VCU Center for Clinical and Translational Research
Virginia Commonwealth University

Regulatory Process

Preliminary Documentation

1. CRC completes pre-study questionnaire and sends to sponsor.
2. CDA reviewed by OSP Red if VCU CDA template is not used.
3. CDA signature obtained by CRC and returned to OSP Red for execution and forwarded to sponsor.
4. Synopsis reviewed by PI, study team and Nurse Manager and decision made to participate or not.

Initial Packet

1. Site Contact information_____
2. Final Protocol_____
   Signature page: ❑Yes ❑No ❑N/A
3. Draft consent_____
4. FDA 1572 _____
5. Financial Disclosure Form _____
6. Investigator's brochure _____
   Signature page: ❑Yes ❑No ❑N/A

Initiating the Regulatory Process

1. CRC sends regulatory documents to RAS
2. RAS routes protocol
3. RAS completes site contact info sheet and forwards to sponsor
4. RAS forwards consent template to CRSadmin@vcu.edu for review/negotiation
5. RAS contacts WIRB to see if protocol is already on file
6. RAS sends email to WIRB for information needed to complete submission form and WIRB invoicing information
7. RAS obtains PI signature on protocol signature page and IB
8. RAS obtains signature from PI & Sub-Is on financial disclosure
9. RAS completes 1572 and obtains PI signature
10. RAS distributes IB to PI, CRN and Pharmacy
11. RAS routes protocol and application to peer review committee if applicable
12. RAS completes IRB packet upon approval of peer review committee
13. RAS sends sponsor-approved consent along with protocol, application, IB, to CRS for review and distribution to VCU IRB office
14. CRC forwards electronic versions of documents to CRS for electronic WIRB submissions.
15. RAS sends sponsor the following items upon IRB approval
    - Protocol Signature Page
    - Investigational Brochure Signature Page
    - FDA 1572 form
    - Curriculum Vitae of all persons listed on 1572
    - Medical Licenses of all persons listed on 1572
    - Financial disclosure (to be done at start-up, close-out, one year post close-out)
    - IRB membership list
    - Laboratory certification (CLIA & CAP), lab normals
    - IRB approval letter/receipt letter
    - Final consent form

Amendments and Updated Investigational Brochures

1. CRC writes a memo to IRB to summarize amendment/update
2. CRC makes any required changes to consent form and sends to RAS
3. RAS routes the consent and memo to the IRB
4. RAS routes amendment to appropriate staff
5. RAS obtains signature on amendments and IB signature pages
6. RAS responsible for sending all approval letters, signature pages to sponsor (RAS will ensure CRC gets a copy of all documents sent to sponsor)

Contracts/Budget/W-9

1. OSP Red will review contract after receiving budget and IAF.
2. CRC to determine budget based on standard of care vs. research procedures.
3. CRC or CRS will obtain research quotes, set up hospital and physician billing accounts, negotiate budget with sponsor and complete IAF.
4. CRC or RAS will deliver IAF and supporting documents to Dean's office.
5. CRS will review IAF and budget and submit complete packet to OSP Red for Contract review/finalization.
6. CS to negotiate contract with sponsor based on approved budget.
7. CS notifies CRC when ready to obtain signature on contract.
8. CRC notifies CRS when study is open to enrollment for website.

Abbreviations

RAS	Regulatory Affairs Specialist
CDA	Confidentiality Agreement
CP	IRB Compliance Coordinator
CRC	Clinical Research Coordinator/Nurse
CS	Contract Specialist
IB	Investigational Brochure
IRB	Institutional Review Board
CRS	Clinical Research Services