

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
	Identification	Page 1 of 1
Title: What Needs Review by CHR	Date Effective 10/12/04	Supercedes P&P dated

Is the activity *public health research* or *public health practice*?

Some public health activities that involve human subjects are research and others are practice. Determining whether public health activities such as surveillance, emergency responses and program evaluation are research or practice may be difficult. The key to this issue is in the latter part of the definition of research, i.e. is the activity “*designed to contribute to generalizable knowledge?*”. The NIH defines generalizable knowledge as “*knowledge related to health that can be applied to populations outside the population served.*” Participants may or may not benefit directly, but there is an expectation that a larger group (others with the same disease or condition, the local community, or a segment of a larger population) will gain from the knowledge obtained.

Intent is also an important consideration. In general, if the primary intent of the activity is to prevent disease, to improve a public health program, or to provide emergency relief, and no research is *intended*, the activity is not research. If, however, the intent changes to generating knowledge that can be generalized, the activity becomes research and is subject to review by the CHR. For example, a survey to gather information that would be used to strengthen an educational program for HIV/AIDS prevention would be research if the investigators believed their results could be applied to other populations and intended to publish them. If, however, the results were intended only to benefit the HIV/AIDS prevention program in the population from which the data were obtained, the activity would not be *generalizable* and would not be considered research.

Some questions to consider when determining whether a public health activity is research or practice are:

- Will participants be subjected to additional risks or burdens beyond usual practice to make the results generalizable?
- Will the information that is generated from the activity be presented at a scientific meeting or contribute to peer-reviewed scientific literature?

If the answer to any of these questions is “yes”, the activity should be considered human subjects research and must be reviewed and approved by CHR.

Whenever there is any question, JHSPH faculty should describe the proposed activity in a memorandum and request a written opinion from CHR as to whether a particular public health activity is research or practice. If it is considered that a project begun as public health practice *might* provide information that would later be considered generalizable, it should be reviewed by CHR *before the project is begun*. In *no instance* can CHR approve research that has already been performed.