webIRB Updates

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Updates

- webIRB & researchCONNECT
- webIRB regular maintenance

webIRB & researchCONNECT

- 6/19 e-mail from Arash Naeim
- Integration with CRMS
- CRMS will be a home for:
  - Coverage Analysis
  - Study Management
  - Subject Management
  - Sponsor Billing
- CRMS will also interact with CareConnect and other systems

webIRB & researchCONNECT

- Significant push toward:
  - Consistency of information
  - Elimination of duplication
  - Parallel processing
- Overlap with goals for webIRB

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webIRB & researchCONNECT

- Changes to Main SmartForm:
  - Section 1.1
    - Study staff roles harmonized
  - Section 1.1a
    - Protocol's home department
  - Section 2.1
    - "Who developed" and "cancer related" moved up

webIRB & researchCONNECT

- Changes to Main SmartForm
  - Section 2.3
    - Study descriptors moved up from 8.1
    - Coverage Analysis trigger
  - Section 2.4
    - New section for Coverage Analysis
    - CRMS upload moved
    - Drug/device billing questions moved

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- Changes to Main SmartForm
  - Section 8.3
    - Harmonized drug trial phases
  - Sections 8.5 and 8.6
    - Deleted improper IDE exemption
    - Added dates of IND/IDE paperwork
    - Made additional questions required

webIRB & Coverage Analysis

- Trigger Question and new 2.4
- Change in CA process
  - Uses webIRB more
  - No separate document submission
- Trigger question:
  - **Will the study require services or resources owned/rented/operated or provided by the UCLA Health System (e.g. clinic and/or hospital visit(s), professional medical services, clinical treatment, diagnostics, labs, medical supplies, etc.)?**

webIRB & Coverage Analysis

- Trigger Question
  - Important to answer this correctly
    - Don't be afraid
    - Avoid extra work later
  - IRB does not review this
  - Contact CTAO with questions clinicaltrials@mednet.ucla.edu

webIRB & Coverage Analysis

- If Trigger Question is "Yes"
  - New Section 2.4
  - **Will <u>all</u> protocol-required items and services that produce data for the study be funded by intramural or extramural funding/support?**
    - **Yes- not billed to subjects**
    - **No- some or all billed to subjects**
    - **Not Applicable (e.g. observational)**
  - **Consent form guidance sidebar**
    - **This is important for subjects**

webIRB & Coverage Analysis

- Also in Section 2.4
  - Is your study any of the following?
    - Investigator-initiated study
    - Expanded Access
    - Humanitarian use device study
    - Chemo/radiation therapy study
    - UCLA to rely on another IRB
  - Copy of study protocol
  - Investigational Product billing documentation

webIRB Regular Maintenance

- New schedule
- Thursday evenings 7-9pm
- Sunday mornings 12am-12pm

Thank you!

- For questions:
  - North & South General IRBs
    - x57122
    - gcirb@research.ucla.edu
  - Medical IRBs
    - x55344
    - mirb@research.ucla.edu