

## Guidance on Interventions in Research Studies

The Office of Research Compliance (ORC) uses the following definitions of “intervention” to determine when research activities involve an intervention and whether the study meets the criteria for Exempt review under category B2 or must be reviewed under Expedited review procedures:

45 CFR 46.102(f) – Federal regulations governing the conduct of research involving human subjects:

**Intervention** includes both 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.

Official from the federal oversight body for the protection of human subjects in research, Office for Human Research Protections (OHRP), Department of Health and Human Services (DHHS), 6/26/2007:

An **intervention** is an experimental manipulation intended to effect change in behavior, cognition, etc.

A research study meets the Exempt category B2 criteria only if it **exclusively** uses one or more of the following research activities:

- Educational tests
- Survey procedures
- Interview procedures
- Observation of public behavior

If an “intervention” is being used in conjunction with the activities listed above, the research study **does not** meet the criteria for Exempt review under category B2.\*

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\* Exempt Category B2 includes further restrictions, which are not addressed within this guidance document.