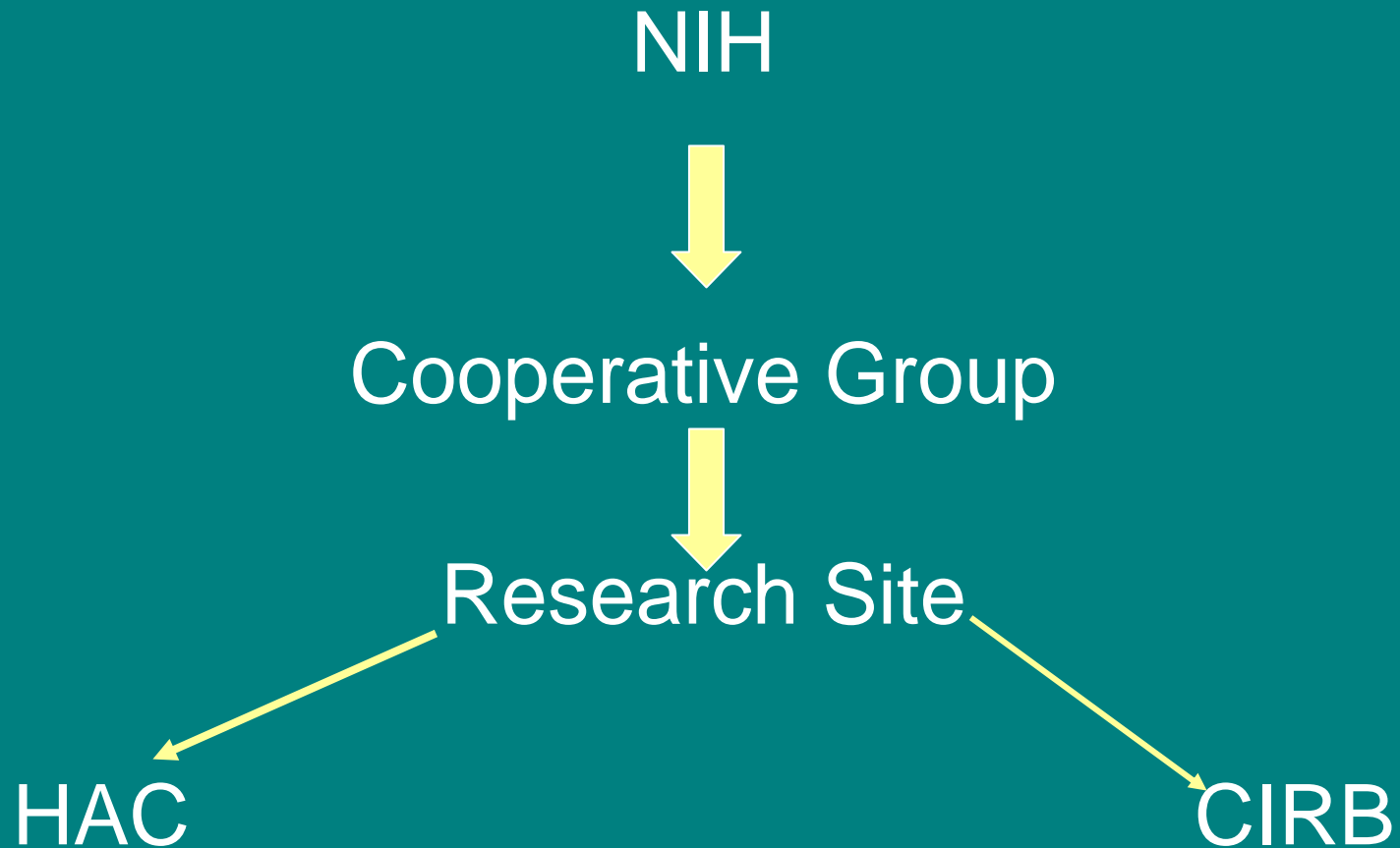


NCI Central IRB and MCG

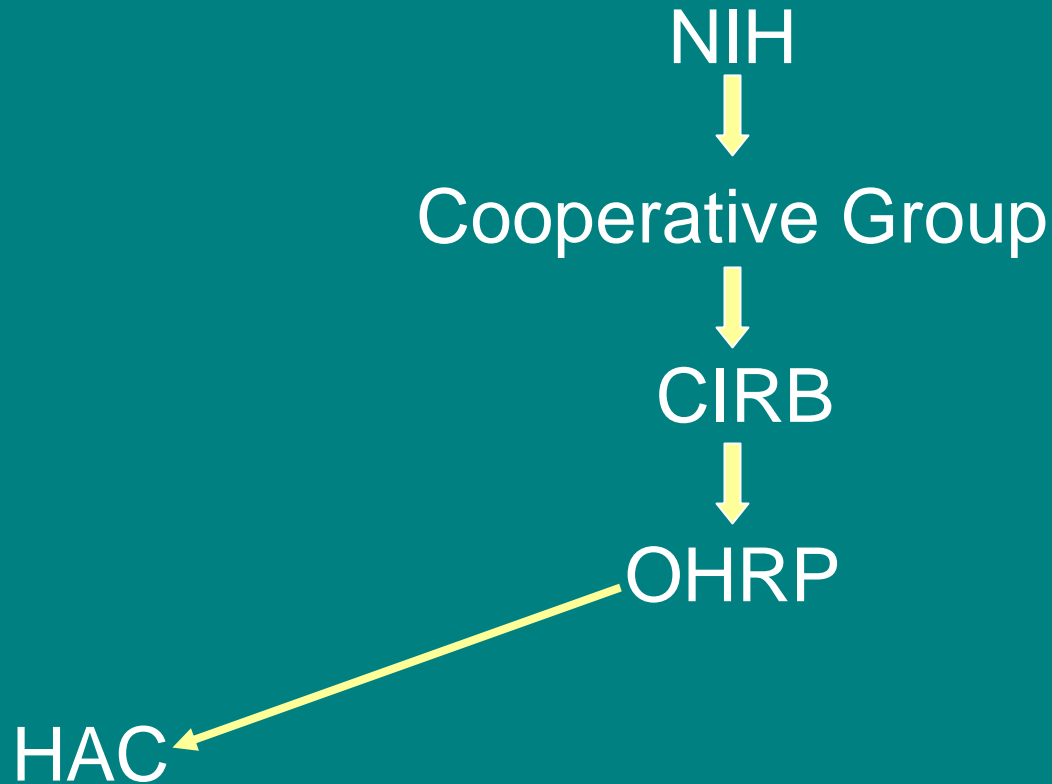
Objectives

- Discuss the division of responsibilities
- Discuss the procedure for transferring HAC- approved studies to CIRB
- Examine the SOPs for Facilitated Review and Reporting Requirements
- Review the CIRB Participant's Website
- Questions

Current Process for New Studies



New Process for New Studies



Facilitated Review

Facilitated Review

- Conducted by Marjorie Phillips, RPh, MS, FASHP, HAC Vice-Chair
- See SOP for details

Responsibilities of the research team members

Items to Submit via email

- Email submission packet to HAC@mcg.edu
- All current review materials
 - CIRB Application
 - Protocol
 - Informed Consent
 - Correspondence
 - Any SAE reports
 - Amendments
 - Primary review
 - Minutes
- OHRP Form for Ancillary IRB Review

Email Template

- Subject Line: Study Name (Approved by CIRB); PI Name
- Content:
 - Include the name, email address and campus telephone number of the primary administrative contact for the study

Informed Consent Document

- STEP 1: Download from CIRB website
- STEP 2: Place MCG required formatting
- STEP 3: Insert MCG HIPAA language (verbatim)

OHRP Staff Responsibilities

Facilitated Review Processing

- Turn-around time: 2-5 business days
- An email will be sent from the HAC mailbox once the facilitated review is complete.
- The email will include the following:
 - Date of completion of facilitated review
 - Outstanding approvals or institutional requirements (needed for the OHRP Release)

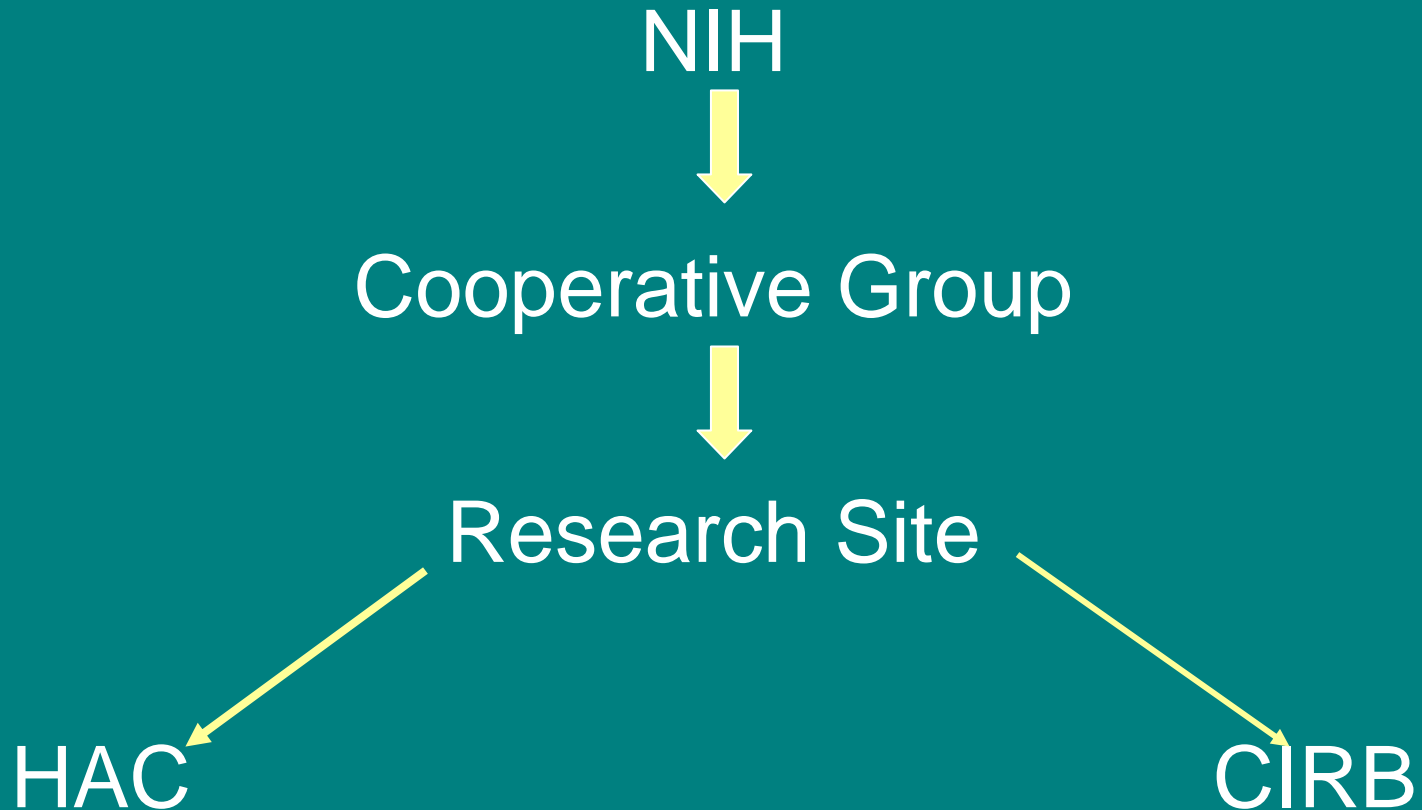
MCGHI Billing and Support

- *OCIS Review Office will be given the ICD to conduct a review to ensure the correct billing language is used based on a comparison of the study billing grid and budget (if applicable)*

OHRP Release

- Required for all new NCI CIRB approved protocols
- Ensures all institutional requirements have been met:
 - CITI completion/recertification
 - Authorized signatures for pharmacy orders
 - Other applicable approvals (i.e. MCGHI, ITSS, IBC, etc...)

Current Process for Amendments and Continuations



New Processes Amendments and Continuations

Cooperative Group



CIRB



Research Site

When changes in an amendment include changes in the informed consent document, the investigator/research staff will submit one copy of the updated informed consent document to the HAC for date stamping.

Amendments Involving Personnel Changes

- Must be submitted to OHRP via email, HAC@mcg.edu
- Items to email:
 - OHRP Form for Ancillary IRB Review
 - CV of personnel
- OHRP Release Letter will be sent to PI
- Note: The personnel change cannot be implemented until the OHRP Release Letter has been received.

Current and New Process for SAEs, UAPs, and Violations

Research Site



HAC

Facilitated Review

Process for Reporting SAEs, UAPs, and/or Violations

- OHRP Ancillary IRB Review Form
 - Email form with scanned copy of CRF (if applicable) describing the event to HAC@mcg.edu.
 - No additional forms are required as we will accept the NCI form

Transferring HAC Approved Studies

- STEP 1: Ensure that all HAC approved studies have been identified.
- STEP 2: Download ICDs for existing protocols and submit CIRB ICD (with required MCG language) by September 25th.
 - Priority: Studies actively enrolling subjects- must be submitted to OHRP Assistant Director by October 16th
 - All other study ICDs (i.e. those on “hold” must be submitted by October 28th).

Resources

- NCI CIRB liaison
 - Ivy Tillman, Assistant Director
itillman@mcg.edu, 1-1379
- OHRP Website
- NCI CIRB Website
 - Handbook for local sites
 - Participant's Area

Timeline

- Implementation Date:
 - October 1, 2009
- Note that this date has been revised based on guidance from DHHS-OHRP

Timeline

- What does this mean for my research?
 - Continue to submit all continuations by the due date until further notice
 - Continue to submit all amendments, as required by cooperative group and institutional policy
 - Complete approvals/stipulations for pending studies by September 26th.

Review of NCI CIRB Participant's Area

Questions?