



## Community Consultation and Public Disclosure Activities Menu

### Background and Instructions

When determining whether the community consultation and disclosure process is adequate for an EFIC study, the IRB needs to have a good idea of what consultation and disclosure activities will take place at each participating research site.

Each participating site should customize their consultation activities to address the needs of their local context, so it is recommended that the study protocol include a “menu” of activities the lead study team will accept and then allow each site to choose from the menu as they each develop their local Community Consultation and Public Disclosure plan. The menu we recommend is outlined below.

In the protocol, each participating site should be directed to choose activities for their site-specific Community Consultation & Public Disclosure plan, which will be submitted to the IRB for review and approval.

At a minimum, each site should include the following:

- **Community Consultation (Pre-Study):**
  - Three (3) Interactive Activities from Group A
  - Three (3) Passive Activities from Group B
  
- **Public Disclosure (Pre-Study):**
  - Three (3) Collaborative Activities from Group A
  - One (1) Purchased Ad Activity from Group B
  - Two (2) General Activities from Group C
  
- **Public Disclosure (Post-Study):**
  - Same standards as Pre-Study Public Disclosure

### Community Consultation (Pre-Study)

Group A (Interactive)	Group B (Passive)
Existing Community Meeting	Telephone Survey
Study-Specific Town Hall Meeting	Online Questionnaire
Focus Group	Social Media Posts
Community Event(s)	Targeted Mailings/Flyers
Local Radio and/or Television Talk Shows	Articles/Advertisements

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.



## Description of Activities

### Group 1 (Interactive):

**Existing Community Meeting:** A study team schedules a presentation of the proposed study at standing meetings (such as local civic public forums, disease-related support groups, service organizations, schools, faith-based organizations, etc.). At the meeting, investigators would present and then direct a question and answer session.

*Requirements:*

- Members of the study team (preferably an investigator) must attend to conduct the presentation and the Q&A.
- Take minutes of the meeting to document the discussion.
- Provide a summary of the event to the IRB.

**Study-Specific Town Hall Meeting:** The study team sets up a “town hall”-style meeting specifically to discuss the project with an interested audience, such as participant advocacy groups, support organizations, etc. Individuals from several different communities can be invited, with the possibility of opening to the public so anyone may be included.

*Requirements:*

- Members of the study team (preferably an investigator) must attend to conduct the presentation and the Q&A.
- Take minutes of the meeting to document the discussion.
- Provide a summary of the event to the IRB.

**Focus Group:** A facilitator conducts a focus group to allow for more in-depth information collection because people are able to interact more with the moderator and other participants. Participants for focus groups might be recruited from special populations (e.g., advocacy or support groups), volunteer pools, public data sets, etc.

*Requirements:*

- Follow best practices for designing and conducting a focus group session.

**Community Events:** Investigators set up a display or table at a community event (fairs, markets, festivals, concerts, fundraisers, sporting events, etc.) and speak with interested individuals about the prospective study.

*Requirements:*

- Written materials such as flyers or brochures outlining study details (objectives, population, timing, etc.) should be provided.
- Several study team members must be available for discussion with interested individuals.

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**Local Radio and/or Television Talk Shows:** Study team members participate in a local talk show, presenting study information. This method differs from a public service announcement because a portion of time should be allotted for community members to call with questions for investigators.

## Group 2 (Passive):

**Telephone Survey:** Conduct a telephone survey via a third-party vendor who gathers data about the study. The survey questions must be carefully drafted and tested to ensure efficacy, keeping in mind that phone bank operators will be unable to answer follow-up questions.

### *Requirements:*

- Operators must be provided a script that includes a summary of the study and pertinent details to give to participants.
- Questions must be “closed-ended” so telephone operators are not attempting to field follow-up questions.

**Online Questionnaire:** Email questionnaires to potential respondents or post them to websites or similar platforms. Consider including visual components (e.g., charts or diagrams) to help educate the community about the study.

**Social Media Posts:** Post on social media platforms (Facebook, Instagram, Pinterest, Snapchat, YouTube, Twitter, etc.) to gather community opinions about the study. Social media allows for a lot of interaction, including direct messaging toward select, targeted groups. Posts may be a one-time static message requesting feedback, but study team members should engage the community where possible.

**Targeted Mailings:** Send study information via mail or in-person flyer to households in targeted communities. Include information about the study, a survey for individuals to respond with opinions or concerns, and study team contact information.

**Articles/Advertisements:** Create written, study-specific content for inclusion in online or print newspapers or similar media outlets. This content may include reference to a study website that provides more-detailed materials or contact information for investigators.

### *Requirements:*

- Messaging must be presented in lay-person terms and should be free of jargon and/or complex medical terminology.
- Public outreach documents should be translated into common languages in the community where the research will occur.



### Public Disclosure (Pre-Study)

Group A (Collaborative)	Group B (Purchased Ads)	Group C (General)
Study Website	Print	Public Service Announcements
Social Media	Outdoor	Television/Online News Segment
Mailings (Electronic and Print)	Radio/Television	Press Release/Conference
Community Event(s)	Internet	Print Distribution

### Description of Activities

#### Group A (Collaborative):

**Study Website:** Investigators may create and maintain a website for the study including the items listed above (“study-specific materials”). A website can be easily referenced in other methods of public disclosure as a hub for information that provides study transparency.

**Social Media:** Post study-specific materials or a link to the study website on social media platforms (Facebook, Instagram, Pinterest, Snapchat, YouTube, Twitter, etc.) to notify target audiences in the community. These posts can take the form of videos, infographics, or written summaries.

**Mailings (Electronic and Print):** Distribute study information via mail or email to individuals in targeted communities. Include study-specific information and study team contact information.

**Community Event(s):** Set up a display or table at a community event (fairs, markets, festivals, concerts, fundraisers, sporting events, etc.) and disburse written materials to inform the attendees about the prospective study.

#### Group B (Purchased Ads):

Investigators should consider purchasing advertising for more widespread access to disclosing study information to the community. The disclosure may be brief but should be suited to the medium and audience. Advertisements must supply an overview of the study, the study website address, and site study team contact information.

**Print:** Newspapers, magazines, or other types of regularly printed periodicals.

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**Outdoor:** Billboards, posters on public transportation, banners, etc.

**Radio/Television:** Brief 30-60 second ads (audio or visual) or longer, more informative spots that allow for disclosure of more study-specific information.

**Internet:** Banner ads, Facebook or other social media ads, YouTube videos, etc.

### **Group C (General):**

**Public Service Announcements:** Work with radio, television, and/or internet content providers to issue a concise, community-oriented public service announcement (PSA) about the study. Using proper distribution, they can be targeted to specific demographics and groups.

**Television/Online News Segment:** Inquire at television or online media outlets to discuss a segment about the study, incorporating an interview with investigators that describes why the community is being notified. Information about how to contact the study team may be included.

**Press Release/Conference:** Issue a release or hold a brief conference with media outlets to provide basic information about the study, which can then be disseminated more broadly among the community.

**Print Distribution:** Create newsletters, flyers, brochures, etc. to post or display in public spaces where community members may see the study-specific information.

### **Public Disclosure (Post-Study)**

Once the study is finished (all participants have been enrolled and follow-up of primary endpoint data on all participants has been completed) the investigators must disclose information about the conduct of the study to the community(ies) and to other researchers. The information should be reviewed by the IRB prior to distribution and should clearly describe the study design and its results, both positive and negative, including:

- information about the primary outcome(s) of the study;
- the number and nature of adverse events associated with the test article;
- whether the study was terminated, and the basis for that decision.

Investigators should consider using similar methods as utilized in pre-study disclosure; however, there is an advantage in the study being published in scientific journals. It should be noted that merely posting results on [clinicaltrials.gov](http://clinicaltrials.gov) is not a sufficient approach. Returning results to participants and their families may engender trust and confidence in the research process.