



About the DHSS IRB

1 What is the DHSS IRB?

The Institutional Review Board (IRB) of the New Jersey Department of Health & Human Services (DHSS) is a multi-disciplinary committee that reviews research involving human subjects in order to ensure that the rights and welfare of human subjects are protected. Federal law mandates that all research involving human subjects must receive IRB approval prior to the start of the research.

2 How do I know if my project meets the IRB definition of “research”?

As defined by federal regulations (45CFR §46.102(d)), “research” means “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Some surveillance projects, emergency responses, and evaluations are research;

others are not. Each project must be reviewed on a case-by-case basis by the Department’s Human Protections Administrator to determine whether it meets this definition of “research”.

3 What types of secondary data analyses require DHSS IRB review?

As defined by federal regulations (45CFR §46.102(f)), a human subject is “a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.” Private information is considered “identifiable” if “the identity of the subject is or *may be* readily ascertained by the investigator or associated with the information.” Thus, IRB review may be required for any research involving secondary analysis of data files containing identifiable private information even if the only personal identifier consists of a unique code that can be linked to

identifying information stored elsewhere.

4 Does DHSS IRB review research projects that have been approved by another registered IRB?

As stipulated by federal regulations (45CFR §46.103(a)), the institutions that are “engaged” in the research project are responsible for the IRB review. In general, “an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.” Thus, if the role of DHSS employees is limited to releasing the identifiable private information pertaining to the subjects of the research, duplication of another IRB review may not be necessary.