



Community Consultation and Disclosure Data Collection Expectations for EFIC Studies

Background and Instructions

When determining whether the community consultation and disclosure process is adequate for an EFIC study, the IRB must consider the community's opinions and concerns, assess the adequacy of the consultation and disclosure process, and incorporate the results of community consultation and discussion into its decision making.

The IRB may wish to directly hear the community discussions and concerns expressed in those discussions, and not rely solely on summary documentation by the clinical investigator or feedback reported by others, so it is recommended that community discussions be recorded in some way, and that community members be informed that the minutes and/or audio/video recordings of discussions may be reviewed by the IRB.

The lead and participating study teams conducting consultation and disclosure procedures must provide the IRB with the results of the process in a Community Consultation and Disclosure Report. Quantitative results are helpful, but qualitative information is also requested. The lead study team must compile the results reports from each participating study team and add an executive summary for submission to the IRB.

If the University of Utah IRB is only responsible for the activities of the participating study team at the University and/or affiliated hospitals in Utah, a Community Consultation and Disclosure Report is only required for the participating site(s) for which we are responsible.

Data Collection Expectations

Interactive Consultation Methods

For example, live events, standing meetings such as local civic public forums, public community meetings or other special meetings specifically organized to discuss the research, focus groups and surveys, and local radio and/or television talk shows:

- Date, time, and location of event, if applicable
- Information presented by the study team and the length of the presentation
- Number of community members in attendance
- Responses to survey/focus group questions, if applicable
- Amount of time allotted for community questions and feedback
- Questions or concerns raised by community members (grouped by common themes), if applicable
 - How were questions or concerns from the audience collected? How were questions or concerns from the audience addressed? What were the outcomes of these discussions?

Passive Methods

For example, mailings, websites, fliers, letters, announcements, press conference briefings, advertisements, newsletters, etc.:

- Date information was made public
- Location(s) the information was posted or sent
- Questions or concerns raised by community members (grouped by common themes), if applicable
 - How were questions or concerns from the audience collected? How were questions or concerns from the audience addressed? What were the outcomes of these discussions?

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