
FDA Research: Clearance Requirements and Implications

Steven L. Bradbard, Ph.D.
Team Leader, Consumer Studies
CFSAN/ORPSS



Importance to FDA

- Helps set program priorities
- Supports policy and rule-making
- Offers possible evidence for litigation
- Informs communication – advisories, risk communication, education
- Provides information for Economic Regulatory Impact Analyses (RIA's)



Impetus for Studies

- We get our direction from numerous sources including:
 - The Department
 - Office of the Commissioner and Office of the General Counsel at FDA Headquarters
 - Other FDA Centers
 - Center Director
 - Center Program Offices



Typical Research Methods

- Surveys
- Experiments
- Focus Groups
- Interviews
- Mental Modeling



The Extramural Research Process

- Obtain a request and funding for a study
- Collaborate with Contractor
- Collaborate with Program Offices
- Clear the protocol with Center/FDA/HHS
- Obtain OMB and RIHSC approvals
- Complete cognitive interviews and pre-test
- Conduct the actual study
- Analyze, peer review, and clear the results



The ABC's of OMB

- OMB = Office of Management and Budget
- PRA = Paperwork Reduction Act
- OIRA – Office of Information and Regulatory Affairs
- FR = Federal Register
- ICR = Information Collection Request
- IRM – Information Resources Management



Paperwork Reduction Act

- The PRA was enacted in 1980 and reauthorized in 1995.
- It created the OIRA within OMB
- It established within each agency an Information Policy Office and an Information Officer to carry out IRM activities



OIRA and Agency PRA duties

- Develop IRM policies
- Review and approve ICR's
- Promote public access to information
- Oversee information privacy/security policies
- Coordinate statistical policies
- Implement records management



More about the PRA

- The Paperwork Reduction Act stipulates that Agencies must:
 - Seek public comment on proposed collections of information through "60-day notices" in the Federal Register;
 - Certify to OMB that efforts have been made to reduce the burden of the collection on small businesses, local government and other small entities, and
 - Have in place a process for independent review of information collection requests prior to submission to OMB.



Implications for social science

- Each time an agency proposes collecting information from ten (10) or more people, the ICR must first be approved by OMB
- Before you submit an ICR to OIRA, it must be:
 - Reviewed and cleared by the Center's liaison to the Agency IO,
 - reviewed and approved by the Agency IO, and
 - announced (published) in the FR as a 60-day notice



The 60-day notice

- The research protocol is available to the public upon request
- The public provides comments to the open docket during the 60-day period
- The Center requesting the ICR reviews and responds in writing to these comments in a way that is satisfactory to OMB



Is followed by the 30-day notice

- The Center then publishes its response to the public comments in a 30-day FR notice, which re-opens the docket for additional public comment period
- When this comment period closes, the Center again reviews and provides OMB with written responses to the comments, and answers any remaining OMB concerns



Exceptions to standard PRA

- **Focus Groups and Interviews**
 - Strong stipulations from OMB on use of data
- **Rapid Response Surveys**
 - Limited data collection purpose
- **30-Day Emergency OMB Approval**
 - Limited circumstances



Title 45 of the Code of Federal Regulations (CFR) Part 46

- Human subject research (except for those categories of research specifically exempt or granted a waiver under the DHHS regulations and not otherwise included by FDA policy) conducted, supported, or funded in whole or in part by FDA will be reviewed and approved by an IRB established by FDA.



RIHSC Human Subjects Research

- Studies conducted, supported, or funded, in whole or in part, by FDA.
- Off-site studies, domestic or foreign, including studies with other government agencies.
- Studies with IRB approval from other organizations, including other government entities.
- Clinical, feeding, or interventional studies.



Human Subjects Research

- Studies involving focus groups, tests, or surveys.
- Retrospective studies involving record reviews.
- Studies using human biological materials.
- Studies using FDA's private database information, either alone or in collaboration with another government agency.



FDA's RIHSC

- The Research Involving Human Subjects Committee (RIHSC) is FDA's Institutional Review Board (IRB) tasked with reviewing all studies using human subjects
- Every FDA Center has a RIHSC Liaison who reviews the "packages" submitted in support of human subject research
- Often, RIHSC review proceeds concurrently with OMB review



RIHSC and Social Sciences

- A study reviewed by the Center RIHSC liaison are forwarded to the RIHSC Committee with a recommendation that it be EXEMPT from review, or be considered for EXPEDITED or FULL review.
- Most social science research with adults, unless it uses high-risk populations and/or studies highly sensitive topics, is considered EXEMPT.
- All social science research with non-adults will undergo an EXPEDITED or FULL review.



More on “Exempt”

- A researcher can **not** self-exempt!
- The researcher must provide the Center RIHSC Liaison with a completed RIHSC Exemption Status Application
- If the Center RIHSC Liaison agrees that the study meets the criteria for exempt, she makes this recommendation to the core members of the FDA, who makes the final determination
- An exempt study does not go to the full RIHSC for review.



Beyond OMB and RIHSC

- Many other factors influence the timeline for social science research in FDA
 - Funding cycles and budgets
 - Internal collaborations
 - Sensitive topics
 - Emerging science and new research
 - Review and clearance SOP's at the level of the Center, Agency, and Department

