Agency for Healthcare Research and Quality

Advancing Excellence in Health Care www.ahrq.gov

Paperwork Reduction Act: How it Affects Your Research Project

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AHRQ Health IT Grantee and Contractor Meeting

Outline

- What is “OMB clearance”
- When is clearance required
- What are the options for clearance
- When should I think about clearance
- What is the process for clearance
- How can I make this easier on myself/my program

What is OMB clearance?

--Paperwork Reduction Act of 1995

--Collection of information from 10 or more persons/entities

--Around since 1946 and in its present form since 1995

--Process is periodically subject to review and reform

What is the purpose

-- Minimize the public burden

--Ensure greatest public benefit from the collection of information

--Minimize cost and duplication

--Ensure the quality of the federal statistical system

When is clearance required?

--For rulemaking

--Forms and recordkeeping requirements

--For information collections from 10 or more persons or entity, or 10 or more responses from a single person or entity; responses here means complete data collections, not responses to individual questions.

Determining whether an activity requires information collection clearance

- Does the Agency conduct or sponsor the collection? (By DHHS interpretation – all contracts and cooperative agreements
- Is information being solicited from 10 or more persons (includes entities other than persons, businesses, partnerships, states)?
- Mode of collection is not relevant. Mail, phone, web based interviews are all covered, as well as group interviews, focus groups

Exclusions from the PRA

--Current federal employees and military personnel when the collection is related to their professional capacities

--Some kinds of clinical trials are in part, exempt.

--Ten categories of information 1)affidavits, oaths, receipts etc 2)Samples of physical objects 3) Facts/opinions obtained by direct observation 4) Facts or opinions made in response to general solicitation of comments to the general public 5) Information from persons in clinical trials when obtained 6) Facts or opinions from a single person 7) Aptitude examinations alone 8) Facts or opinions solicited in connection with public hearings 9) Information solicited in non-standardized follow-up questions for an APPROVED collection 10) Like items OMB declares exempt

Clinical Exemptions

--Collections of information from or about patients (including controls)

--Under care for the prevention or treatment of a specific condition

--Does not apply to “process” type information collected from providers or others

--Exempt from OMB review, but not from review. The Agency will conduct a review in house for projects likely to be eligible for a clinical exemption.

Other important information

- Identical questions
  - Questions with variations tailored to specific respondent circumstances are considered “identical”
  - Nondirective requests for facts or opinions are not “identical”
  - A “suggestion box” is not subject to the PRA, nor are general solicitations for comment
- Person
  - Asking substantively different questions of several persons within an establishment counts as “one” persons.
- 10 or more persons
  - Number of persons expected to answer within a year
  - Collections addressed to a majority of an industry or group are presumed to be subject to the PRA (a majority of States, firms in the domestic auto industry)

Types of clearance

- Regulation/rulemaking (not discussed here)
- Generic Clearances
  - Pretest
  - Customer
- Regular Clearances

Generic Clearances

- AHRQ proposes standardization of requests for routine collections
- OMB reviews the standardized request once
- Specific instances are approved quickly
- Usually have restrictions
- AHRQ has 3 generic clearances and could initiate others
- In exchange for constraining the project, OMB waives the public comment period and generally responds in 2-3 weeks

Pretest generic clearance

- Limits AHRQ's pretest burden over a 3 year period (Limit is quite high)
- Restricts what AHRQ can do with data collected under this authority
- Very useful for starting small projects

Customer Generic Clearance

--Used for evaluation of Agency programs

--Customer is defined broadly

General Process

- Contact the Reports Clearance Officer
- Issue 60 day Federal Register notice. At this point you need a draft supporting statement and instrument
- Issue a 30 day notice
- OMB has 60 days to rule

Outcomes

- Approval
- Approval with conditions/terms
- Disapproval or agreement to withdraw

WHEN should I think about this

- Whenever you write a task order, contract or cooperative agreement that asks or implies that the recipient obtain data
- We can help you start the process before the contract is awarded
- We may be able to suggest modifications that
  - Make clearance unnecessary
  - Make clearance easier on you by describing what you will need from your contractor
  - Make clearance easier to obtain by suggesting a design modification

Typical hold ups in the clearance process

- Lack of specificity in design
- Misalignment of aims and methods
- Attempt to generalize without sufficient rigor
- Letting the “ball drop”

Important Information

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Links:
http://whitehouse.gov/omb

http://www.hhs.gov/ocio/policy/collection/index.html