PRE-APPROVAL

Initial CTC Submission (PI/Dept.)
- PI/Department submits to CTC
- CTC sets Feasibility Meeting
- Submits to IRB **after** Feasibility has been approved

Feasibility Process (CTC & PI/Dept.)
- Assess the need for support
- Review and negotiate budget with sponsor
- Finalized documents to be sent to Department for IRB submission
- Contract information to Industrial Relations (IR) for review.

Start-Up Process (May occure parallel to IRB review) (CTC)
- Requests letters of support
- Reviews and negotiates agreements
- Performs Medicare Coverage Analysis
- Obtains required billing documents
- Builds LLEAP Research Record
- Establishes LLEAP In-Basket

POST-APPROVAL

Establishing Study Accounts (CTC)
- Requests Study Account be created with LLUH Finance
- Provides Letters of support to PI/Department
- Provides Start-up Kit to PI/Department
- Sets LLEAP Research Record to Active

LLEAP Documentation Requirements (PI/Dept)
- PI/Department must enroll each subject in LLEAP
- Associate each patient encounter with the study
- Document the research related activity in LLEAP
- Associate research orders with study

Billing and Reimbursement (CTC & PI/Dept.)
- Department Capture charges in LLEAP
  - Confirms accuracy : Ensures activity codes are documented, assigns the proper provider (MD vs. CRC)
  - Clears Workqueues in real time
- CTC receives a monthly report of activity posted in LLEAP
  - Verifies data and provides report to LLUHC Finance for Department reimbursement
- Department is reimbursed using:
  - Patient charges posted in LLEAP
  - Administrative charges submitted for reimbursement

AMENDMENTS

Applies to changes to study protocol or investigator brochure that require a change in study required procedures or visits and/or a change in PI

Change Notification (PI /Dept)
- Submit Amendment Form to the CTC via the CTC website
- Submit IRB Change Request as required
- Review and confirm accuracy of the change to billing grid

Review and Modify Documents (CTC)
- Review amendments to assess any required changes to budget or contract
- Modify study billing grid as needed
- Notify Billing Offices of changes
- Submit change to IR for amendment if necessary
- Return updated billing documents to the Department

STUDY CLOSURE

Closure Notificaiton (PI/Dept.)
- Submit Study Closure Form to the CTC via the CTC website
- Submit IRB Closure, unless informed by the CTC of contract issues that may need to be addressed.
- Complete all sponsor required closure activity.

Reconciliation and Closure (CTC)
- Review study closure items within the study agreement
- Notify department of any concerns identified
- Reconicles the study account
- Notifies Ancillary support departments of study closure
- Requests LLUHC account closures
- Sends closure letter to the PI.

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