Institutional Review Board Guidance

An Institutional Review Board (IRB) is an ethics review board that is set up to ensure that research involving human subjects is conducted in accordance with the Federal-Wide Assurances (FWA) of the Office of Human Research Protections (OHRP)- U.S. Department of Health and Human Services.

The Community Profile is an assessment of the state of the breast cancer burden and needs in a particular service area utilizing public health best-practices. This assessment is essential to Affiliates in developing funding and programming priorities. The Community Profile process is not research that requires IRB approval; sometimes, however, an organization (e.g. university, health care system) with which an Affiliate contracts to assist in completing the Community Profile will require an IRB review regardless of whether or not it is actually required.

If the Community Profile Team has connected with an assessment expert from a university or health care system, the team may want to consider contracting with the expert as an independent consultant---and not as an employee or agent of the university or health care system in order to avoid having to participate IRB review.

If, however, the Community Profile Team decides to contract with a university or health care system, then the following items need to be addressed:

- Contract for services must be with the university or health care system- not the individual.
- Contract must stipulate when payment for completed services will be received. For example, upon approval of the qualitative section by either the local Affiliate Board of Directors and/or Susan G. Komen Global Headquarters.
- Contract must state the respective responsibilities of the university or health care system and the Affiliate/Community Profile Team.
- The Community Profile Team and/or Board of Directors must review all materials prior to their submission to the IRB.
- The IRB materials must be submitted prior to the beginning of the Community Profile process. This may result in a shortened timeline for the Community Profile Team.
- The IRB materials must include the following information:
  - A local Affiliate staff member must be listed as a co-investigator on the form and must complete the required human subjects research training of the organization or health care system.
  - Introduction, Purpose, Background and Summary sections of the form must be Komen Affiliate specific- referencing the Susan G. Komen Community Profile Guidebook appropriately in terms of purpose, process, timelines and deliverables.
o The Community Profile should be referenced as an assessment, not research or a study.
o The university or health care system may temporarily house the data during the profile process, but all final data should only be stored at the local Affiliate for a period determined by the IRB (usually 7 years) or destroyed upon final Community Profile approval from Susan G. Komen. This includes written and electronic materials. At the end of the process, no data should be kept with the university or health care system. The university or health care system may not use the data outside of its Community Profile responsibilities.
o The local Komen Affiliate owns all materials and data collected during the Community Profile process. Therefore, the local Komen Affiliate retains all publication and presenting rights. The local Affiliate may decide to collaborate with the university or health care system to publish and present information from the Community Profile; however, the university or health care system may not publish or present the information on its own without Affiliate involvement. If data or information from the Community Profile is going to be published in a journal, the manuscript should be submitted to the Komen Headquarters Community Health Team via e-mail (communityprofile@komen.org) for review prior to final submission to the journal.

If the Affiliate Community Profile Team needs further guidance regarding the IRB process, please contact Komen Headquarters at communityprofile@komen.org.