IRB Office Operations
&
Procedures

Presented by Tanna MacReynold, CIP
Assistant Director, Institutional Review Office
Fred Hutchinson Cancer Research Center

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Introductions

- Name
- Position
- Years in position
- What is one issue you would like to discuss today?

Purpose and Mission Statement for the Institutional Review Board (IRB) & The IRB Office

- Protect the research subject's capacity for self-determination;
- Maximize possible benefits and minimize possible harms; and
- Treat people fairly.

IRB Office
Focus

To assist the Institutional Review Board in reviewing research projects to ***assure*** that the ***rights and welfare*** of human research ***participants*** are ***protected*** and that the regulations are followed.

Who Works in the IRB Office

- Director
- Assistant Director
- 2 IRB Analyst
- 2 Administrative Assistance
- 1 IRB Specialist

IRB Staff Roles & Responsibilities

- Human Subjects Protection Shared Responsibility
  - IRB/IRB Staff
  - PI/Researchers
  - Institution
- Today our focus is the IRB Staff

Policies & Procedures

- Establish complete SOP's
  - Regulations
  - Institution Policy
- Communicate the SOP's to those that need to know:
  - Staff
  - IRB
  - Researchers

IRB Staff Roles & Responsibilities

Examples of the Roles & Responsibilities of
Large & Small Institutions

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IRB Staff Roles & Responsibilities

- Office Structure
  - Large Office – (Attachment 1)
    - Example Organization Chart
    - Director
    - Manager
    - IRB Analyst (Administrator)
    - Administrative Assistant
  - Small Office – (Attachment 2)
    - Example Organization Chart
    - IRB Analyst
    - Part-time or no Administrative Assistant

Large Institution Roles & Responsibilities

- Director
  - The focus is on the outside agencies and the overall institutional policy and procedures
    - OHRP, FDA, and International issues
    - Working with Institutional Officials
    - Liaison between Institutional Officials, IRB Members, and PI's
    - Complete knowledge of Federal Regulations
  - Oversee Regulator compliance
  - IRB Membership recruitment
  - Maintain and update Annual Assurance with OHRP
  - Oversee Budget

Large Institution Roles & Responsibilities Cont.–

- Manager
  - Primary focus is on the day to day operations
  - Oversee Regulator compliance
  - Recruit, hire and dismiss staff
  - Supervise staff
    - Performance review, discipline, and positive reinforcement
    - Review minutes & result letters
  - Education/Training – Staff and IRB Members
  - Maintain IRB office policies and procedures
  - Knowledge of Federal Regulations
  - Manage Budget
    - Staffing, supplies, and space

Larger Institution Roles & Responsibilities Cont.

- IRB Analyst
  - Knowledge of Federal Regulations
    - Provide regulatory guidance as needed by PI's, IRB Members, and staff
  - Knowledge of Ethical Principles
    - Belmont Principles
  - Effective Communication with Institutional Officials, PI's, IRB Chair and Members
    - Ensure that the PI and Institutional Official are informed of actions and findings of the IRB

Large Institution Roles Cont.

- Maintain accurate records of IRB actions per regulations
- Ensure that the continuing review of research is conducted appropriately and in a timely manner
- Oversee the adequate IRB membership review per regulations
- General office duties
  - Filing, date stamping, and data entry as needed
- Supervise Admin. Asst. as needed

Large Institution Roles Cont.

- Administrative Assistant
  - General office duties: filing, date stamping, and data entry
  - Send timely notices to PI's on reporting mandates
    - Continuation Review notices
    - IRB certification - multi-site trials
  - Support the IRB Analyst (Administrator) as needed
  - Support the IRB Members as needed
  - Electronic Systems – set up computers, scanning, specific data entry
  - Logistics of the meeting – calendar, location, and catering

Small Institution Roles

- IRB Analyst
  - Knowledge of Federal Regulations
  - Knowledge of Ethical Principles
  - Interact with outside organizations – OHRP, FDA, International, and Institutional Officials
  - IRB Membership recruitment
  - Manage and Maintain Budget
  - Maintain IRB office policies and procedures
  - Focus on day to day operations
  - Ensure submitted research is reviewed efficiently and consistent with regulations
  - Maintain accurate records of IRB actions

Small Institution Roles Cont.

- Ensure that the PI and Institutional Official are informed of actions and finding of the IRB
- Ensure that the continuing review of research is conducted appropriately and in a timely manner
- Provide regulatory guidance as needed by PI's, IRB Members, and staff
- Oversee the adequate IRB membership review per regulations
- Supervise Admin. Asst. as needed
- Process incoming and outgoing activities
- Logistics of the meeting – calendar, location, and catering
- General office duties: filing, date stamping, data entry, etc.

Role and Responsibility of IRB Analyst (Administrator)

- Apply institutional and federal policies, procedures and regulations as needed
- Support the IRB Chair and Committee Members
- Monitoring and ensuring compliance with OHRP, FDA, and Institution requirements
  - Ensure submitted research is reviewed efficiently and consistent with regulations
    - Exempt
    - Expedited review
    - Full review
    - Continuation Review
    - Revisions

Role and Responsibility of IRB Analyst (Administrator)

- Ensure meeting is run within regulations
  - Quorum
    - How many members are required?
  - Membership makeup
    - What members are required?
  - Conflicts of interest
    - What is your institutions policy?
  - Need for Consultants
    - When and Why?
- Setting up the meeting
  - Notification
  - Who will review

Role and Responsibility of IRB Analyst (Administrator)

- Maintain accurate records of IRB actions per regulations
  - Minutes of IRB meetings are detailed. Document IRB deliberations
    - But not to much detail
    - Special considerations documented (Subpart A – General Protections; Subpart B – Pregnant Women, Fetuses, and Neonates; Subpart C – Prisoners; Subpart D – Children)
  - Result letters
    - Clear – What and Why
  - IRB file documentation – If it is not documented it did not happen
  - Data entry and accuracy is critical
- General office duties: filing, date stamping, and data entry as needed

How to Enhance your Position as an IRB Staff Person

- Know the Regulations
  - 45 CFR part 46, Subpart A
  - FDA 21 CFR parts 50, 56
- Know your Institutions Policies and Procedures
- Know your Job Description
- Read Institutional Review Board – Management and Functions
- Training – CITI – Local Lectures – Regional & National Conferences
- Obtain your “CIP” Certified IRB Professional certification

Workload & Staffing Considerations

- Data to be considered
- Definition of “Activities”
- Staffing
- 5 years of data to include:
  - IRB Activities
  - Number of open protocols
  - Number of IRB FTE’s
- Additional workload influences
- Database tracking/reporting capabilities

Data to be Considered

- Number of open protocols
  - Full – Expedited – Exempt
- Number of activities
- Number of staff and their duties that are dedicated to IRB activities

Definition of “Activities”

- Initial Review
- Annual Review
- Modifications
- Closures
- Multi-sites
- Cooperative files
- Miscellaneous Activities
- Emergency Treatment
- Funding review
- Adverse Events
- Protocol Violations & Deviations

How do You Define “Activities” ?

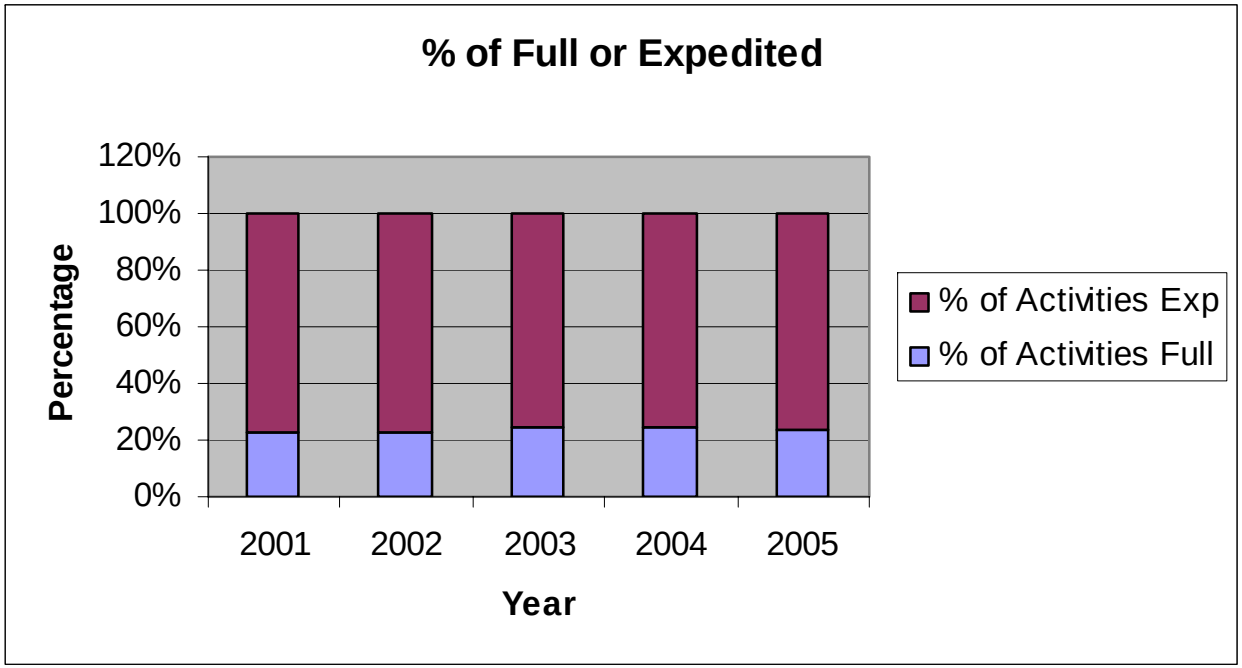
- Tracking follow-up SAE’s ?
- Tracking modifications w/in CRR’s ?
- Tracking “miscellaneous” items?
- Tracking consultations with study staff?

Activities 2001 - 2005

- 2001 - 2713
- 2002 - 3075
- 2003 - 3665
- 2004 - 3765
- 2005 - 3852

42 % ⇑

Full Review versus Expedited Review



80% Over 20%

Staffing Considerations

- Duties
- Not all staff work on IRB 100%
- Not all staff are at the same skill level
  - New – In training
  - Organized – “or not”

FTE's 2001 - 2005

	2001	2002	2003	2004	2005
IRB Analyst	1	2	2	2	2
Admin Asst II	1.4	2	2	2.5	2.5
Admin Asst I	0	0	0	0	.25
Director	.75	.75	.75	.75	.75
Manager	.75	.75	.75	.75	.75
IRO Specialist	.5	.6	.6	.6	.75
IT	0	0	0	.5	.5
Total	**4.4**	**6.1**	**6.1**	**7.1**	**7.5**

71 % ⇑

Open Protocols 2001 - 2005

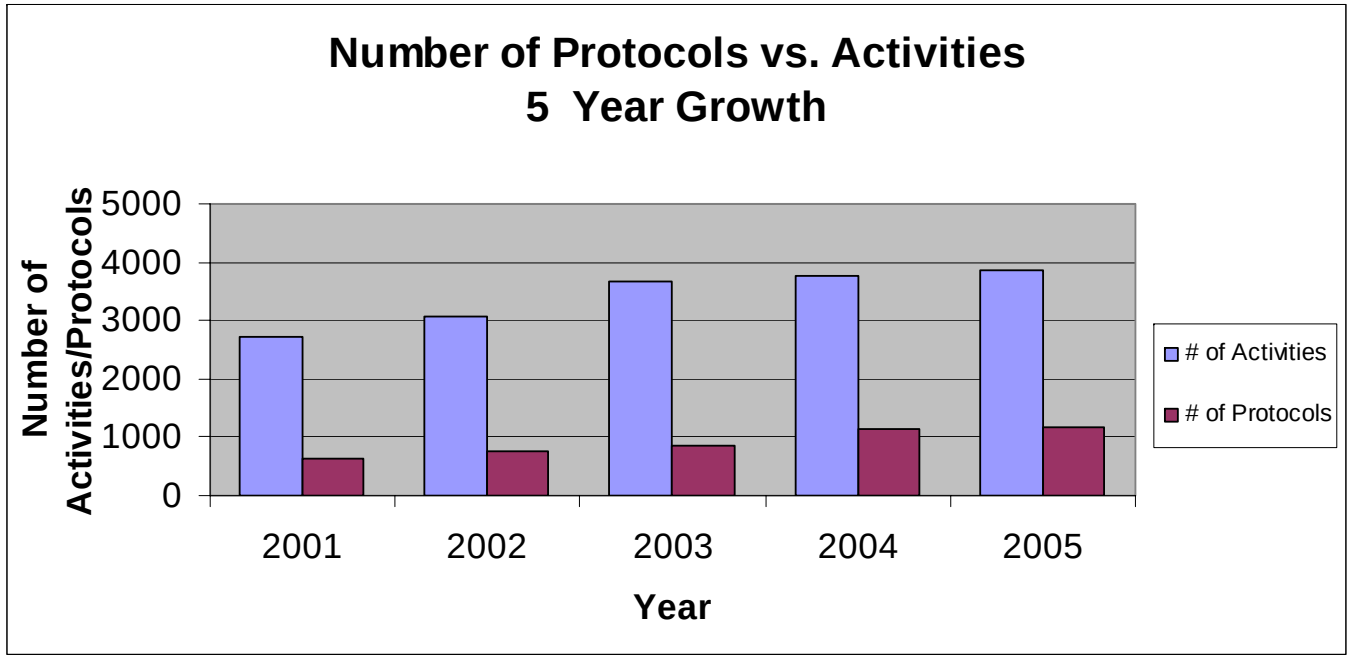
- 2001 - 621
- 2002 - 751
- 2003 - 854
- 2004 - 1142
- 2005 - 1180

90 % ⇑

Protocols per FTE
2001 - 2005

- 2001 - 141
- 2002 - 123
- 2003 - 140
- 2004 - 161
- 2005 - 157

Summary of 5 Year Growth



Number of Activities	**42 %**	⇑
Number of Protocols	**90 %**	
Number of FTE	**70.5%**	

Additional Workload Influences

- Training
  - Staff, IRB Members, and Research Staff
- Policy and Procedures
- Web Master
- Forms Creation and Maintenance
- Consent Editor
- Auditing – Internal and External
- Sub-Committees (Consent Issues, Recruitment, etc)
- Regulatory Changes

Additional Workload Influences Cont.

- Level of Screening
  - One page screener to three
  - Actual time to screen
  - Pre-screening and follow-up
    - Tracking systems – ticklers
- Re-review by IRB
  - Only one entry goes into database
- Problem solving
  - Committee Members
  - Study Staff

Summary
Staffing Formula

 # Activities

+

 # Protocols

+

Additional Considerations

=

# of FTE's

Tools for Managing Workload

- Database
  - Make sure you are capturing what you need
  - Information must be easy to obtain

- Reports
  - Monthly
  - Annual for Budget

- Questions ?