The Seven Habits of Highly Effective IRBs
Creating the Balance Between Satisfying Regulatory Requirements While Creating a Productive Clinical Research Enterprise

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Objective

- Using the flexibility of Qatari policy
- Appropriate evaluation of risk
- IRB models to streamline research
- Following the regulatory criteria for approval
An effective Human Research Protection Program (HRPP) is a shared responsibility of the institution, investigators, and the IRB.
The Seven Habits of Highly Effective HRPPs

1. Establish a strong organizational official
2. Limit the IRB’s authority to the regulations
3. Centralize research support
4. Mentor investigators
5. Follow the criteria for approval
6. Flexibly review minimal risk research
7. Use full-time, professional IRB members
1. Establish a strong organizational official
What is an “Organizational Official”

- Leader of the HRPP
- Sets compliance culture
- Respected liaison to investigators
  - Investigator
  - Leader
  - Similar profession
- Promotes responsible conduct of research
- Assumes authorities not granted to the IRB
Authorities

- Allocate resources
- Appoint/remove IRB members/chairs
- Hire/fire research review staff
- Determine problems are unanticipated and involve risks to subjects or others.
- Determine non-compliance is serious or continuing.
- Limitation/condition research privileges
- Create policies binding on institution
- Suspend, terminate, or disapprove research
Responsibilities

- Oversee review and conduct of research
- Ensure compliance with ethical and legal requirements
- Institute training programs
- Ensure the IRB is independent
- Act on allegations regarding human research
- Implement monitoring to improve compliance
- Investigate and remediate systemic problems
Behaviors

- Communicator to IRB manager/chair and investigators
- Promoter of research and compliance
- Insist that the IRB apply the regulations and no more
- Insist that the investigators comply with regulations
2. Limit the IRB’s authority to the regulations
Question

- The IRB is responsible to protect the rights and welfare of subjects.
  - True
  - False
IRB Responsibilities

§56.101 Scope.
  – (a) This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.
IRB’s authority according to the regulations

- Approve
- Require modifications in (to secure approval)
- Disapprove
- Suspend approval
- Terminate approval
- Observe or have a third party observe the research
What IRBs do not have authority to do

- Decide what research has to be reviewed by full board
- Determine whether non-compliance is serious or continuing
- Review and approve IRB SOPs
- Bar use of data
- Require destruction of data
- Prohibit publication
- Sanction investigators
- Reprimand investigators
Authority of the organizational official

- Review and approve SOPs
- Decide whether non-compliance is serious or continuing
- Manage research conducted without IRB approval
  - Bar use of data
  - Prohibit publication
  - Require destruction of data
- Deal with difficult investigators
  - Require remedial actions
  - Bar from conducting research
IRB versus institutional obligations

**IRB**
- Follow the regulations to take action on protocols to protect subjects

**Organizational Official**
- Use executive authority to take action on individuals to protect subjects and ensure compliance
3. Centralize research support
Question

• Which individual on the research team is most critical to ensure compliance and effective human?
What do Milgram’s experiments on obedience to authority tell us about research non-compliance?
Observations

- Behind almost every research disaster is:
  - An untrained coordinator
  - or
  - An investigator whose authority status prevented a trained coordinator from speaking out
Why is air travel so safe?
Solution

- Centralize research staff
- Do not allow investigators to hire their own coordinators
- Maintain standards for hiring and responsibility
- Establish safe outlet to express concerns
4. Mentor investigators
How do we train physicians to be:
  – Internists?
  – Pediatricians?
  – Surgeons?

How do we train physicians to be:
  – Investigators?
Did you learn to practice medicine?

Reading a book?  

Sitting at a computer?
Let’s train and credential investigators to conduct research like medicine

- Learn by doing
- Structured supervision
  - Attending - fellow
- Graduated responsibility
- Targeted didactics
- Learn by training others
5. Follow the criteria for approval
Common IRB problems

- Inconsistency
- Focus on scientific review
- Non-scientists feel left out
- Scope creep
- Picking on nits
- Lack of focus on important issues
How do you decide whether research can be approved?
How do you decide whether research can be approved?

Wrong answers

- Is the science good?
- Is the consent readable?
- Would I let my grandfather take part?
- Are risks minimized?

Right answer

- Are the criteria for approval all met?
IRBs must apply the regulatory criteria for approval

• Criteria for IRB approval of research.
  – In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied: ...
Mandatory use of regulatory criteria for approval

- Require the IRB to use the criteria for approval
- Require use of a checklist
- Require everyone to read all materials
- Require IRB to justify each problem by the criterion not met
- Items unrelated to a criterion are “off the table”
Off the table items

- Pay subjects more money
- Improve the science
- Safety of investigator
- Legal risk of institution
- Compliance with laws not directed at research
IRBs that understand and rigorously apply the regulatory criteria for approval:

- Are more consistent
- Have better focus on the protocol
- Avoid getting mired in consent wording
- Have greater involvement of non-scientists
- Stay mission driven – Have less scope creep
- Better explain their decisions to investigator
6. Flexibly review minimal risk research
Flexibly review of minimal risk research

- Review all activities for the least restrictive level of the following categories:
  - Not human research
  - Human research, but the institution is not engaged
  - Exempt
  - Expedited
  - Convened IRB review

- Provide advice for how to lower the level of review
Not human research determinations

- Ask in order:
  - Is this research? Stop if no.
  - Does this research involve human subjects?

- Not all ethical issues belong to the IRB

- Ask yourself:
  - If outside the academic context would this require IRB review?
  - If this is human research, what else is research?
Use the regulatory definition of private

Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.
Use the regulatory definition of identifiable

- The identity of the subject is or may readily be ascertained by the investigator or readily associated with the information by the investigator.
Engagement determinations

- Employees or agents refers to individuals who:
  1. Act on behalf of the institution;
  2. Exercise institutional authority or responsibility; or
  3. Perform institutionally designated activities.

- Decision of whether someone is doing 1-3 is policy
Exemptions

• Approve all exemptions according to ethical criteria

• Exempt does not prevent IRB from requiring:
  – Consent
  – Parental permission
  – Procedures to ensure minimal risk

• What counts is what you approve
Expedited review

- Approve all expedited reviews according to regulatory criteria
- Expedited review does not prevent IRB from obtaining:
  - Consultation
  - Input from another IRB member
  - Input from all IRB members
- What counts is what you approve
7. Use full-time, professional IRB members
When the chair is the expedited reviewer

- IRB staff spend two hours
  - Read all the materials
  - Use the checklists
  - Write a memo about what is missing or needs to be changed to grant approval
  - Document the findings

- The protocol file is placed on the chair’s desk

- Who is the real reviewer?
Use full-time, professional IRB members

- Assign IRB staff members to be IRB members
- Train IRB staff members to:
  - Grant non-human research determinations
  - Grant non-engagement determinations
  - Approve exempt research
  - Conduct expedited review
- Designate IRB staff members as experienced IRB members
Compared to “part time” IRB members with a primary job, full time IRB staff members:

- Spend more time
- Better attention to detail
- More actions per day
- Better understanding
- More professional
- IRB staff who do “pre-review” for the chairs are the real reviewers
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