

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE FOR DATA TO SUPPORT CROSS-CENTER COLLABORATION FOR SOCIAL BEHAVIORAL SCIENCES ASSOCIATED WITH DISEASE PREVENTION, TREATMENT AND THE SAFETY, EFFICACY, AND USAGE OF FDA REGULATED PRODUCTS (0910-NEW)

Qualitative methods generally yield data that are not statistically generalizable. As such, they are useful for testing and refining ideas, and for developing hypotheses that can be further explored using quantitative methods, which is the preferred method for informing important policy and resource allocation decisions.

TITLE OF INFORMATION COLLECTION: [insert]

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Type of Collection:

[Check all that apply.]

- In-depth, one-on-one interviews
- Small groups
- Focus groups/town halls
- Observations

2. Statement of need:

[Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort please include this in your explanation.]

3. Description of study participants:

[Describe participants and provide justification for your selection.]

4. Date(s) to be conducted:

[insert]

5. How the information is being collected:

[Describe how the participants will be recruited into the study and also how the data will be collected.]

6. Amount and justification for any proposed incentive:

[insert]

7. Questions of a sensitive nature:

[insert]

BURDEN HOUR COMPUTATION

No. of Participants: Provide an estimate of the number of participants.

Participation Time: Provide an estimate of the amount of time required for participation.

(Number of participants X estimated response or participation time in minutes (/60) = annual burden hours):

Activity	No. of Participants	Participation Time (minutes)	Burden (hours)
Individual In-Depth Interview Screening			
Individual In-Depth Interviews			
Focus Group/ Small Group Participant Screening			
Focus Group/ Small Group Discussion			
Observation Screening			
Observations			
TOTAL			

REQUESTED APPROVAL DATE: [insert]

NAME OF PRA ANALYST & PROGRAM CONTACT: [insert]

Please make sure that all instruments, instructions, and scripts are submitted with the request.