Department of Corrections
WASHINGTON STATE

Research Guide

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1. PURPOSE

This Washington State Department of Corrections (DOC) guidebook establishes criteria for determining whether a DOC operations activity constitutes research involving human subjects. It also establishes procedures for verifying and documenting the non-research status of operations activities and provides general guidance on the DOC research process.

The target audience of this guidebook is DOC employees. External researchers and collaborators who wish to conduct research activities with DOC staff or with DOC data may also find this guide useful.

2. SCOPE

The requirements of this Research Guide apply to all operations activities conducted by individuals when acting as DOC employees, including full and part-time employees and contractors, as well as investigators from other institutions who submit research studies to DOC or WSIRB for review and approval. These requirements supplement, but do not replace, other requirements applicable to DOC personnel, including DOC, state, and Federal requirements for the conduct of research and requirements related to publications or presentations by DOC personnel.

3. APPLICABLE POLICY

U.S. Department of Health & Human Services (HHS) 45 CFR 46. This regulation provides requirements for human subjects research, including the use of Institutional Review Boards.

RCW 42.48 Release of Records for Research. RCW 42.48 Release of Records for Research defines requirements regarding access to personal records, privacy, and disclosure.

Washington State Agency Policy on Protection of Human Research Subjects. The Washington State Agency Policy on Protection of Human Research Subjects applies to research involving human subjects conducted at some Washington state agencies, including the Department of Corrections (DOC).

DOC 260.050 Research & Data Use. WADOC 260.050 Research Review and Use covers department-wide research request and data use responsibilities and requirements, including requirements of the DOC Research Review Committee (RRC) and research participation.

4. BACKGROUND

a. The conduct of human subjects research requires careful consideration of the risks and benefits to participants, as well as specific ethical standards and regulatory requirements. Institutional Review Boards (IRB) reviews help to ensure that research participants are protected from research-related risks and treated ethically, a necessary requirement for maintaining the public's trust in the research enterprise and allowing science to advance for the common good (HHS). Additionally, IRB review and

oversight of research is a condition of DOC's Federal-wide Assurance (FWA) and is a requirement for the receipt of grant funding from some federal agencies.

The U.S. Department of Health & Human Services (HHS) regulations in 45 CFR 46.102(d) defines research as *a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*.

Activities intended to fulfill DOC's research and program evaluation mission and may be subject to the regulations, policies, and ethics standards that govern research. Other activities that are not primarily designed to fulfill DOC's research and program evaluation mission may, nonetheless, constitute human subjects research and therefore be subject to the requirements that govern research.

Operations activities primarily designed to support non-research activities may constitute research under applicable regulations or policy. This guide supplements existing policy in order to ensure appropriate review and oversight of all DOC activities that involve human subjects research.

b. The following are DOC units and functions that are relevant to DOC research activities:

(1) **Research & Data Analytics Unit (RDA)** is the primary DOC unit responsible for developing policy related to all WADOC research activities and providing oversight of DOC's research and program evaluation objectives.

(2) **Contracts and Legal Affairs (CLA)** assists with development and review of data share agreements and other contracts.

(3) **Public Records Unit (PRU)** ensures compliance with RCW 42.56 Public Records Act, provides guidance and direction to the public and agency staff in accordance with the Public Records Act, and provides direction to the public on how to access agency records and the department's public disclosure procedures.

(4) **Ethics/Internal Audit Office** assists with addressing the complex ethical issues that arise in patient care, health care management, and research.

(5) **Research Review Committee (RRC)** reviews proposed research projects per DOC Policy 260.050, and provides recommendation (to approve, not approve) to the Executive Strategy Team.

(6) **Executive Strategy Team (EST)** is comprised of DOC leadership and has authority to approve department support of research projects.

(7) The **Washington State Institutional Review Board (WSIRB)** is the IRB of record for DOC and is responsible for regulatory review and oversight of all human subjects research involving DOC per federal and state requirements (see RCW 42.48).

5. DEFINITIONS

The following definitions are used for the purposes of this guide.

a. Generalizable Knowledge. Generalizable knowledge is information that expands the knowledge base of a scientific discipline or other scholarly field of study by applying findings to situations or populations beyond those that are studied. Systematic investigations designed to develop or contribute to generalizable knowledge constitute research.

b. Operations Activities. Operations (or operational) activities are administrative, financial, legal, quality assurance, quality improvement, safety, security, and public health endeavors that are necessary to support DOC's mission. Operations activities may or may not constitute research.

c. Research. Research is a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge. Given the definition of generalizable knowledge, research may also be defined as a systematic investigation designed to produce information to expand the knowledge base of a scientific discipline (or other scholarly field of study). Activities that meet this definition constitute research for purposes of DOC policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and services programs may include research activities.

d. Systematic Investigation. A systematic investigation is an activity that is planned in advance and uses data collection and data analysis (either quantitative or qualitative), to answer a question.

Examples of systematic investigations include:

- surveys and questionnaires
- interviews and focus groups
- analyses of existing data or biological specimens
- cognitive and perceptual experiments
- epidemiological studies
- evaluations of social or educational programs
- medical chart review studies

Although research must include systematic investigation, non-research operations activities may also include systematic investigation to ensure reliable outcomes. Use of systematic investigation methods does not, in and of itself, indicate whether a project involves research.

e. DOC Facility. A DOC facility is any entity that is operated by DOC, including, but not limited to, WADOC prisons, camps, work release and community field offices, and health care units; space owned, leased, or rented by DOC; and space that is "shared" with a non-DOC entity. A DOC facility may include multiple campuses and satellite components.

f. IRB Review. The purpose of IRB review is to ensure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research. To accomplish this purpose, IRBs use a group process (the board) to review research protocols and related materials (e.g., informed consent documents, recruitment materials, and investigator brochures) to ensure protection of the rights and welfare of human subjects of research. While the IRB assumes responsibility for oversight and continuing review, the investigator (Principal Investigator) and

the agency conducting the research (the research site) retain the responsibility for the conduct of the study.

g. Other Definitions. Other relevant terms and definitions used in the guide:

Human subject 46 CFR § 46.102(e)(1) defines "human subject" a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. 45 C.F.R. § 46.102.

Investigator means a research professional, student, or consultant involved in the design, conduct, or reporting of research.

Conduct means the carrying out of activities involved in human subjects research.

Common Rule means the federal regulation for the protection of human subjects currently adopted by nineteen federal agencies. The rule is codified for the Department of Health and Human Services in Title 45 CFR Part 46.

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Personally Identifiable Information (PII) or ***Identifiable private information*** is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual.

6. DETERMINING WHEN OPERATIONS ACTIVITIES CONSTITUTE RESEARCH

a. Non-Research Operations Activities. Activities that are not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field) do not constitute research. Thus, a DOC operations activity does not constitute research if both of the following criteria are satisfied:

(1) The activity is designed and implemented for internal DOC purposes (i.e., its findings are intended to be used by and within DOC or by entities responsible for overseeing DOC, such as the Governor's Office; and

(2) The activity is not designed to produce information that expands the knowledge base of a scientific discipline (or another scholarly field).

b. Examples of Non-Research Operations Activities. Routine data collection and analyses associated with the following DOC activities do not typically constitute research, in and of themselves:

(1) Quality assessment and quality improvement activities designed for internal DOC purposes, including routine data collection and analysis for operational monitoring, evaluation, and program

improvement purposes. Examples include, but are not limited to the routine data collection and analysis activities of the following programs/activities:

(a) Employee surveys

(b) Care Quality Improvement Initiative (CQIP)

(c) Public Health Surveillance

(d) Organization performance measures (e.g., ResultsDOC)

(2) Patient satisfaction surveys, case management and care coordination, policy and guideline development and related evaluation activities, and benchmarking activities and similar comparisons.

(3) Competence or qualification reviews of DOC employees and health care professionals, including performance evaluation activities; provider and health plan performance evaluations; root cause analyses; peer review activities; training and education of health care and non-health care professionals; accreditation, certification, licensing, and credentialing activities; and Joint Commission visits and related activities.

(4) Medical reviews, legal analyses, auditing services, and regulatory compliance programs, including fraud and abuse detection, or other reviews and investigations.

(5) Business planning and development, such as cost-management and planning analyses related to managing and operating a business unit; including business management and general administrative activities; financial auditing activities; and risk management activities.

(6) Activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits and ceding, securing, or placing a contract for reinsurance of risk relating to health care claims.

c. Activities deemed not to be Research. The following activities are deemed not to be research under the Federal Policy for the Protection of Human Subjects (Common Rule) in Title 45 Code of Federal Regulations Part 46 (45 CFR 46.102(l), effective July 19, 2018 (definitions are from the CFR):

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities. These activities include the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural disasters).

(3) Authorized activities solely for criminal justice or criminal investigative purposes. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities refer to authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions." 45 CFR § 46.102(l)(4).

d. Operations Activities Constituting Research. An operations activity is considered research for the purpose of this manual if it the activity entails systematic investigation designed to expand the knowledge base of a scientific discipline (or other scholarly field of study) by applying findings to situations or populations beyond those studied. Further, the Department considers an operations activity as research if it meets the definition of research provided in 45 CFR § 46.102(l), or as provided by Washington State law (RCW 42.48.010(4)).

(1) An operations activity that is designed or modified to develop or contribute to generalizable knowledge. This can occur if the conceptualization, plan, or implementation of the activity is supplemented or modified to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study). For example, the activity constitutes research when an operations activity collects additional data or adds analyses not needed for internal operations purposes but for a systematic investigation to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study).

(2) Data originally used for non-research operations then used for research. If data collected for an internal evaluation of a DOC program are subsequently accessed and analyzed in a different way to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study), the subsequent systematic investigation or analysis using the collected data constitutes research. However, if these data are subsequently accessed and analyzed in a different way for operations purposes, the activity does not constitute research. If a project involves both research and non-research activities, however, then the entire project is likely considered to be research.

(3) Modification of the operations activity to generalize knowledge. An activity initially designed as a non-research operations activity subsequently becomes research when modified or supplemented in such a way that systematic investigation produces information that expands the knowledge base of a scientific discipline (or other scholarly field of study). In such situations, the modifications and additions to the original activity constitute research. Components of the original activity that were not used to expand the knowledge base of a scientific discipline (or other scholarly field of study) remain non-research activities. For example, if identifiable patient data originally collected for non-research operations purposes are subsequently accessed and combined with additional data to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study), the activities performed to obtain the additional data and analyze the combined data constitute research. Uses of the original data for operations purposes unrelated to this research activity remain non-research activities.

(4) Governmental Mandates. Activities mandated by Congress, the State Legislature, or another oversight body or authority has no bearing on whether the activity meets the definition of research. In other words, the activity is research when it meets the established definition of research.

e. Activities Always Considered Research. For the purposes of this guide, the following activities are always considered research:

(1) Activities funded or otherwise supported as research (by the established definition) by the Legislature, a Federal grant, or any other sponsor.

(2) Food and Drug Administration (FDA)-regulated clinical investigations.

NOTE: This includes clinical investigations of FDA-regulated drugs, devices, and biologics, regardless of whether the investigation or comparison requires an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE), and regardless of whether the investigation or comparison involves approved or unapproved (i.e., off-label) uses. Policy DOC 260.050 explicitly prohibits medical experiments, pharmaceutical testing, and cosmetic research.

f. Consideration of Design Characteristics. Whereas high-quality research requires sound methodological design, non-research operations activities may also utilize similar design characteristics to properly analyze data that fulfill program objectives. Sound design characteristics do not, in and of themselves, define the activity as research. When determining whether an activity constitutes research, it is important to consider whether the activities' design characteristics are included for the purpose of fulfilling operational needs versus expanding the knowledge base of a scientific discipline or other scholarly field of study.

A project that entails a design characteristic such as a comparison group, that is necessary to generate information required for prudent programmatic decision-making is a non-research operations activity if the activity was not designed to expand the knowledge base of a scientific discipline (or other scholarly field of study). For example, the application of a case-control type design with populations "A" and "B" business intelligence predictive modeling for the purpose of supporting agency planning and resource mobilization for population "C". However, use of the same design characteristic (e.g., comparison groups) to produce information to expand the knowledge base of a scientific discipline (or other scholarly field of study) does constitute a research activity and required IRB review.

(1) Particular design characteristics (such as use of placebo controls, double-blind interventions, and prospective patient-level randomization to clinical interventions for the purpose of intervention evaluation) are almost always associated with research. Consultation with the RDA Unit is strongly recommended during the planning of and prior to the use of such design characteristics.

(2) Analytic design characteristics that are typically associated with research may also be used in non-research, operations activities. Their use in non-research operations activities must be based on and justified by specified operations needs. Inclusion of design characteristics as a systematic investigation for producing information that expands the knowledge base of a scientific discipline (or other scholarly field of study) constitutes research. Examples of analytic design characteristics for which care may be needed to ensure that their use is based on well-justified operations needs

include prospective randomization to interventions, prospective designation of matched pairs, prospective comparisons of clinical interventions, and interventions with patients to collect clinical information that is not medically necessary. Given the additional protections afforded prisoners under 45 CFR 46 and the risks of incorrectly categorizing research as non-research, this seems like an area where it might be helpful to require a written determination by WSIRB.

g. Educational Activities. Educational activities are operations activities necessary to support DOC's mission, including training corrections staff and healthcare and other professionals, and may constitute research if the activities are designed to expand the knowledge base of a scientific discipline or other scholarly field and entail a systematic investigation. Such activities do not constitute research, however, if they are designed and implemented for internal DOC purposes or are not designed to expand the knowledge base of a scientific discipline (or other scholarly field).

7. DEPARTMENT RESEARCH PROCESS

a. Research Review and Procedures. The DOC has established policies and procedures for research project review prior department approval and WSIRB submission (see policy DOC 260.050). RDA internal research proposals and data use requests are reviewed based on the same standardized criteria as all internal and external research proposals, as specified in policy DOC 260.050. These general criteria for projects that meet the definition of research are:

- feasibility,
- scientific rigor,
- risk, and
- alignment to mission and priorities.

The purpose of review based on these criteria is to ensure high value, rigorous research that is aligned to DOC mission, transferable to practice, ethical, cost-effective, and compliant with law and policy.

The RDA uses a checklist to document determination of non-research activities.

b. Internal Research. All RDA initiated research proposals are first discussed with and reviewed by the RDA Senior Research Manager, the RDA Director, and other designated professional staff prior to submission to the Research Review Committee (RRC). This step ensures situational awareness, prioritization of work, linkages to other internal/external stakeholders as needed, and scientific expertise.

All internal RDA initiated research projects must be reviewed and approved per policy DOC 260.050. The RRC and executive leadership review process ensures research proposals are adequately reviewed based on established criteria and to provide the authorization, oversite, and situational awareness of research projects that are conducted by RDA for the Department.

8. CONSULTATION AND DOCUMENTATION

a. Consultation and Documentation. Anyone involved in the project has a responsibility to consult their supervisor as soon as possible whenever there may be doubt about the research versus non-research status of an operations activity.

(1) All operations activities that will involve the collection and/or analyses of data that may be or become research (as defined in this manual), must be reviewed by the RDA Unit (see policy DOC 260-050). When applicability of the policy and/or the guidance specified in this manual is in doubt, consult with the RDA Unit prior to initiation of the activity.

(2) The RDA Unit is responsible for completing and filing the Data Use and Research Determination Checklist (see Policy DOC 260.050).

(2) Consultation with the WSIRB, coordinated through the RDA Director, Senior Research Manager, or designee, is required when the research versus non-research determination of an operations activity is in doubt.

b. Risks and Prevention. Individuals conducting non-research operations activities (as well as the relevant unit or facility) are obligated to ensure the safety, rights, and welfare of affected incarcerated individuals, patients and staff are appropriately protected. Potential risks (including physical, psychological, social, financial, privacy, confidentiality, and other reasonably foreseeable risks) associated with non-research operations activities must be thoroughly evaluated, and appropriate protections must be established to mitigate them. Consultation with the DOC Risk Management Office and RDA, and documentation of risk analysis, consultation, and the resultant protections is strongly encouraged when more than nominal risk may be involved or may be perceived to be involved.

c. Additional Consultation. When unable to reach a determination about the research versus non-research status of an operations activity, RDA staff shall request written guidance from WSIRB regarding the activity. RDA will also consult with DOC CLA or the Attorney General's office (AGO), when needed.

d. Consultation with RDA Process Steps.

When requesting a consultation with RDA the following information must be submitted by email to mailto:DOCRDA@doc.wa.gov:

(a) Name, title, and email of contact person for request.

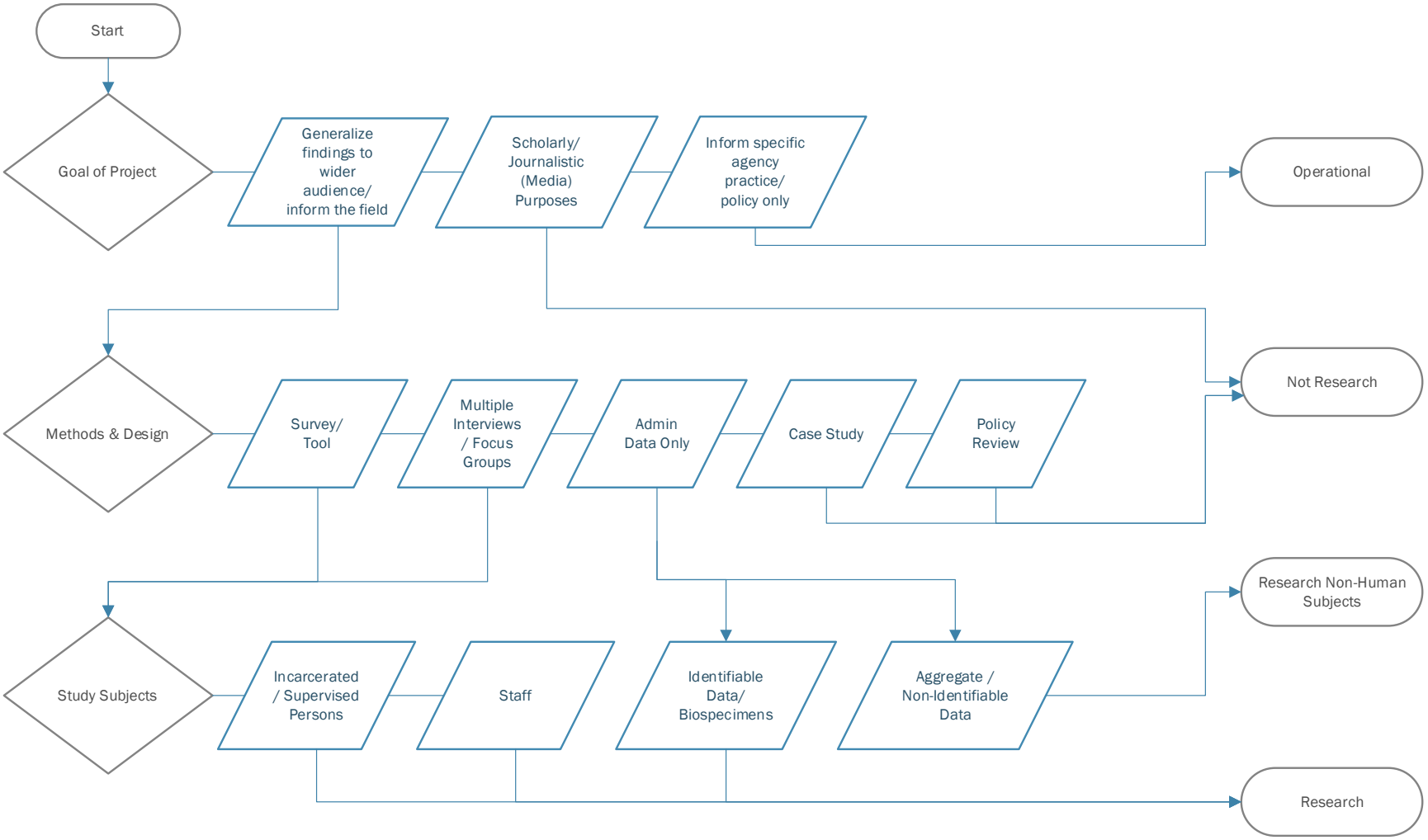
(b) DOC Program Office, or Facility (i.e., sponsor of the activity).

(c) Description of the activity, including types of data obtained or to be obtained.

(d) Description of the purpose of the proposed or conducted activity.

(e) Description of how the results of the proposed activity will be used, including a description of any future uses of results of the activity and whether results are intended for publication.

PROJECT TYPE DECISION TREE



*Please consult with Research staff regarding applicability of Research Review Committee or Washington State Institutional Review Board review
** Not Research and Operational projects may still require RRC and WSIRB review and final determination

ADDITIONAL RESOURCES

Washington State Institutional Review Board
https://www.dshs.wa.gov/ffa/human-research-review-section

Washington State Agency Policy on Protection of Human Research Subjects
https://www.dshs.wa.gov/sites/default/files/hrrs/documents/policy.pdf

Office for Human Research Protections of U.S. Department of Health and Human Services
https://www.hhs.gov/ohrp/

Security, Privacy, Protection of Identity - Research Subjects
42 CFR Part 2a ("HIPAA Privacy Rule") 45 CFR Part 160

Protection of Human Subjects in Clinical Trials
21 CFR parts 50, 56, 312, and 812

Confidentiality of Substance Use Disorder Patient Records
42 CFR Part 2

Protection of Identity - Research Subjects
42 CFR Part 2a

General Administrative Requirements - ("HIPAA Privacy Rule")
45 CFR Part 160

Security and Privacy ("HIPAA Privacy Rule")
45 CFR Part 164

Responsible Prospective Contractors
45 CFR Part 94

Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements
HHS OHRP

REFERENCES

Title 45 CFR Part 46, Protection of Human Subjects.

Washington State Agency Policy on Protection of Human Research Subjects, Department of Social and Health Services.

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