NRG Oncology
Breakout: "Becoming Research Ready"

Define the job expectations

- Tailor the education to realistic expectations
- Explain the Lead coordinator role/your site study coordinator role

Acronyms (see handout)

Introduction to Human Subject Research

- Human Subject Protection Training: includes the history that contributed to current practice, regulation and guidance
- International Conference on Harmonization (http://www.ich.org/)
- Declaration of Helsinki (http://ohsr.od.nih.gov/guidelines/helsinki.html)
- Belmont Report (http://ohsr.od.nih.gov/guidelines/belmont.html)
- Education-requirements of each institution as well as sponsor-specific(e.g. CITI training) CITI on-line Training: http://www.citiprogram.org/
- Roles and responsibility of the IRB (the governing board for human subjects' protection)
- Federal Regulations, FDA Guidances: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/default.htm
- GCPs: The complete GCP guidelines can be found at: http://www.fda.gov/oc/gcp/guidance.html. Scroll down the page to find: ICH E6: Good Clinical Practice
- Sample training : at the Fred Hutchinson U of Washington: http://www.cancerconsortium.org/rto/training/gcp/index.html

IRB Review Process

- Local policy
- CIRB
- When to submit (initial, annual, amendments, third party safety reports and SAEs)
- Full Board vs Expedited review requirements

Regulatory Related

- Mandatory documents to be kept on file (IRB approvals, OSRs submitted to the IRB, etc)
- How a protocol is set up-where to find what you need to know
- ICF: Required elements for your IRB can be incorporated into the NSABP template
- When to ask NRG Oncology to review your ICF

Navigating the Clinical Trial Network (formerly Cooperative Groups)

- NRG Oncology Structure
- Legacy Groups NSABP/RTOG/GOG
- Group orientation recommended
- CTSU https://www.ctsu.org/public/
- OPEN
- PMB http://ctep.cancer.gov/branches/pmb/default.htm
- CTEP http://ctep.cancer.gov/default.htm

Study Activities and Compliance

- Feasibility of selecting a study
- Communication tree
- SIV/prep (order drugs, kits, etc
- Plans to ship specimens/Dangerous Goods Training
- Who to contact for troubleshooting and protocol guidance
- Documentation-where to find the most current ICF, how to document that you have consented a subject
- ICF is a process, not a document
- Source documentation
- Scans, tumor measurements
- CRF Completion
- Logs (delegation of duty, training, enrollment, etc)
- Visit schedules
- Registration/randomization-use of OPEN
- Queries/monitoring/auditing
- Neurocognitive testing/credentialing
- Quality of life forms – paper or electronic

Radiation Oncology Systems and Communication

- Equipment Requirements - Review
- Credentialing – study specific vs. cross over
  - http://www.irocqa.org/
  - http://rpc.mdanderson.org/rpc/
  - http://irocri.qarc.org/
  - http://irocstl.wustl.edu/
- Include dosimetry and physics as part of feasibility process – communication KEY
- RT submission process – TRIAD
  - TRIAD information sheet http://www.rtog.org/LinkClick.aspx?fileticket=R39x3gYuNJU%3d&tabid=399
  - Triad download and Manual http://www.rtog.org/LinkClick.aspx?fileticket=cvphTdp0aw0%3d&tabid=399
    Use CTEP-IAM password

- Forms: DDSI, T5, T1
  - DDSI form located at (must have ACR password) https://cr-rtqa-web.acr.org/DDSI/User/Login?ReturnUrl=%2fddsi
  - To obtain a password http://www.rtog.org/AboutUs/RTOGPasswordApplication.aspx

- Education Module _ RTOG Legacy website http://www.rtog.org/ResearchAssociates/EducationTraining/RAEducationMaterials.aspx

Drug Accountability
- PMB slideshow as a resource http://ctep.cancer.gov/branches/pmb/idh_slideshow.htm

Fiscal
- Contracts at your site
- Research billing practice/regs
- Designated funds for specific protocol tests/procedures – CTSU website

Event Reporting
- How to read the CTEP tables re: SAE reporting expectations
- CTCAE: http://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm#ctc_40
- CTEP AERS: https://eapps-ctep.nci.nih.gov/ctepaers

Satellite sites
- Need orientation/oversight

Monitoring/Auditing of Clinical Trials
- Understands purpose and scope of audits and monitoring visits (industry trials frequently have monitors)
- Understands who to notify when audits are scheduled
- Understands how to respond to comments/create CAPs from audit findings

FDA Inspections
- Understands the purpose and scope of FDA inspections
- Understands who to contact in the event of a FDA inspection
- Understands how to prepare and host a FDA inspection
- Understands the general process of how to respond to audit findings

Other

- ONS Competencies: http://www.ons.org/media/ons/docs/publications/ctncompetencies.pdf
- SoCRA: http://www.socra.org/
- ACRP: http://www.acrpnet.org/
- NCI In-Depth Information Slides: http://www.cancer.gov/clinicaltrials/education/clinical-trials-education-series
- NCI Cancer Clinical trials Basic Tutorial: http://training.cancer.gov/clinicaltrialsbasics/index.php