Sue Flynn
Human Subject Compliance Manager
Your Resources at the Broad

- Sue Flynn, Human Subjects Compliance Manager
  sflynn@broadinstitute.org or 714-7221
- Jackie Murphy, Human Subjects Compliance Coordinator
  jamurphy@broadinstitute.org or 714-7211

WE ARE LOCATED AT 301 BINNEY ST, office 5086 and our fax is: 617-714-8935
Initial FACT FINDING should include:
- Sample source, types of samples
- Expected project start date
- Scope of research at Broad, plans for data generated, publication or data release
- Determine funding source for research

Contact Sue for a discussion or meeting at sflynn@broadinstitute.org
• Our IRB of record is MIT’s Committee on the Use of Humans as Experimental Subjects (COUHES)
• Submissions types for Human Subjects Research
  – Application for an “exemption”
  – Standard application (full or expedited)
  – Amendment to existing protocol
How do you know which application you need?

• Gather facts about sample cohort
• Discuss with Sue Flynn
• Most common process at the Broad is application for an “exemption”

Document gathering begins now!
Fact finding leads to the appropriate application process…

• **Exempt application**
  - We are receiving de-identified material
  - The PI has no access to identifiers or the link
  - We are not conducting or funding a prospective collection

Document gathering begins now!
Fact finding leads to … an amendment

- **Amendment** to an existing protocol for a new sample cohort
  - PI agrees with addition of cohort
  - Science goals must be similar, but can be expanded at this time
  - Funding can determine this decision

Document gathering begins now!
Fact finding leads to … a “standard” application process: decision based

• The PI has access to the link to the subjects identity
• The Broad is funding the collection
• Determined by local IRB, cohort deemed not “exempt”, example FHS
• Utilized for rare disease cohorts
Next Steps............

• Yes, again I say, “continue document gathering from collaborator”!
• Prep application for review by Sue/ Jackie
• Include summary of science to be done at the Broad in “lay terms”
• Determine list of study personnel
• Verify funding source for scope of work
Documents we need …

• Draft of IRB application for review
• IRB “letter of approval” from the collaborator
• “BLANK“ Consent Form template from the collaborator
• Final application back to Sue/Jackie for final review ready for signature by PI
Why are we the compliance team here at the Broad?

- The Broad is obligated to protect human subjects
- To ensure the Broad Institute remains compliant with federal regulations related to humans subjects research
- To help “YOU” & the Broad reach research goals
- You are not “rocket” scientists but...
- …the clock is ticking on new discoveries
The Broad requires this training for all to ensure protection of all human subjects involved in research.

In a recent quote from Stacey Donnelly, the Broad’s Director of Sponsored Research & Planning stated, “We’re asking everyone at the Broad to do this – it’s part of the Broad culture.”
The facts on training...

- We use the Collaborative Institutional Training Initiative program (“CITI”) course at https://www.citiprogram.org
- This link can be found on the Broad Intranet, type in “Human Subjects Training”
- There are three levels of training
- Save a copy for your own records!
- Renew every 3 years
Other Resources at the Broad

• NOT Human material, but you have a animal (vertebrates) sample to bring into the Broad, contact Stacey Donnelly at donnell@broadinstitute.org or 617-714-7130 for assistance

• MIT Human Subjects guidelines at: http://web.mit.edu/committees/couhes/policies