NUR520 – DISCUSSION 3

***How will you protect the rights of the agency and participants in your study?***

U.S. government follows a system of federal rules and regulations that were designed to protect human participants and ensure that clinical research is conducted in an ethical manner. As a researcher, one needs to follow these rules to protect the rights of the agency and participants in their study. These include obtaining participant consent, maintaining participants’ confidentiality, respond quickly to all participant concerns and questions, and notify participants regarding changes to the risks or benefits of the study (ahrq.gov, n.d.).

***How will you protect the data? How long will you keep it?***

Anyone who conducts research with human subjects has a responsibility to protect the data collected and used for their research. As a rule, researchers working with human subjects should avoid collecting personal identifiable information whenever possible, data collected should be encrypted, limit access to only those that require it and have identified within an approved IRB protocol, and do not email PHI without encryption (UMASSED.edu, 2018). In general, regulation requires that all raw data be kept for a minimum of 3 years after the study is completed and up to 5 years after final publication. Data can be kept longer if researchers need to re-analyze data results and publish again (Deakin University Library, n.d.).

***Will you need informed consent? Why or Why not?***

According to Manti and Licari (2018), informed consent is required in the following cases: (1) when the research involves patients, children, incompetent/incapacitated persons, healthy volunteers, immigrants or others (i.e. prisoners), and (2) when the research uses/collects human genetic material, biological samples or personal data. In some circumstances, informed consent can be waived and research without consent is possible but under strict regulation. To be considered justifiable, a research without consent should meet the following conditions according to 45 CFR 46 Section 46.117 (c): (1) the research presents no more than minimal risk and the researcher involves no procedures for which written consent is normally required outside of the research context, or, (2) the principal risks are those associated with a breach of confidentiality concerning the subject’s participation in the research and the consent document is the only record linking the subject with the research (AAPOR.org, n.d.).

My replication research study does not need informed consent. According to American Association for Public Opinion Research (AAPOR, n.d.), “if requested by the researcher, the IRB may waive he signature requirement for certain types of minimal risk research, such as surveys, which is referred to as “waiver of documentation of consent””. Because surveys are conducted outside of a research context, most survey research studies do not require informed consent from the participants.