



Office of Research Administration Clinical Research Support Services

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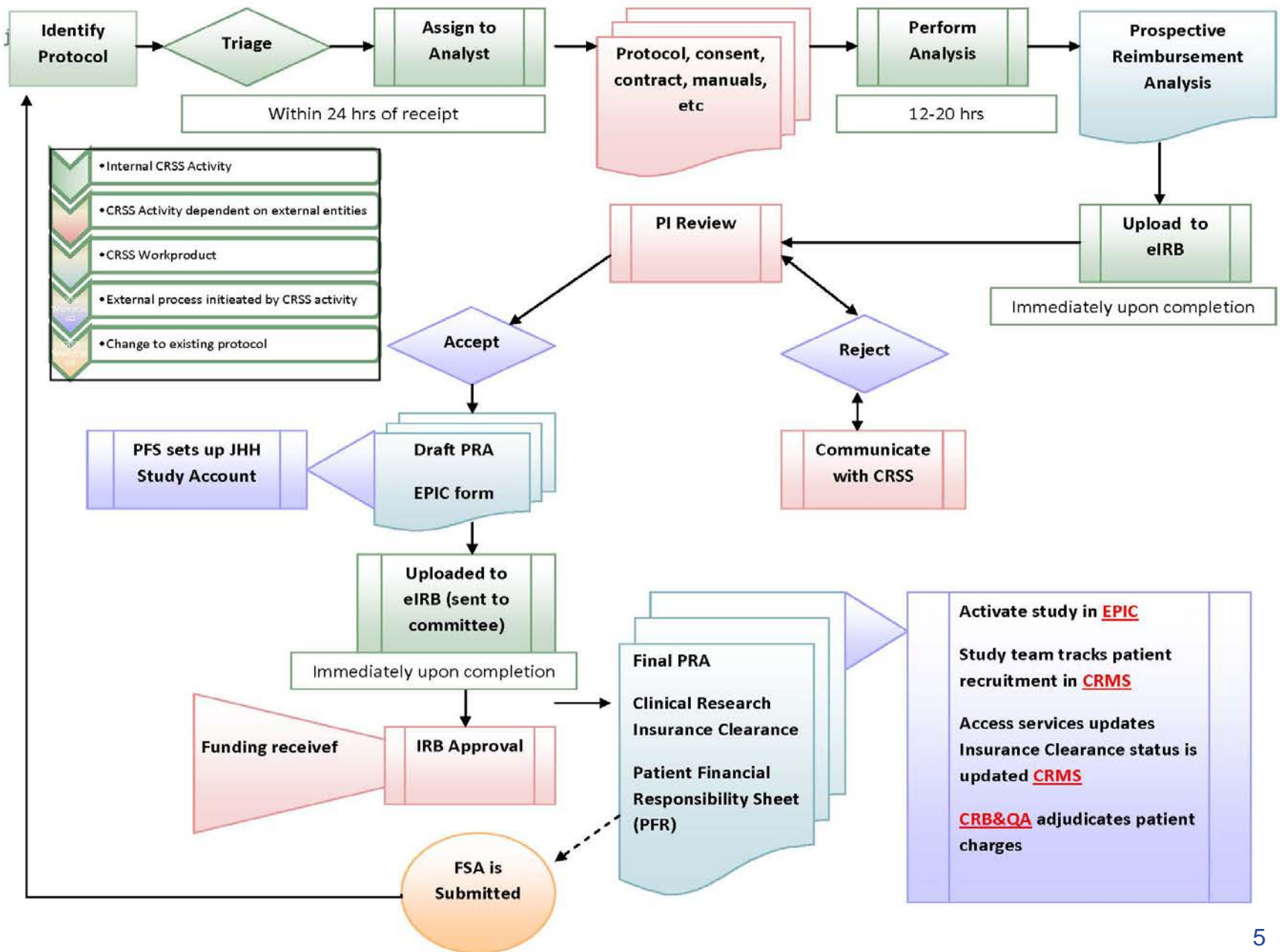
Clinical Research Support Services



- Primary Function
 - Prospective Reimbursement Analysis
- Multiple Secondary Functions
 - Study Budgeting
 - Initiate JHH Research Account through Patient Financial Services (PFS)
 - Patient Financial Responsibility Sheet
 - Clinical Research Insurance Clearance determination
 - Etc. etc. etc...

Prospective Reimbursement Analysis (PRA)

- Complex process
- Simultaneous with
 - IRB review
 - Contract negotiations
- Constantly changing
 - Changes to regulations/coverages/care standards
 - Changes in institutional processes



Prospective

Reimbursement Analysis (PRA)

Conventional Care Standard

- National Guideline Clearing House
- American College of Cardiology
- American College of Radiology
- National Comprehensive Cancer Network (NCCN)

Items and Services

- Standard of Care
- Research
- Free
- Non-billable

Additional Comments

Prospective Reimbursement Analysis (PRA)

Schema

- Can be very simple or very complex
- Details participant timeline
- Details items/services described in protocol
- Details location where items/services *are expected* to be provided
- Delineates reimbursement analysis (i.e. Standard of Care vs. Research vs. Free vs. Non-billable)
- May include extensive footnotes

Prospective

Reimbursement Analysis (PRA)

Draft PRA

- EPIC form
- Draft Budget (if requested)

Final PRA

- IRB Approval
- Funding Awarded
- Insurance Clearance status
- Patient Financial Responsibility Sheet
- EPIC Activation
- CRMS

Further Study Actions

- Revised accordingly
- PRA used for charge adjudication is the one in effect at the time of participant consent

Prospective Reimbursement Analysis (PRA)

- Summary
 - The PRA is the internal tool developed to document how each study meets the NCD criteria for billing routine costs to Medicare.
 - A systematic review of clinical trial related documents to determine the billing status of items and services that are documented within the research protocol
 - A method for ensuring that all the documents pertaining to a research protocol are consistent with each other



Budget Development and Negotiations

Budget Development

- Concurrent with PRA development
- How CRSS can help:
 - Identify “hidden” costs
 - Identify and document “routine” vs. “research”
 - Provide completed budget template
 - Negotiate with your sponsor

Budget Development

- Study Team must:
 - Provide salary information
 - Identify amount of effort for all personnel
 - Identify cost amounts (i.e. cost of special labs, radiology procedures)
 - Maintain timely communication with CRSS
 - Process proposal through standard methods

Budget Negotiations

- Service offered by CRSS
- Benefits
 - Maintain rapport with sponsor
 - Removed from “business” aspect of research
 - Institutional backing
- By request only
 - Some PIs prefer to be “hands-on” with the negotiation process

Clinical Research Revenue Cycle

Clinical Research is an integral part of the Johns Hopkins mission statement. In order to participate fully and completely in clinical research at Johns Hopkins, it is vital to understand the financial as well as the regulatory and clinical aspects of clinical research. The Clinical Research Revenue Cycle encompasses the search for and receipt of funding, whether commercial or non-commercial; appropriate budgeting and management of those funds; and, maintaining compliance with regulations guiding the use of those funds and ensuring that our patients are fully-informed as to what costs they are responsible for as well as what the sponsor is covering as part of the research. This interactive learning session brings together six offices involved in the Clinical Research Revenue Cycle at Johns Hopkins and will provide you with information on what are the responsibilities of the Principal Investigator and other study team members in regards to the Clinical Research Revenue Cycle at Johns Hopkins. There are many tools and resources available to assist with this process and this learning session will introduce you to all of them as well as provide you with a network of people that can assist you as you initiate and manage your research activities.

Clinical Research Revenue Cycle

My Learning

Course Catalog

Compliance

Research Compliance and Ethics

Clinical Research Billing Orientation (CRBO) online

Clinical Research Management Systems (CRMS) online

Clinical Research Revenue Cycle

(CRBO & CRMS must be completed prior to CRRC)

Questions?

Thank you