Decentralized Exemption Determination Process

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Problem

The Office for Human Research Protections:

- Recommends that investigators not determine whether their own research is exempt from the Common Rule
- Does not specify who has the authority to make these determinations

Many institutions designate the IRB as the decision authority, causing:

- Increased burden on the IRB
- Lack of timeliness in the reviews
- Perception of regulatory creep

Background

The National Human Research Protections Advisory Committee (NHRPAC):

- Formed a social and behavioral sciences working group (WG)
- Charged the WG with suggesting ways to reduce regulatory burden in low risk research while maintaining protections for research participants
- The WG provided specific recommendations for achieving the above (see handout)

OUSD (P&R) Environment

- 8 institutions engaged in research
- Each institution is equivalent to a university department in terms of management structure
- Institutions include a K-12 school system, a health care program, a medical school, and a personnel research center
- The institutions conduct between 3 and 500 human subjects research protocols per year
- Exemption determinations range from 90% of protocols at the K-12 school system to 10% at the medical school

OUSD (P&R) Solution

- Each institution designates an Exemption Determination Official (EDO) to serve as the program manager for the HRPP

Knowledgeable about research | No vested interest in the research | Sufficient stature and authority

- Activities that appear to involve human subjects research are forwarded to the EDO for review
- EDOs determine what level and type of review each project needs and document the decision

Exempt Determination Official (EDO)

EDOs:

- Receive direct training from the HRPP oversight office and "on-the-job" mentoring
- Report to both the oversight office and the Institutional Official (IO) to balance their authority
- The authorities of the EDO are separate from and independent of the IRB and the regulation
- Until they are proficient, all of their determinations must be approved by the oversight office
- Once they complete training and make independent determinations, their files are subject to review by the oversight office

Keys for Success

- The EDO needs a deputy or Co-EDO for purposes of continuity
- The number of EDOs per institution varies by volume
- Determine beforehand which EDO conducts reviews to prevent EDO shopping
- The EDO must have strong support from the IO and the oversight office
- Encourage open dialogue between the EDO and the oversight office
- Develop an appeal process for EDO decisions
- Conduct periodic routine group training to promote networking
- Conduct periodic formal and informal audits for both quality assurance and quality improvement purposes

Measures

Efficiency is measured by processing time as determined by:

- EDO reviewer files
- Self reports

Effectiveness is measured in correctness of EDO determinations as identified by:

- Review outcomes
- Total number of compliance problems program wide

Results

Using these measures, most determinations are made within 48 hours of receipt of proper documentation

With at least one informal review of each of our institutions completed, we have not found any significant review errors

Higher overall rate of compliance is shown by reduction in non-compliance issues comparing audit results and reports from other sources from the year we initiated the program to the present: FY05 to FY09

Conclusion

This program:

- Sets standards for human subject protections across the institutions
- Provides higher consistency in research reviews
- Opens communication between the oversight office and local institutions
- Produces remarkably efficient reviews that are based in the research environment

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