Clinical Trial Revenue Cycle Overview

Quick Tips – Updated January 10, 2019

New Process for getting Clinical Trial Agreements executed:

1. Clinical Trial (CT) Identified
2. Confidentiality Disclosure Agreement (CDA) received by USA/Dept./Unit
3. CDA Sent to Brandon Strickland Via Steve Hadley or Ashley Turbeville
4. CDA finalized and approved by Brandon Strickland
5. Sponsor releases protocol to USA/Dept./Unit
6. Dept./Unit cursory protocol review performed by PI/Study Coordinator
    a. Review for competing trials
    b. Review for Patient Population for Accrual
    c. Review Individual Unit Goals
7. Required documents for clinical trial review by Brandon Strickland, Steve Hadley and Ashley Turbeville
    a. Confidentiality Disclosure Agreement (CDA)
    b. Protocol
    c. Informed Consent
    d. Institutional Review Board (IRB) Submission/Pending Status by Research Coordinator
    e. Clinical Trial Agreement (CTA)
    f. Investigator brochure (if applicable)
    g. Investigation New Drug (IND)/Investigational Device (IDE) (if applicable)

Concurrent Activities and Submissions

1. Submit Institutional Review Board (IRB) documents
2. Submit Conflict of Interest(COI) to Brandon Strickland
3. Submit Material Transfer Agreement (MTA), if required to Brandon Strickland and the Office of Commercialization whom and Industry Collaboration
4. Provide IND/IDE, if required to Brandon Strickland
5. Clinical Trial Agreement (CTA) negotiation by Brandon Strickland
6. Budget Negotiation by Brandon Strickland
7. IP/Technology Transfer Issue Resolution to Brandon Strickland and the Office of Commercialization and Industry Collaboration
8. Other Issues as required
9. Coverage Analyses is being done concurrent to these activities by Huron for now.

Final Executed CTA

1. Lynne Chronister signs for USA
2. John Marymont signs for SAMSF and Lynne Chronister acknowledges for USA

Final Documents Routed in Evisions

1. Protocol Approval Letter
2. CTA
3. CDA
4. Budget
5. CA

Account Setup by SAMSF

1. Clinical Trial Account sent to Coordinator, Jennifer Giangrosso (ACS), Betty Boykins (USA Business Office) and Susan Hargrave PPM (#secure)

Clinical Trial Revenue Cycle

1. Patient Identified as possible candidate for Trial

2. Consent Patient

3. Enroll Patient - Send Enrollment Form to All Billing Offices: ACS Gidget Dugas, gdugas@acsmd.com Hospital Business Office Janna Wright JlWright@health.southalabama.edu , gosborne@health.southalabama.edu and Lori White lwhite@health.southalabama.edu and PPM Partners, Susan Hargrave shargrave@health.southalabama.edu

4. Clinical Trial Patients must have an appointment/registration for all visits, procedures, tests, labs and treatments. Green Sheets should be filled out for each encounter.
   a. If encounter is at the clinic green sheet should be taken to front desk clerk in clinic to set up an appointment/registration and emailed to Gidget at ACS.
   b. If encounter is at the hospital faxed green sheets to admitting: CW – Everything NOT surgery 251-415-1002; Surgery 251-410-5102; MC - Everything NOT surgery 251-471-7275; Surgery 251-445-9021. Any question for hospital admitting contact (CW)-Charese Bowman cbowman@health.southalabama.edu or Andrea Fox atfox@health.southalabama.edu, (MC) Jeri Nelson jnelson@health.southalabama.edu and Lawree McGrew lmcgrew@health.southalabama.edu. Please email green sheet to Janna Wright, Lori White and Gwynne Osborne (emails above) in the hospital business office, Gidget Dugas at ACS (email above) and Danielle Miller in ORED daniellemiller@southalabama.edu
   c. Please note any trial have anesthesia as a service must also send green sheet to PPM Partners, Susan Hargrave shargrave@health.southalabama.edu

5. Upon arrival clinical trials patients should follow the same check processes as all other patients prior to receiving care. Front Desk/Admitting Clerk will check in patient and choose the appropriate trial (payer) for the encounter. If a billable service, the Provider/Nurse will post charge in EHR or fill out fee ticket to be posted into billing system. Charges will be routed accordingly.

6. All Business offices will create claim/invoice and send to Research Coordinator fill out direct pay to SAMSF and if MCI, Expense Transfer to Grants and Contracts of Accounting to process payment back to the business offices to post against patient account using a 40% discount.

7. Revenue Cycle –Research Subcommittee Contacts:

a. Priscilla Smith, Director of Patient Business Services, psmith@health.southalabama.edu, 251-445-9815
b. Ashley Turbeville, Executive Director, Health Systems Grants Administration and Development, aturbeville@southalabama.edu , 251-460-6307
c. Cathy Faison, Manager Hospital Systems, Patient Access, cfaison@health.southalabama.edu, 251-470-1644
d. Betty Boykins, Hospital Business Service Manager, bboykin@health.southalabama.edu, 251-434-3546
e. Jennifer Giangrosso, ACS Revenue Cycle Manager jgiangrosso@health.southalabama.edu, 251-405-5387
f. Steve Hadley, Associate Business Manager, COM shadley@southalabama.edu , 251-460-7195