Human Subjects Research Routine Reviews – A tool for Your Quality Improvement Arsenal

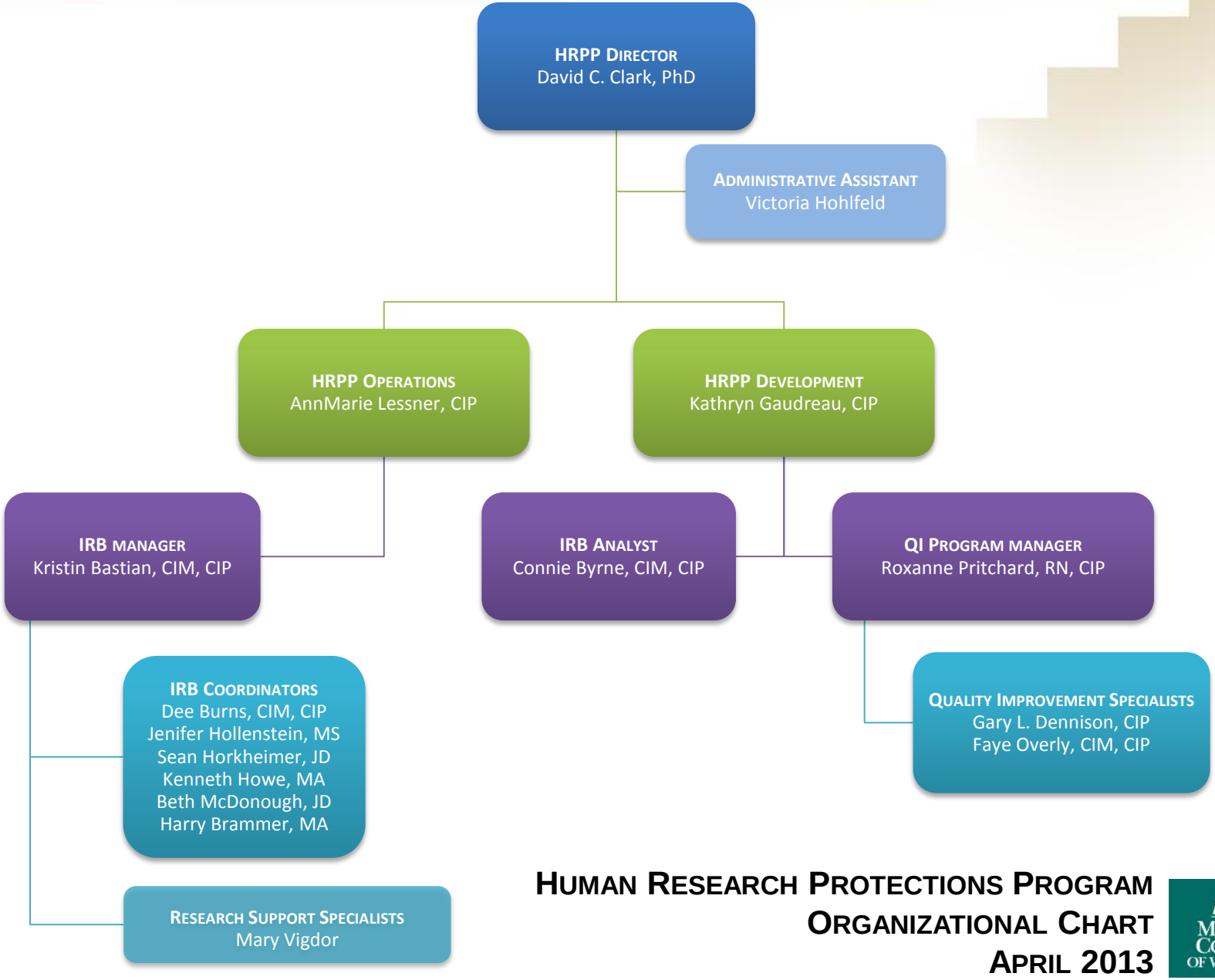
- Deborah A. Epps, MBA: Research Coordinator, Department of Orthopaedic Surgery, Medical College of Wisconsin – Panel Moderator
- David Clark, PhD: Assistant Dean for Clinical Research, Director, Human Research Protections Program, Medical College of Wisconsin
- Roxanne Pritchard, RN, BSN, CIP: Quality Improvement Specialist III, Human Research Protection Program, Medical College of Wisconsin
- Jessica Fritz, MS, Research Associate, Department of Biomedical Engineering, Marquette University, Orthopaedic and Rehabilitation Engineering Center, Marquette University and the Medical College of Wisconsin

Topics

- IRB Quality Assurance Prospective – Broad overview – David Clark, PhD
- Routine Review Process from the IRB prospective – Roxanne Pritchard, RN, BSN, CIP
- Preparing for an IRB Review from the PI prospective – Jessica Fritz, MS

David C. Clark, PhD
Medical College of Wisconsin

IRB Quality Assurance Mechanism



Human Research Protections Program Organizational Chart April 2013

Medical College of Wisconsin

QA and Regulatory Requirements

Assurances applicable to federally supported or conducted research shall at a minimum include:

- (4) Written procedures which the IRB will follow… (ii) for determining… which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review…
  - 45 CFR 46.103.b.4

QA and Regulatory Requirements

- An IRB shall… have the authority to observe or have a third party observe the consent process and the research.
  - 45 CFR 46 109.e

Benefits beyond regulatory requirements

- To the IRB
  - supplements and amplifies Continuing Review reports
  - broader and deeper view of investigator understanding and compliance

Benefits beyond regulatory requirements

- To senior Research Administrators
  - Identify education/training needs
  - Identify need for specific policies or guidances
  - Identify compliance problem areas (institutional vulnerabilities)
  - Confirm good practices of bulk of investigators

Benefits beyond regulatory requirements

- To investigators and study team
  - More personal interaction with IRB
  - Identify gaps in understanding or knowledge
  - Teach/demonstrate regulatory and IRB expectations
  - Independent assessment of compliance problems
  - Praise good practices (identify “best practices”)

Documenting audits / routine reviews

- 95% of reports are non-emergent
- Summary + corrective action plan
  - Review by investigator
  - Review by IRB Chair
  - Part of study IRB file, incorporated into Continuing Review

Routine Review Process

Roxanne M Pritchard, RN, BSN, CIP
Manager, Quality Improvement
Human Research Protection Program
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Routine Review Process

- The routine review process for MCW/FH IRB approved human subject research became mandatory January 1, 2010
- Established a “review” period for each department/division
- Annual email to Department Chairs/Division Chiefs and the key contact person for department/division
- Goal: review 3 studies per department/division annually
- Eligible studies
  - Reviewed and approved by a MCW/FH IRB
  - Have at least one progress report on file with the IRB
  - Not reviewed by the QI Specialists in the previous 12 months

Components of the Routine Review Process

- Preparatory activities
- Onsite activities
- Post review activities

Preparatory – Study selection

- Annual report of potentially eligible studies
- Select studies for routine review on month basis
- Parties included in initial notification
  - Principal Investigator, Lead study Coordinator, and key contact person for department/division

Preparation

- Negotiate with PI/study coordinator for date and time of onsite review activities
- Send follow-up email with date of review and description of onsite activities to PI and study coordinator and
  - IRB office(s)
  - Other parties as necessary
- Review information in IRB file for research project
- Prepare our checklists for review

Checklists

- Interview questions
- Study file checklist
  - study history
  - study team
- Informed consent tracking log
- Study subject file checklist (if applicable)
- Regulatory and institutional requirement checklist

Onsite activities

- Interview member(s) of study team
- Review regulatory file
- Review signed informed consent documents
- Review sample of study subject files
- Debriefing meeting

Post review activities

- Prepare and submit draft summary and regulatory requirement checklist to PI and study coordinator for review and comment
- Submit final summary and regulatory requirement checklist to PI and study coordinator
- Submit final summary and regulatory requirement checklist ,and if applicable PI's Corrective Action Plan (CAP), to IRB Chair for review
- Post the final summary and associated documents in the IRB's study file

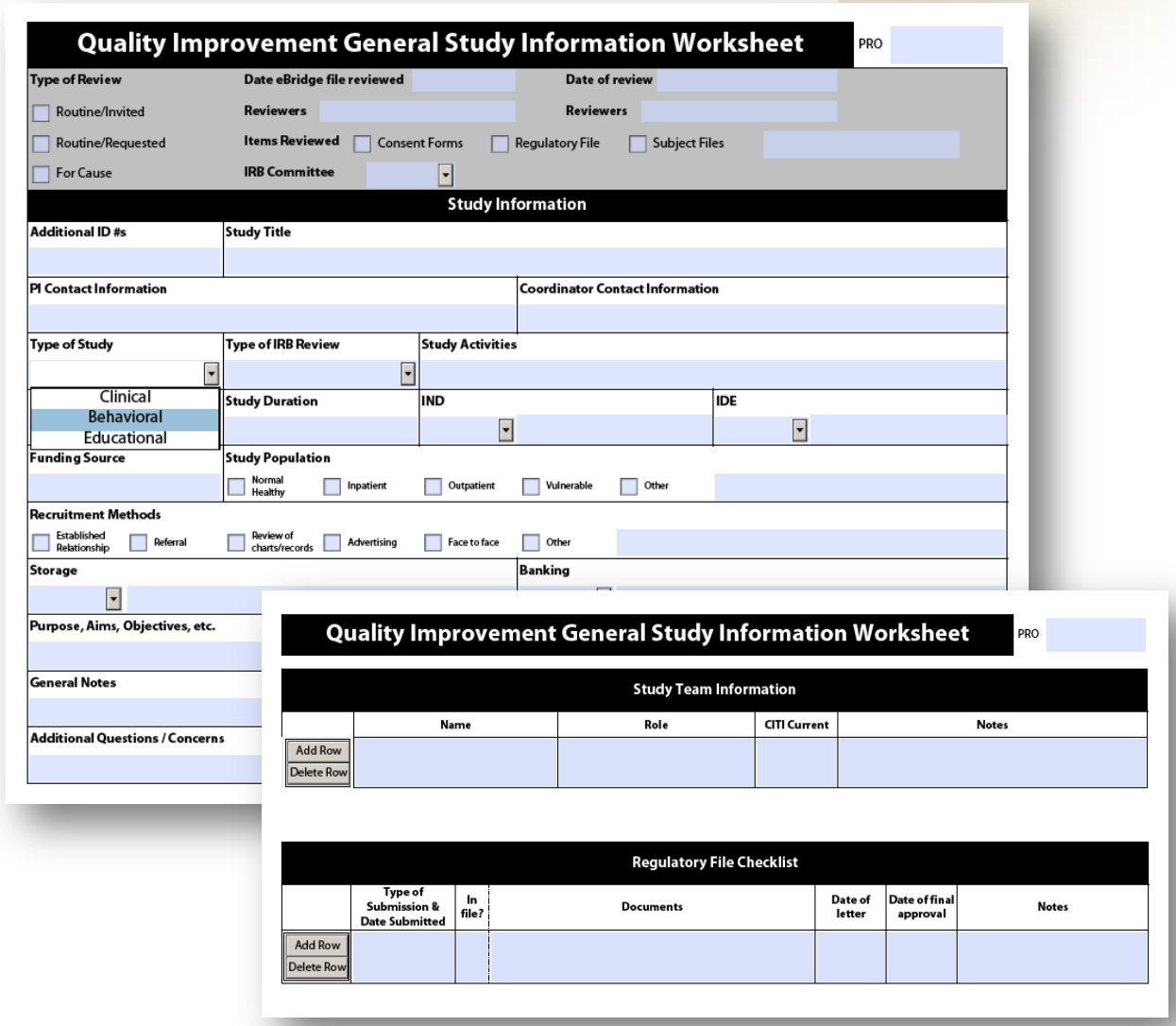
Post Review Activities – Continuing Progress Report

- QI Specialist is contacted when a progress report is received for a previously reviewed project

- QI Specialist will review the final summary, and if applicable the PI's CAP, and provide follow up information to the IRB for consideration when reviewing the progress report

Routine review checklists

- Quality Improvement General Study Information Worksheet



Quality Improvement General Study Information Worksheet

PRO

Type of Review
- Routine/Invited
- Routine/Requested
- For Cause

Date eBridge file reviewed
Reviewers
Items Reviewed: Consent Forms, Regulatory File, Subject Files
IRB Committee

Date of review
Reviewers

Study Information

Additional ID #s
Study Title
PI Contact Information
Coordinator Contact Information
Type of Study: Clinical, Behavioral, Educational
Type of IRB Review
Study Activities
Study Duration
IND
IDE
Funding Source
Study Population: Normal Healthy, Inpatient, Outpatient, Vulnerable, Other
Recruitment Methods: Established Relationship, Referral, Review of charts/records, Advertising, Face to face, Other
Storage
Banking
Purpose, Aims, Objectives, etc.
General Notes
Additional Questions / Concerns

Quality Improvement General Study Information Worksheet

PRO

Study Team Information

	Name	Role	CITI Current	Notes
Add Row / Delete Row				

Regulatory File Checklist

	Type of Submission & Date Submitted	In file?	Documents	Date of letter	Date of final approval	Notes
Add Row / Delete Row						

Informed Consent Checklist

- Correct version of IRB approved consent form used in consenting process
- Consent form complete for signature and date of the:
  - Subject/Legally Authorized Representative (LAR)
  - Individual who obtained informed consent, if required
  - Witness and investigator signatures, if required
- All required fields completed
- Informed consent obtained by authorized individual approved by IRB
- Informed consent obtained prior to initiation of any study related activities
- Original signed document filed with research records in a secure fashion

Additional Information

- MCW/FH Human Research Protection Program's Quality Improvement Program

http://www.mcw.edu/hrpp/QualityImprovementProgram.htm

Activities

Routine Review Schedule

SOPs for our investigators

Checklists

Contact information

Preparing for an IRB Review

Jessica M Fritz, MS

Tuesday, April 16, 2013

NCURA Region IV 2013 Spring Meeting – Milwaukee, WI

Preparation Process

- Study initiation
- Throughout the study
- Review notification
- During the review
- After the review/corrective actions

Preparation Process

- Study initiation
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Start at the Beginning

- Know the rules and regulations
  - IRB
  - Federal
  - Funding agency/sponsor
- Utilize checklists and templates provided by your IRB
- Ask questions

Communicate

- Sponsor
- IRB
- Co-investigators
- Study team
  - Inclusion/exclusion criteria
  - Protocol
  - Consenting process
  - Questionnaires/forms

Study Submission

- Make sure protocol adequately describes your study
- Attach all forms
  - Consent
  - Questionnaires
- Start a binder or electronic folder for study files

Preparation Process

- Study initiation
- Throughout the study
- Review notification
- During the review
- After the review/corrective actions

Ongoing Preparation

- Keep IRB binder updated
  - Amendments
  - Continuing Progress Reports
  - Updates/changes
    - Adding staff
    - Changing dates
- Maintain subject files
  - Consents
  - Questionnaires/forms
- Ensure all study team members know and follow proper procedures
  - Recruitment
  - Consent
  - Testing
  - Data analysis and storage

Preparation Process

- Study initiation
- Throughout the study
- Review notification
- During the review
- After the review/corrective actions

After Notification

- Schedule a time that works for the reviewer, PI and Study Coordinator
- Review your study binder/file folder
  - IRB submissions
    - Original
    - Amendments
    - Progress reports
  - Documents
    - Consent forms
    - Questionnaires
- Review subject files (paper and electronic)
  - Record of signed consent
  - Any data sheets from testing
  - Questionnaires
  - Data files

Preparation Process

- Study initiation
- Throughout the study
- Review notification
- During the review
- After the review/corrective actions

The Review

- Have all files accessible and ready to be reviewed
  - Study binder/folder
  - Subject files
    - Paper
    - Electronic
- Communicate with your IRB reviewer
  - Answer their questions
  - Ask them questions
  - They are there to ensure you are following protocol, but also to help you properly manage your IRB

Preparation Process

- Study initiation
- Throughout the study
- Review notification
- During the review
- After the review/corrective actions

Review Follow-Up

- Your reviewer will send you a report of your review
  - Their conclusions
  - Any corrective actions that need to be taken
    - MCW has a Corrective Action Plan (CAP)
  - Suggestions for the future
- The review may require completion of a CAP or a response on your part
  - Respond in a timely manner
  - Implement CAP
- Keep final review report and CAP (if appropriate) in study file

Conclusions

- Reviews are necessary to ensure compliance
- Use them to your benefit
  - Keep your studies organized
  - Ensure study staff follows rules and protocol

Conclusions

- Start preparing at study initiation
  - Follow all regulations
    - IRB
    - Sponsor
  - Communicate
    - IRB
    - Study staff
- Preparing from the beginning will make for a smoother routine review for you and the IRB staff