

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 2.2	PAGE 1 OF 1
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1.0 BACKGROUND

Virtually all federally funded research involving human subjects is governed by regulations of the Department of Health and Human Services (DHHS) found at Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46).

2.0 DEFINITIONS (also see IRB Manual)

2.1 Research - Defined:

Research is defined by 45 CFR 46 as "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge".

2.2 Human subject - Defined:

Human subjects are defined by 45 CFR 46 as "a living individual about whom an investigator (whether professional or student) conducts research and obtains:

- data through intervention or interaction with the individual; or
- identifiable private information.

2.3 Intervention - Defined:

The regulations define intervention as "both the physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

2.4 Interaction - Defined:

The regulations state that interaction "includes communication or interpersonal contact between investigator and subject".

2.5 Private information - Defined:

The regulations state that private information "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (i.e. a medical record)".

If the identity of the subject is ascertainable from the information/data, the information is deemed "private information".

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