Hospital Study Approval Process

Human Research Academy
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CTS Research Development Services
706.721.6247
www.CTSRDS@gru.edu
Objectives

Participants will be able to:

1. Identify hospital resources

2. Explain how to obtain hospital study approval
Research Development Services

• Formerly the OCIS Research Review Office
• Work with researchers to obtain hospital approval for a study
• Provide research prices for hospital services and professional fees (Medical Associates)
• Implement hospital research scheduling and billing processes
• Obtain Medicare approval for device studies and non-standard trials
• Administrator for PowerTrials and PowerTrials Screener
RDS continued

• Provide research access to the electronic health record
• Administrator for i2b2 - hospital clinical data warehouse
• Provide technical assistance for clinicaltrials.gov
• Prepare IND and IDE applications and waivers
• Provide Coordinating Site services and study monitoring
Hospital Resources

- Patients
- Ancillary Services
- Research Pharmacy
- Hospital facilities and clinics
- Hospital databases and programs
When is Hospital Approval Required?

Hospital Approval is required prior to initiating your research study if any of the following apply:

1. Research is conducted at any GR Health locations - Cancer Center (AN), Cardiovascular Center (FW), Children's Hospital of Georgia (BT), Medical Office Building (BP), Medical Center (BBA, BB,BI, BO, BP), GR Cancer Center Radiation Therapy (HK), Wheeler Road Clinics

2. Patients are recruited from GR Health locations for participation in a research study conducted at another location.

3. GR Health medical records, databases, or other electronic patient information is accessed.
When is Hospital Approval Required?

• If your study involves any of the scenarios indicated on the previous slide, notify Research Development Services
  – Email CTSRDS@gru.edu:
    • IRB #
    • Study Title
    • PI Name
Approval Process – Billable Services (For OnCore Users)

- Upload Medicare Qualifying Worksheet
- Upload Study Billing Grid
- Upload fully executed contract
- Pick-up study labels at RDS
Approval Process-Billable Services (Sites currently not using OnCore)

• Notify RDS via Email at CTSRDS@gru.edu:
  • IRB #
  • Study Title
  • PI Name

• Complete:
  - Medicare Qualifying Worksheet
  - Study Billing Grid
  - Hospital Internal Budget

• Enter study in eSPRoute
• Email fully executed contract to RDS
• Pick-up labels
Approval Process-Device Studies

• Follow same process EXCEPT:
  - Do not complete Medicare Worksheet
  - Contact RDS to obtain Medicare Approval
How to Obtain Hospital Prices

• Contact RDS

• Non-standard Pathology Price Form

• Radiology Request Form

• Clinical Research Pharmacy Proposal
Billing Grid Essential Elements

• Template on website

• Header:
  - PI/Coordinator/Phone/Email

  - Study Short Name and Sponsor

  - CPI#

  - RDS#

  - NCT#

  - # of patients
Billing Grid Elements, cont’d

- Procedure
- CPT code
- CDM code
- Charge

- Visit Schedule

- Billing Designations:
  - INS, STUDY, PT
Billing Grid Elements, cont’d

• Designations:
  - QO, Q1
  - CL
  - RES-V
  - X

• RDS sign-off

• PI Certification/signature

• Footer: Version Date
Questions