



## Wyoming Department of Health Institutional Review Board

### **INSTRUCTIONS FOR COMPLETION OF RESEARCH THAT DOES NOT INVOLVE DIRECT HUMAN SUBJECT PARTICIPATION APPLICATION**

#### **INTENDED USE OF THIS APPLICATION:**

This application should be submitted **along with a WDH-IRB Table of Elements for Protocol Summary** when proposed research has no direct involvement of human participants but where personal information or biological material, that has been collected, or will be collected, for non-research purposes, or material that will otherwise be discarded, is used for the research.

#### **DETERMINATION OF QUALIFICATION:**

Existing biological specimens or data are materials already collected prior to the initiation of the research using these materials. Based on 45 CFR 46.101 (b) (4) which allows an IRB to exempt research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the one of the following is true :

- These sources are publicly available
- The information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the subject.

**It is important to note that only the IRB has the power to grant this exemption and it does not mean that such activities are exempt from IRB review.**

#### **DISQUALIFICATION:**

If the study material is not publicly available or if the researcher records information in a manner that participants can be identified, **even indirectly**, it is research that requires **IRB approval**. In this case, informed consent is required unless permission to use the material for research was in place at the time the data or specimens were obtained, or the research meets the criteria for waiver of informed consent. If the biological specimens or data are not in existence at the time the research is initiated, the only permissible way the material could be acquired without direct involvement of the participants in the research is for non-research purposes, such as during the course of the delivery of health care.

#### **DOCUMENTATION:**

- The WDH-IRB expects that the arrangements made by investigators to acquire data on file or some of existing biological specimens for research be documented as well as the priority of the health care-related use of the data or specimens.
  - A Business Associate Agreement should also be executed fully prior to release of either data or biological material to ensure researcher compliance with federal privacy regulations.
  - If the material is to be acquired for research purposes, and participants can be identified the WDH-IRB Protocol Submission Guidelines should be used to apply to the WDH-IRB along with a specific informed consent, for routine review and approval.