Introducing Flexibility in Practice While Maintaining Regulatory Compliance

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Established by the Vice President for Research at the University of Minnesota in January 2011, the risk recalibration initiative is an essential step toward achieving operational excellence.

This effort takes a more strategic approach to managing risks in all aspects of university operations.

It involves a strategic analysis of all operations, policies, procedures, job descriptions, and decisions.

The goal is to manage risk appropriately, tolerate some risk taking, but NEVER lower standards for actual or perceived protection of research subjects.

http://www.research.umn.edu/about/risk.html#.UC5zTqP65c4
Applying the concept to the Human Research Protection Program (HRPP)

- Examine your organizational level of risk tolerance:
  - Does the IRB/EC presume all research involves risk?
  - Are the IRB members extremely cautious and risk averse?
  - Is the organization cautious in most areas and transactions?
Are there policies or procedures which over-reach the regulatory or guidance requirements?

Are policies linked to an actual requirement?

Does the HRPP develop “rules” based on exceptions or single cases which occur rarely?

Is the IRB or the HRPP staff overworked with minor administrative tasks?
Examples of over regulation

- Requiring written informed consent when waiver of documentation is permissible
- Requiring review by convened board when expedited review is permitted
- Requiring screening for all research activity even when it is exempt from IRB review
- Requiring continuing review of exempt research
- Duplicating effort—scientific review
- Requiring checklists and rigid forms for minor communications or transactions
- Requiring repeated education on basic information
- Reviewing all problems/adverse events even those outside of requirements in regulations
Constitution of IRB itself

- Are members appointed for political or prestige reasons, not for expertise?
- Is the membership large and meetings difficult to convene?
- Do meetings last for hours—are they run inefficiently?
- Does the IRB membership trust researchers?
Is there a sense of paternalism?

- Presumption that all research involves risk, even behavioral or psychological research?
- Presumption that asking sensitive questions or research on difficult topics introduces risk rather than relieving stress?
- The IRB must protect people from all risk
  - Especially women, children, the elderly
- Research participation is of greater risk than daily life
Fear of litigation drives decisions

- Over involvement of legal counsel in IRB deliberations

- The organization sees all decisions as having potential for litigation. Fear of lawsuits hinders research.
Involvement of the entire HRPP

- IRB
- IRB staff
- Organizational official
- Legal counsel
- Grants and contracts staff
- Communications personnel
- Compliance and monitoring functions
- Conflict of interest review process
- Scientific review process
Some action steps

- Solicit feedback from researchers on restrictive practice and its impact on studies. Convene a group of active, perhaps critical, researchers and get their input on possible changes.
- Analyze every policy/procedure for a link to a requirement or guidance directive.
- Get researcher feedback on how IRB stipulations affected research implementation—helpful, burdensome, added protection??
Results:

- streamlined forms,
- eliminated some signature requirements,
- eliminated phone trees,
- established different process for medical chart research
- eliminated unnecessary policies
- streamlined policies into “guidance”
Risk based monitoring

- Post approval review:
  - Established a risk-based process to identify priority research requiring monitoring and verification
    - High risk research
    - High profile research
    - Researcher on-compliance history
    - Large centers with many studies
  - NOT random audits
Exercise existing regulatory flexibility

- Grant exemptions
- Don’t review research that does not meet the definition of research with human subjects
- Waive documentation of consent when possible
- Waive consent when possible
Shift thinking in minimal risk research

- Ask researchers to justify why they need documentation of consent in minimal risk research rather than ask for justification of waiver.
Do the minimum necessary:

- Records retention standards
- Signature requirements on forms
- Formal or rigid meeting management protocols
Focus on the essential

- Ask if activities are designed to maximize protection
- Concentrate on the requirements, not “extras” that do not enhance protections
Example of the process for policy and procedure analysis

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Questions ?

Suggestions ?

Other ideas ?