5.0 REVIEW PROCESS

5.1 Determining if an Activity Requires WSIRB Review and Approval

Activities that include many of the features of research may not necessarily require review and approval by the WSIRB. Some activities resemble research but are not research as defined in the federal regulations. Other activities meet the definition of research but are exempt from needing WSIRB review and approval.

5.1.1 Research versus Non-Research Activities[2]

Research is defined in the federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." There are a variety of activities that employ many of the features of research, such as rigorous design, systematic data collection, and statistical analyses, which are nevertheless not considered research under this definition. The key to distinguishing between research and non-research activities is to determine the primary intent of the activity. The primary intent of research is to generate or contribute to generalizable knowledge. The primary intent of similar activities that are not research may be to prevent or control disease in a population or to identify methods of improving services for a group of clients or customers.

Some activities conducted by or on behalf of institutions which involve systematically collecting and analyzing data are not research. Included in this category are audit activities, resource and/or drug utilization studies using institutional records, and client outcome monitoring in which individual level data are routinely collected and analyzed to determine the extent to which clients are experiencing the intended outcomes of a program. Client satisfaction and needs assessment surveys which only collect information from clients who are eligible to receive program services are also included in this category. <u>If the primary intent of these activities is to support the administration of the program, and if data collection is limited to information needed to administer the program, these activities are not considered research</u>. The HIPAA Privacy Rule classifies such activities as part of "health care operations" and not research. However, data collected through such activities could be used secondarily for research, in which case WSIRB review and approval would be required.

Program evaluation, surveillance activities, disease investigation and/or emergency response activities, and quality assurance and/or quality improvement are activities that may or may not constitute research that requires IRB review. The WSIRB uses the following guidelines to determine

[2] This section draws heavily on the "Distinguishing Public Health Research and Public Health Non-Research," published by the Centers for Disease Control and Prevention, July 2010.

when activities in these categories constitute research that requires IRB review and approval:

Program evaluation activities in which the primary intent is to assess the success of an *established* program or intervention in achieving its objectives in a specific population, and in which the information gained will be used only to provide feedback to the program, to ensure service quality, or to make improvements in the program, are not considered research. However, when the primary intent is to test a new, modified, or previously untested intervention, service, or program in a defined population to determine whether it is effective, the evaluation is research. The systematic comparison of standard or non-standard interventions in an experimental-type design is also research.

Surveillance activities which involve the regular, ongoing collection and analysis of health-related data conducted to monitor the frequency of occurrence and distribution of disease or a health condition in a population and which are authorized by state statute or regulation which specify the intent of the activity, its purpose, and uses of the data are not considered research. Quality control activities that assess, for example, completeness of reporting of surveillance data by matching case records with records from other databases are not considered research. However, when health-related data are collected in surveillance systems and analyzed with the primary intent to produce knowledge applicable to other populations and settings from which the data were collected, or to contribute to new knowledge about the health condition, the activities are likely to be research. Surveillance systems that involve longitudinal data collection systems (e.g., follow-up surveys and registries) that allow hypotheses testing, which collect more information than the occurrence of a health-related problem, in which etiologic analyses can be conducted, or in which cases may be identified to be included in subsequent studies, are likely to be research.

Disease investigation and/or emergency response activities authorized under state statute or regulation which are undertaken to identify, characterize, and solve an immediate health problem, and in which the information gained will directly benefit those participants involved in the investigation or their communities, are not considered research. However, when biological samples are stored for future use intended to produce generalizable knowledge, or when additional analyses are conducted beyond those needed to solve the immediate health problem, the activity may have a research component. When investigational new drugs or devices are used, or when drugs are used off-label, the activity is almost always considered research. Whenever a systematic investigation of a non-standard intervention or a systematic comparison of standard interventions occurs, the activity is research.

Quality assurance and/or quality improvement activities[3] in which existing individual-level data are collected and analyzed and in which there is a formal commitment in advance of data collection to a corrective action plan related to any of a number of possible outcomes of the analyses are not considered research. However, prospective interventional activities which may involve systematic comparison of standard or non-standard therapies are considered research even when conducted by the entity responsible for quality assurance and/or quality improvement.

Activities conducted for educational purposes may fall into a category that would not be considered research if the activity was not conducted primarily for educational purposes. For example, the design of a thesis or dissertation project might be classified as program evaluation or a quality improvement activity rather than research if it was being conducted primarily to support the administration of a program or to develop a corrective action plan. However, as the primary intent of the activity is related to training in research methods in partial fulfillment of requirements for an advanced degree, the educational activity is considered research.

Investigators should consult with staff in the Human Research Review Section (HRRS) if they have questions about whether a specific activity is considered research. The IRB Administrator is responsible for making the determination of whether or not an activity is considered research. If the investigator disagrees with the determination made by the IRB Administrator, he/she may provide additional information for consideration. The Human Protection Administrator of the state agency that has jurisdiction over the activity in question shall make the final determination.

5.1.2 Research Exempt from Review

Once an activity is determined to be research, a determination should be made as to whether the activity involves human subjects as defined in the federal regulations. Human subject means "a living individual *about whom* an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

If the activity is determined to be research that involves human subjects, a determination should be made about whether the research falls into a category of research that is exempt from needing review and approval by the WSIRB. To qualify for exemption from WSIRB review, a research proposal must fall into one of the categories that are listed in Section XI of the *Washington State Agency Policy on Protection of Human Research Subjects*. These categories are more restrictive than the federally-approved exemption categories, and reflect a higher local standard for what can be excluded from WSIRB review.

[3] Based on "The Quality Improvement-Research Divide and the Need for External Oversight," Eran Bellin and Nancy N. Dubler, American Journal of Public Health, Sept 2001, Vol 91, Issue 9, p1512