Increasingly, in an effort to foster community engagement in the research process, patients and other community stakeholders are involved in various levels of research design and conduct. In these cases it is important to consider the circumstances when these individuals may either be considered research subjects or individuals "engaged" in the conduct of research. Each of these cases is addressed below:

Community Collaborators as Research Subjects:

There are certain circumstances where community collaborators may be considered research subjects. In cases where the research team wishes to interact with community partners for the purpose of collecting information that will ultimately serve as a source of research data, the community partner would be considered a human subject and traditional requirements for consent would apply.

A human subject is defined by DHHS regulations as follows:

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

To help consider whether a community collaborator qualifies as research subject please consider the following example:

An investigator seeks to collaborate with patients who are part of a support group for cancer survivors. The investigator wishes to obtain feedback on the types of questions that should be asked of cancer survivors in an online survey to understand their impressions of their care within the health system.

Version 1: The collaborators will be consulted for instrument development only and will not be asked to provide any data from their own experiences that will be used for analysis.

Conclusion: These collaborators do not qualify as human subjects as no data will be collected from these individuals that will be analyzed as part of the research study.

Version 2: After the instrument is developed the collaborators will be asked to complete the survey online as these individuals meet the criteria for enrollment in the study. Data from their online survey responses will be analyzed similarly to all other respondents.

Conclusion: These collaborators do qualify as human subjects as they will provide information that will be analyzed as part of this research study.

Community Collaborators as "Investigators" who are "Engaged" in the research:

There are certain circumstances where community collaborators may be considered investigators who are "engaged" in the research. In these cases, the collaborator's role in the research must be overseen by an IRB and the researcher would be required to complete appropriate human subjects training prior to initiating any activities related to that engagement.

Generally "investigators" may include any individual involved in the design, conduct or reporting of research. The types of activities that may qualify a collaborator as an investigator "engaged" in human subjects research may include but are not limited to:

1. Interacting or Intervening with research subjects for the purposes of research (e.g. administering a survey, performing a research test, etc.).
2. Consenting subjects for research participation
3. Participating in the collection of or having access to identifiable data from research subjects

To help consider whether a community collaborator qualifies as an investigator engaged in human subjects' research, please consider the following example:

A researcher seeks to develop a medication adherence support tool for patients with Alzheimer's disease and their caregivers. In order to design the tool and the study intervention, the researcher will work with a group of Alzheimer's patients and caregivers to ensure the ideas of the target population are represented. These individuals will participate in some research team meetings and will be compensated for their time. Their participation will continue throughout the life of the study.

Version 1: The patients and caregivers will have no interactions with subjects and data presented at research team meetings will be shared in aggregate form only. The patients and caregivers will not have access to individually identifiable subject information.

Conclusion: These collaborators do not qualify as investigators as they will not interact with subjects nor will they have access to identifiable data from subjects.

Version 2: The study team believes that the purpose of the research study and the medication adherence tool will be best described to subjects by patients and caregivers. They have asked that their collaborators participate in the consenting process.

Conclusion: These collaborators do qualify as investigators who are engaged in human subjects' research. Their involvement in the research must be overseen by an IRB and these individuals must complete applicable human subjects training prior to initiating any activities related to their engagement.

Please Note: In the event that you have a community collaborator who you feel may qualify as an investigator, please contact the IRB staff to discuss options for IRB review including the potential requirement for execution of an individual investigator agreement.