (Industry? NIH? Etc?)
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  - Etc?

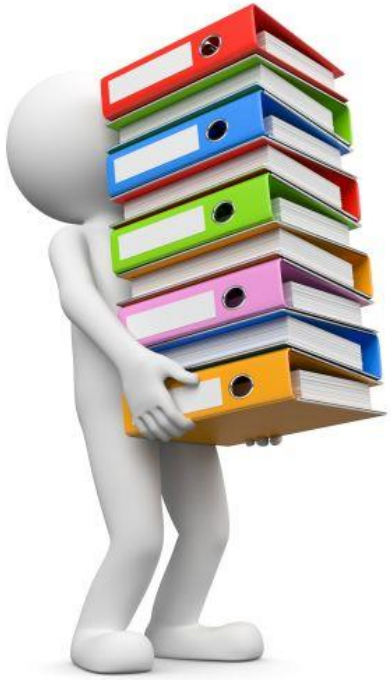
Essential Documents and Submission to the IRB

Protocol

Consent Form(s)

Investigators brochure

Questionnaires or any subject facing materials



Investigators/Advisory Meeting

- Commonly conducted prior to (or just after) subjects are enrolled in the study
- Sponsors share details on the study and investigator/teams can meet to discuss logistics
- Stakeholder advisory meet normally meet regularly and are involved in both the study start-up plans and implementation plans

Recruitment & Enrollment Plan

- Develop a plan to identify potential subjects
- Develop advertising tools
- Develop a plan to screen potential subjects
- Identify potential barriers to recruitment
- Develop a plan to enroll subjects
- Address competing trials are your site
- Develop a plan to obtain informed consent
- Develop educational materials for subjects

Training Site Personnel

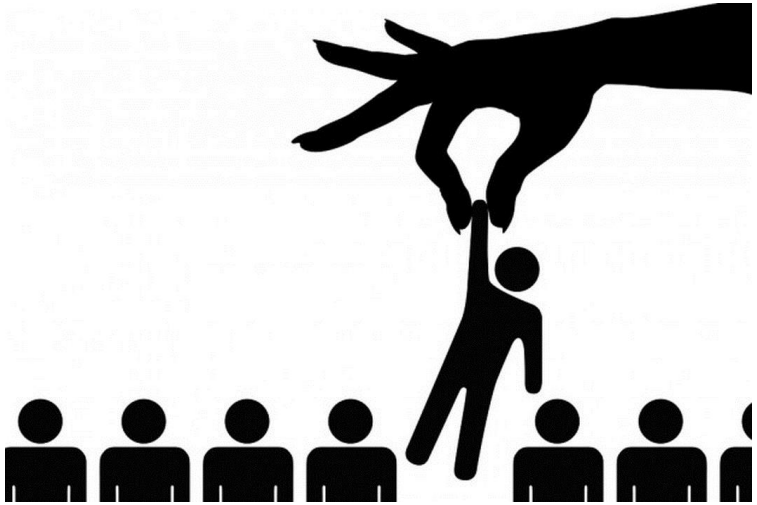
- **All** study personnel should be trained!
- Schedule presentations for key departments that you'll need to work with to ensure they are aware of the trial & to provide them with study materials
- Create and train research staff on data collection resources
- Create and share SOPs with staff

Randomization & Enrollment

Make sure you have all the materials you need for the study PRIOR to recruitment & enrollment

i.e. medical devices/drugs & proper storage

Have a randomization scheme (ie envelopes/IXRS/IVRS) ready to go!



Sample Case Studies

GOALS AS THE STUDY COORDINATOR:

1. **Provide the order in which study start-up activities need to occur.**
2. **Provide the PI with an estimated timeline of when key tasks need to occur in order to proceed without delay.**

Testing whether laughter *is* the best medicine

Thank you!

We hope to see you again soon!

Tuesday November 14, 2017
Classifying & Reporting Adverse Events, Deviations, and Unanticipated Problems
Presenter: Alana Ewen, MPH and Claire Oppenheim, MPH
Time: 3:30 p.m. to 4:30 p.m.
Location: L-212

Thursday December 7, 2017
Monitoring, Auditing, and Self-Assessments
Presenter: Fiona Rice, MPH
Time: 1:00 p.m. to 2:00 p.m.
Location: L-206