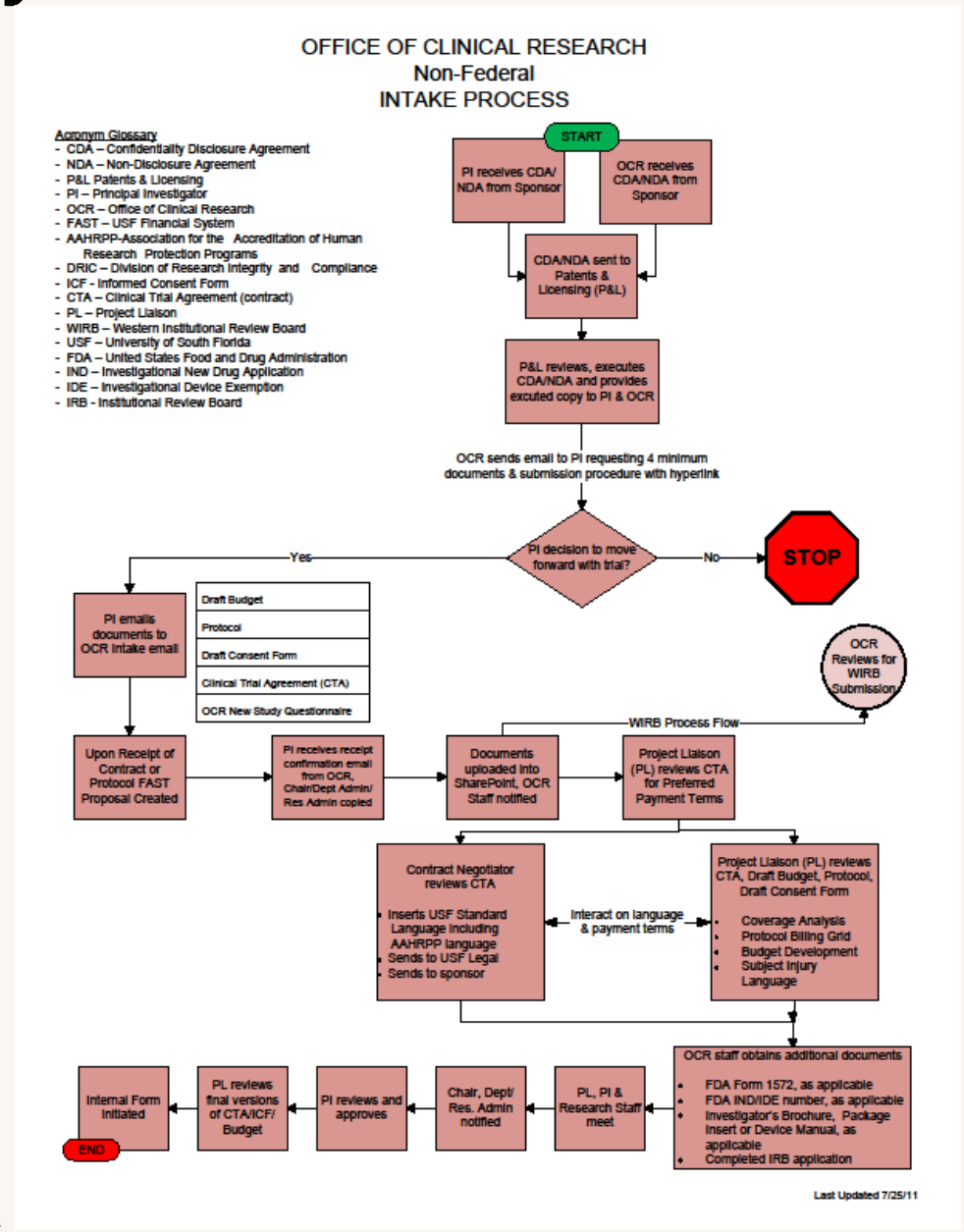
Updates to WIRB Submission Process for Non-Federally Sponsored Clinical Research Projects

Catherine Jahrsdorfer
Director of Clinical Services, USF Health OCR

August 4&5, 2011

New Study Intake Flow



How Do I Start?

- Site staff emails these documents to OCR@health.usf.edu
  - Protocol
  - Draft Informed Consent
  - Draft Budget
  - Draft Contract (Clinical Trial Agreement)
- PL will send an email including the OCR New Study Questionnaire to the site
  - See handouts – OCR New Study Questionnaire and Form Completion Instructions

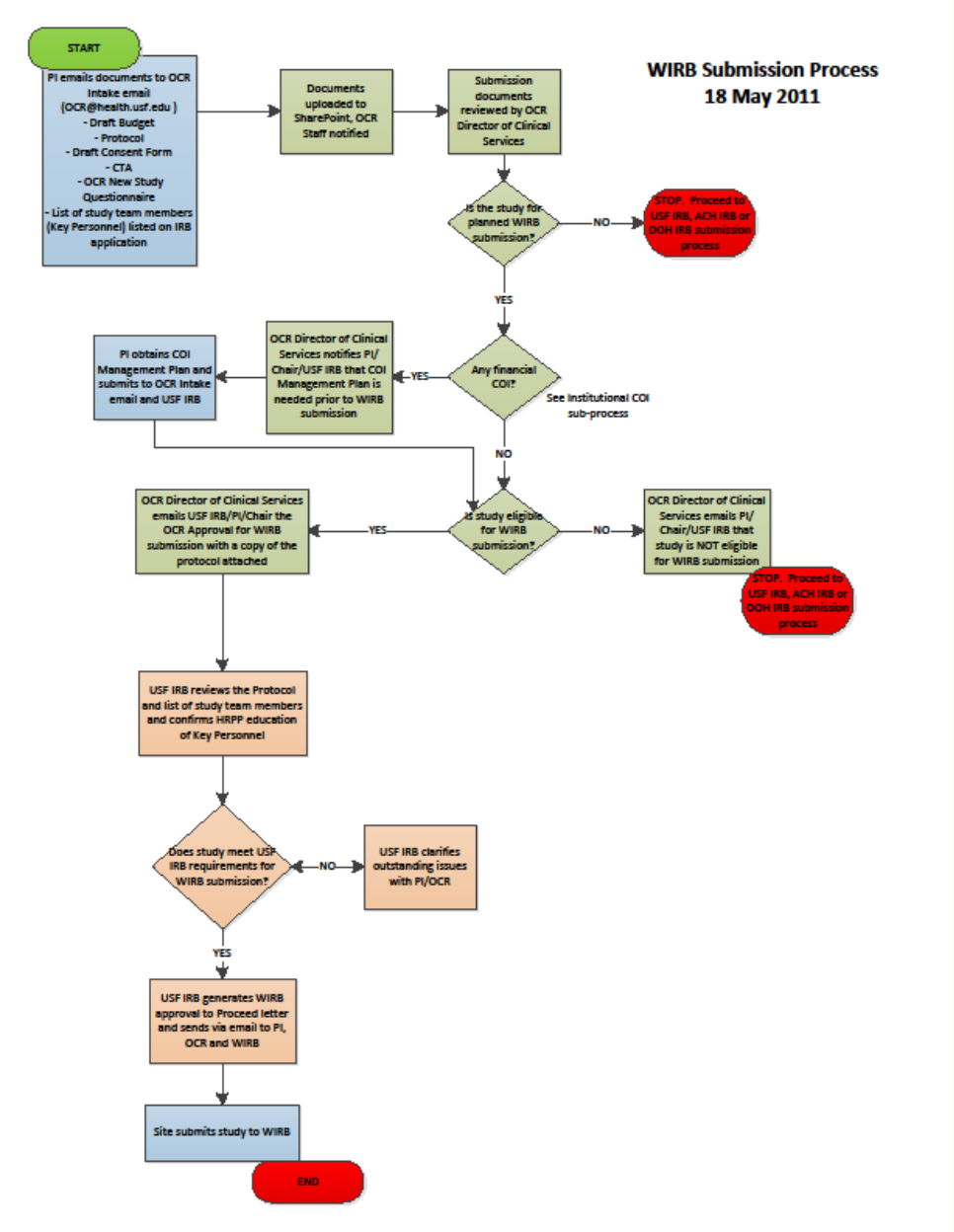
OCR New Study Questionnaire

- Critical Fields
  - IRB: The OCR must know that you intend to submit to WIRB to facilitate WIRB AtP Letter
  - List of study team members: Must be comprehensive and accurate to confirm HRPP education requirement has been met
  - COI questions
    - Financial interest of faculty, staff or students (spouses or dependent children)
    - Institutional COI

Timing and Process for WIRB AtP Letter

- OCR will review for WIRB submission when the four essential documents
  - Protocol
  - Draft consent form
  - Draft budget
  - Clinical trial agreement (contract)
- Plus the OCR New Study Questionnaire have been received and uploaded to SharePoint

WIRB Submission Process Flow



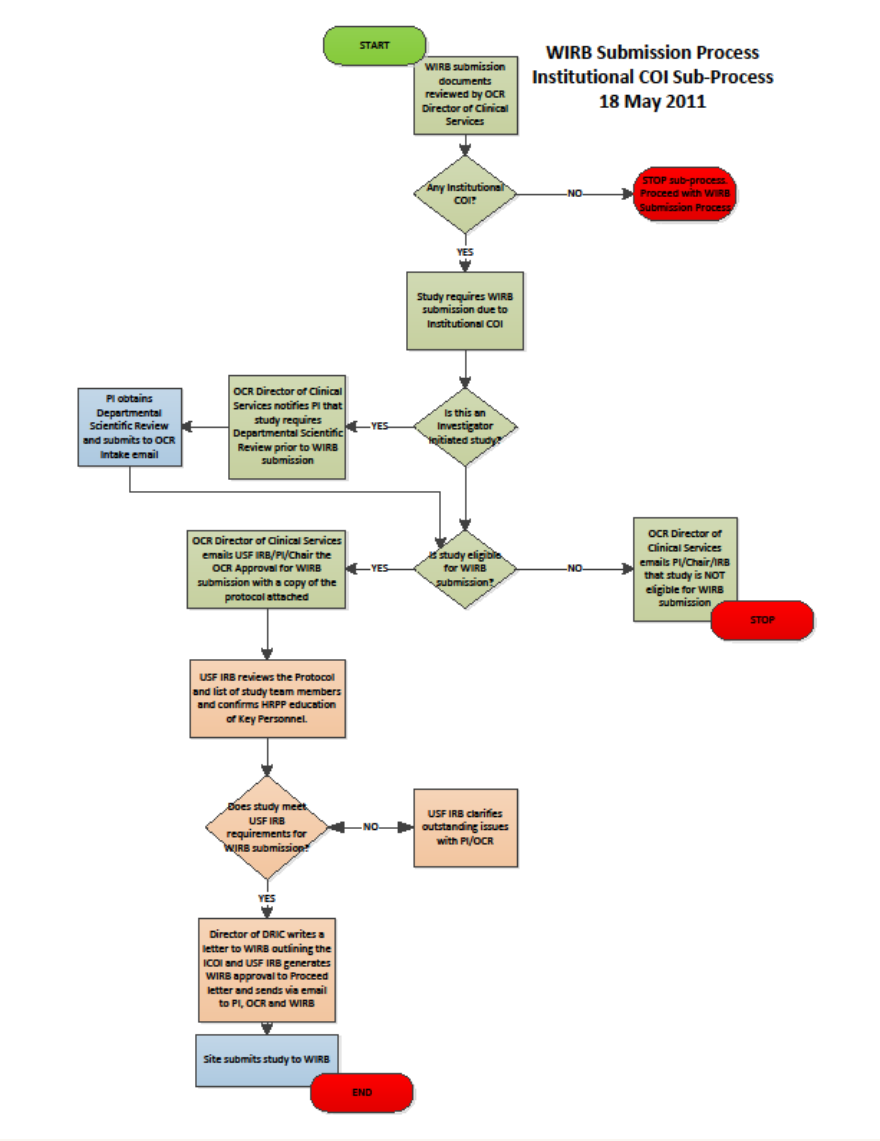
What Studies Qualify for WIRB Review?

- Phase 2 and above foundation, non-profit or industry sponsored multicenter clinical trials involving drugs and devices, registry studies or observation trials
- All clinical research projects in which there is an institutional COI, regardless of funding source
- There is discussion related to submission of Federally funded CR studies to WIRB
  - Would need to develop process

What Studies Do *Not* Qualify for WIRB?

- Phase 1 clinical trials
- Investigator initiated trials where USF Faculty/Staff hold the IND or IDE for the test article and USF PI initiated trials determined by FDA to be IND exempt
- Studies deemed to have significant local impact
- Research which involves rDNA or other biological agents which must be reviewed and approved by USF Biosafety Committee
- JAHVA, ACH, and DOH studies
- Meet exempt or expedited review criteria

WIRB Submission Process Flow for Institutional COIs



What Is an Institutional COI?

- A situation in which the financial investments, licenses, technology transfer or patents of, or gifts to, the USF System or the personal financial interests or holdings of USF System Senior Administrative Officials might affect, or reasonably appear to affect, institutional processes for the design, conduct, reporting, review or oversight of human subjects research.
  - USF owns equity in a company & the company has a financial or business relationship with USF
  - USF licenses an invention to an entity that also has a financial or business relationship with USF
  - Sr. Admin Official at USF has an external business that sponsors USF Human Subject Research Projects
  - A company with a financial or business relationship also donates a gift to USF

What If There Is a COI on Your Project?

- Must submit via eCOI module in ARC
- Must receive Management Plan prior to IRB submission, regardless of which IRB
- Therefore, recommend identifying and submitting COIs early in the process!
- OCR will retrieve the Management Plan from eCOI once notified that it is complete

OCR Responsibilities

- Reviews to be sure study meets WIRB submission criteria
- OCR sends the OCR Approval for WIRB Submission email to USF IRB once the 4 essential documents plus the OCR New Study Questionnaire have been received and reviewed – typically within 2 working days
- A copy of the Protocol is attached to the email
- A copy of the COI Management Plan is attached, if applicable

Win for the Study Site Staff!

- You no longer have to submit a packet to USF IRB when you plan to use WIRB!

USF IRB Responsibilities

- Reviews to be sure study meets WIRB submission criteria
- Chair reviews protocol, sometimes IB, to determine if requires Biosafety Committee review
- IRB staff confirms HRPP education requirements are met for all study team members
- Generates WIRB AtP letter – typically within 2 to 7 working days

What to Do With the WIRB AtP Letter

- Once received from USF IRB, the WIRB AtP letter should be submitted to WIRB with your WIRB Initial Review Submission form (paper or online via WIRBNet)
- If there is a COI, also attach the Financial Management Plan to the WIRB application

Management of WIRB Approval Letters

- C Jahrsdorfer and L Pascal are notified of WIRB actions via email
- Also have access to WIRBNet for all USF study submissions with activity after January 30, 2011
- Lovelyne retrieves Approval letters and approved ICFs from WIRBNet
- Also pulls Continuing Review and Confirmation of Study Closure letters

Win for the Study Site Staff!

- You no longer have to send WIRB Approval letters to the OCR!
  - Almost – if the activity preceded January 30, 2011 we still need your help in collecting the approval letters
  - Remember – no approval letter means no invoicing the sponsor for study activity

IRB Applications

- Still under discussion, but it is likely that OCR will stop collecting IRB applications, regardless of which IRB is being used

Win for the Study Site Staff!

- You may no longer have to submit your IRB applications to OCR!

Internal Form Timing in New Process Flow

- The Internal Form should be completed when the following are complete
  1. Study is Approved by IRB
  2. Contract is fully executed
- Attach the final budget, and if applicable, the COI Management Plan, ROAD and Nepotism Memo
- Note: If your Department has different requirements, please follow your Department's instructions

What Else is New?

- PLs are now performing the comparison between the IRB approved consent document, final budget and the final contract to compare for alignment on subject injury language and responsibility for payment for all study related procedures

Check Out the OCR Website

- http://health.usf.edu/research/ocr/index.htm
- Updates include
  - OCR Newsletter
  - Governance Meeting slide decks
  - Industry Sponsored page
  - Forms page
  - Education & Training page
    - New Coordinator training requirements
    - CRC Meeting training slide decks
  - Patient Resources page

Questions?