webIRB Updates

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August 13, 2015
Updates

- webIRB & researchCONNECT
- webIRB regular maintenance
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
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
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
webIRB & researchCONNECT

- 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
If Trigger Question is “Yes”

- New Section 2.4
- Will all 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
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
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