| University of Washington Human Subjects DIvision | **GUIDANCE Human Subjects Regulations** |
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**1 PURPOSE**

This document lists the regulations for which HSD and the UW IRB are responsible (Table 1) and a few regulations for which it is often mistakenly believed that HSD and the UW IRB are responsible (Table 2).

**2 IDENTIFYING THE APPLICABLE REGULATIONS**

HSD staff use the **WORKSHEET Pre-review** to identify the applicable regulations for a specific study.

**3 RESPONSIBILITY**

**Responsible** means:

* The regulations describe specific responsibilities for an IRB and its supporting office, OR
* Regulatory responsibilities have been assigned to HSD or the IRB by UW policy even though the regulation itself does not specifically assign responsibilities to the IRB or its supporting office.
* The regulations listed below also describe responsibilities for other parties, such as researchers. HSD and the UW IRB are not responsible for ensuring the compliance of other parties with these regulations.

**4 SUPPORT vs. ENGAGEMENT**

4.1 **Support and engagement are two different concepts**. The purpose of determining **support** is to identify which governmental entities (that have formal human subjects regulations) govern the research, so that the governing regulations can be applied. The purpose of determining **engagement** is to identify the organizations or entities whose involvement in the research requires IRB review.

4.2 **Supported by** means one or both of the following:

4.2.1 **Government funding**.

* **Direct funding**. Examples:
  + Federal awards (including grants, contracts, and other types of awards) to a UW researcher (in other words, the UW is the primary recipient)
  + Federal funds awarded to a non-UW institution and then provided to the UW for the specific study through a subcontract, “pass through”, “flow through” or similar arrangement (in other words, another entity is the primary recipient)
  + No-cost extensions of awards
  + Supplements awarded in connection with an existing award
  + Pilot project and small grant awards from a group receiving government funds for the purpose of establishing its own grant award mechanism such as pilot projects and small grants. The pilot projects and small grants funded in this manner are considered to be a type of government support. Example: Small grant from the UW’s ITHS Institute for Translational Health Sciences, because those funds come from the NIH grant that supports ITHS.
* **Indirect funding**. This is generic (i.e., not tied to a specific study) salary or other support for the time that any key personnel spend on the research. Common examples include: support provided by many training grants, fellowships, scholarships, career development awards, program project grants. *Specific example: NIH K02 Career Development Award, if the researcher’s salary for the time s/he is spending on the study is paid for by the award even though the specific study is not described in the K02 application. If the study is described in the application, then this would be considered an example of direct funding.*

4.2.2 **Engagement of a government institution**. Examples: An Office of Naval Research laboratory is analyzing identifiable specimens collected by UW researchers; Department of Justice personnel are collaborating with a UW researcher on the collection and analysis of identifiable data from federal prisons.

4.3 **Examples that are not considered to be support**

* **A federal Certificate of Confidentiality** or Privacy Certificate
* **Obtaining data from a government database**, unless the government agency is engaged in the research
* **Using government equipment**, materials, or facilities, unless they are from a Department of Defense component or the government agency that owns or operates them is engaged in the research.
* **Using a non-government facility** or database that is funded by government funds for general research purposes. Example: conducting research procedures in one of the UW’s ITHS facilities such as the Adult Translational Research Unit (previously called the Clinical Research Center) or the ITHS Pediatric Clinical Research Center
* **RRF Royalty Research Fund grant** for a study, because the funding is from the UW. Although the UW is a government entity, it does not have formal human subjects regulations that govern research.
* **Study drug is provided by the federal CDC** (Centers for Disease Control). The CDC’s involvement does not meet the definition of engagement.

4.4 **Duration of support**. A study is considered to be supported by a government entity for research activities that occur during the time of current support.

**Table 1. Regulations that describe the authority and responsibilities of HSD or the IRB.**

OHRP maintains a list of current Common Rule Signatories: <https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/common-rule-departments-agencies/index.html>.

| **Federal** | | | |
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| **Informal name** | **Government entity** | **Regulatory citation** | **Human subjects research that is governed by it** |
| **Common Rule**  *also referred to as* ***Subpart A***  *Except where indicated, all entities have adopted the revised Common Rule (implementation date 1.21.2019) as well as the version prior to 1.21.2019* | Agency for International Development (USAID) | 22 CFR 225 | Research conducted or supported by USAID |
| Central Intelligence Agency (CIA) | Executive Order 12333, paragraph 2.10 | Research conducted or supported by the CIA |
| Consumer Product Safety Division | 16 CFR 1028 | Research conducted or supported by the Consumer Product Safety Division |
| Dept Agriculture | 7 CFR 1c | Research conducted or supported by the Department of Agriculture |
| Dept Commerce | 15 CFR 27 | Research conducted or supported by the Department of Commerce  *Example of a Commerce component that supports research: National Institute of Standards and Technology (NIST)* |
| Dept Defense | 32 CRF 219 | Research conducted or supported by the Department of Defense  *Examples of Defense components that support research: Department of Army, Office of Naval Research* |
| Dept Education | 34 CFR 97 | Research conducted or supported by the Department of Education |
| Dept Energy | 10 CFR 745 | Research conducted or supported by the Department of Energy |
| Dept Health & Human Services | 45 CFR 46 Subpart A | Research conducted or supported by the Department of Health & Human Services  *Examples of HHS components that support research: NIH National Institutes of Health; AHRQ Agency for Healthcare Research & Quality; CDC Centers for Disease Control & Prevention* |
| Dept Homeland Security | 6 U.S.C. section 112  6 CFR Part 46 | Research conducted or supported by the Department of Homeland Security |
| Dept Housing & Urban Development | 24 CFR 60 | Research conducted or supported by the Department of Housing & Urban Development |
| Dept Justice  *Has not yet adopted the 2018 Common Rule* | 28 CFR 46 | Research conducted or supported by the Department of Justice  *Examples: National Institute of Justice, Bureau of Prisons*  *Has not yet adopted the revised Common Rule (1.21.2019 implementation date)* |
| Dept Labor  *Adopted the 2018 Common Rule but not the previous version* | 29 CFR 21 | Research conducted or supported by the Department of Labor  *Adopted the revised Common Rule (1.21.2019 implementation date) but not the previous version* |
| Dept Transportation | 49 CFR 11 | Research conducted or supported by the Department of Transportation |
| Dept Veterans Affairs | 38 CFR 16 | Research conducted or supported by the Department of Veterans Affairs |
| Environmental Protection Agency | 40 CFR 26, Subpart A | Research conducted or supported by the Environmental Protection Agency |
| National Aeronautics and Space Administration (NASA) | 14 CFR 1230 | Research conducted or supported by the NASA |
| National Science Foundation | 45 CFR 690 | Research conducted or supported by the National Science Foundation |
| Social Security Administration | 42 U.S.C. section 901  20 CFR 431 | Research conducted or supported by the Social Security Administration |
| **Pregnant women**  *also referred to as* ***Subpart B***  *also applies to fetuses, nonviable neonates & neonates of uncertain viability*  *Research with pregnant women may also be subject to Environmental Protection Agency regulations, independently of Subpart B – see below* | Central Intelligence Agency | Executive Order 12333, paragraph 2.10 | Research conducted or supported by the CIA AND that involves pregnant women, fetuses, nonviable neonates or neonates of uncertain viability |
| Dept Defense | DoD Directive 3216.02 | Research conducted or supported by the Department of Defense AND that involves pregnant women, fetuses, nonviable neonates or neonates of uncertain viability  *Examples of Defense components that support research: Department of Army, Office of Naval Research* |
| Dept Energy | DOE Order 443.1C | Research conducted of supported by the Department of Energy AND that involves pregnant women, fetuses, nonviable neonates or neonates of uncertain viability |
| Dept Health & Human Services | 45 CFR 46 Subpart B | Research conducted or supported by the Department of Health & Human Services AND that involves pregnant women, fetuses, nonviable neonates or neonates of uncertain viability  *Examples of HHS components that support research: NIH National Institutes of Health; AHRQ Agency for Healthcare Research & Quality; CDC Centers for Disease Control & Prevention* |
| Dept Homeland Security | 6 U.S.C. section 112 | Research conducted or supported by the Department of Homeland Security AND that involves pregnant women, fetuses, nonviable neonates or neonates of uncertain viability |
| Social Security Administration | 42 U.S.C. section 901 | Research conducted or supported by the Social Security Administration AND that involves pregnant women, fetuses, nonviable neonates or neonates of uncertain viability |
| **Prisoners**  *also referred to as* ***Subpart C***  Note: Research with Prisoners may also be subject to Dept of Justice regulations, independently of Subpart C – see DOJ, below. | Central Intelligence Agency | Executive Order 12333, paragraph 2.10 | Research conducted or supported by the CIA AND that involves prisoners |
| Dept Defense | DoD Directive 3216.02 | Research conducted or supported by the Department of Defense AND that involves prisoners  *Examples of Defense components that support research: Department of Army, Office of Naval Research* |
| Dept Energy | DOE Order 443.1C | Research conducted of supported by the Department of Energy AND that involves prisoners |
| Dept Health & Human Services | 45 CFR 46 Subpart C | Research conducted or supported by the Department of Health & Human Services AND that involves prisoners  *Examples of HHS components that support research: NIH National Institutes of Health; AHRQ Agency for Healthcare Research & Quality; CDC Centers for Disease Control & Prevention* |
| Dept Homeland Security | 6 U.S.C. section 112 | Research conducted or supported by the Department of Homeland Security AND that involves prisoners |
| Social Security Administration | 42 U.S.C. section 901 | Research conducted or supported by the Social Security Administration AND that involves prisoners |
| **Children**  *also referred to as* ***Subpart D***  *Research with children may also be subject to Environmental Protection Agency regulations, independently of Subpart D – see below* | Central Intelligence Agency | Executive Order 12333, paragraph 2.10 | Research conducted or supported by the CIA AND that involves children |
| Dept Defense | DoD Directive 3216.02 | Research conducted or supported by the Department of Defense AND that involves children  *Examples of Defense components that support research: Department of Army, Office of Naval Research* |
| Dept Education | 34 CFR 97 | Research conducted or supported by the Department of Education AND that involves children |
| Dept Energy | DOE Order 443.1C | Research conducted of supported by the Department of Energy AND that involves children |
| Dept Health & Human Services | 45 CFR 46 Subpart D | Research conducted or supported by the Department of Health & Human Services AND that involves children  *Examples of HHS components that support research: NIH National Institutes of Health; AHRQ Agency for Healthcare Research & Quality; CDC Centers for Disease Control & Prevention* |
| Dept Homeland Security | 6 U.S.C. section 112 | Research conducted or supported by the Department of Homeland Security AND that involves children |
| Social Security Administration | 42 U.S.C. section 901 | Research conducted or supported by the Social Security Administration AND that involves children |
| **IRB Registration**  *Also referred to as Subpart E* | Central Intelligence Agency | Executive Order 12333, paragraph 2.10 | Research conducted or supported by the CIA |
| Dept Health & Human Services | 45 CFR 46 Subpart E | Research conducted or supported by the Department of Health & Human Services  *Examples of HHS components that support research: National Institutes of Health (NIH); Agency for Healthcare Research & Quality (AHRQ)* |
| Social Security Administration | 42 U.S.C. section 901 | Research conducted or supported by the Social Security Administration |
| **FDA general regs: consent** | Food and Drug Administration | 21 CFR 50 | Research involving the use of an item regulated by the FDA (drugs, medical devices, some botanicals, some supplements) that is collecting safety and/or effectiveness data for submission to the FDA |
| **FDA general regs: IRBs** | Food and Drug Administration | 21 CFR 56 | Research involving the use of an item regulated by the FDA (drugs, medical devices, some botanicals, some supplements) that is collecting safety and/or effectiveness data for submission to the FDA |
| **Investigational drugs**  *Also known as the* ***drug regs*** | Food and Drug Administration | 21 CFR 312 | * Research involving the use of an investigational drug (or a drug that has an IND for the study) that is collecting safety and/or effectiveness data for submission to the FDA * Clinical use of an investigational drug through a FDA expanded access program (for example, single patient emergency use) |
| **Investigational devices**  *Also known as the* ***device regs*** | Food and Drug Administration | 21 CFR 812 | * Research involving the use of an investigational medical device (or a medical device that has an IDE for the study) that is collecting safety and/or effectiveness data for submission to the FDA * Clinical use of an investigational device through a FDA expanded access program (for example, single patient emergency use) |
| **Humanitarian Use Devices**  *Also known as the* ***HUD regs*** | Food and Drug Administration | 21 CFR 814 | Research or clinical care involving the use of a medical device that has HUD status from the FDA |
| **HIPAA**  *Use of PHI; Health Insurance Portability & Accountability Act* | Office of Civil Rights in the Department of Health & Human Services  *Note: This is not the same as the Office of Civil Rights in the Department of Education* | 45 CFR 164 | Research involving the access to, obtaining of, or use of Protected Health Information (PHI) from a covered entity in the United States.  *“Covered entity” means: healthcare organization, healthcare provider, health insurance / billing companies.* |
| **Section 1557**  *Discrimination based on language or country or origin* | Office of Civil Rights in the Department of Health & Human Services  *Note: This is not the same as the Office of Civil Rights in the Department of Education* | 45 CFR 92 | Research that is a clinical trial being conducted at a UW Medicine facility  *NOTE: HSD has not fully completed its implementation of this requirement.* |
| **ClinicalTrials.gov** | Food and Drug Administration; Department of Health & Human Services | 42 CFR 11 (consent statement requirement is specified in 21 CFR 50) | Research that meets the definition of an “applicable clinical trial” as defined in the regulation |
| National Institutes of Health | NIH Policy NOT-OD-16-146 “Dissemination of NIH-Funded Clinical Trial Information” | Research that meets the NIH definition (and interpretation of that definition) of “clinical trial”, even if it does not meet the definition of “applicable clinical trial” in 42 CFR 11, and that will begin after a specified date |
| **DoD and agencies of DHHS (e.g., NIH, CDC) Certificate of Confidentiality** | Department of Defense; National Institutes of Health;  Centers for Disease Control & Prevention; other DHHS agencies | Section 2012 of the 21st Century Cures Act (42 U.S.C. 241(d));  NIH Policy NOT-OD-17-109 “Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality” | Some agencies issue automatic CoCs as a term of the grant or contract (e.g., NIH, CDC, FDA, HRSA).  Other agencies may issue a CoC through an application process (e.g., NIH, SAMHSA). |
| **NIH Single IRB** | National Institutes of Health | NIH Policy NOT-OD-16-094 “Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research | This requirement applies to most grants and contracts submitted to NIH on or after January 25, 2018. The NIH sIRB requirement is distinguished from that of the Common Rule because there are specific, NIH requirements that must be present in the grant or contract applications and the NIH requirement applies only to multi-site studies in which all sites are conducting the same procedures (not to other types of collaborative research)  The review process for NIH sIRB and Common Rule sIRB are not different. |
| **NIH GDS Certification** | National Institutes of Health | NIH Policy NOT-OD-14-124 “Genomic Data Sharing Policy” and NIH Policy NOT-OD-07-088 “Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS) | Research supported by NIH beginning after a certain date and that generates large-scale human or no-human genomic data as well as the use of these data for subsequent research |
| **NIH Data Management & Sharing** | National Institutes of Health | NIH Policy NOT-OD-21-013 “Final NIH Policy for Data Management and Sharing” | Research funded or conducted by NIH beginning after a certain date and that results in the generation of scientific data. |
| **NIH Data & Safety Monitoring** | National Institutes of Health | NIH Policy June 10, 1998 “NIH Policy for Data and Safety Monitoring” | Research that meets the NIH definition (and interpretation of that definition) of “clinical trial” |
| **NIH Human Fetal Tissue Research** | National Instititues of Health | NOT-OD-19-128  NOT-OD-19-137  NOT-OD-21-111 | Research that involves the use of human fetal tissue obtained from elective abortions and that is supported by a NIH grant or cooperative agreement awarded in response to a grant application submitted to NIH on or after Sept 25, 2019. It is UW Policy to apply these regulatory requirements to all research regardless of NIH funding. |
| **Acquisition & use of fetal tissue** | Federal law | 42 U.S.C. 289g-1 and 42 U.S.C. 289g-2 *(also known as Sections 498A and 498B of the Public Health Service Act)* | Research involving the acquisition or use of fetal tissue.  *These regulations do not apply to the use of cell lines derived from human fetal tissue that historically have been available and are widely used and distributed on a national basis.* |
| **DOD regs**  *Department of Defense*  *These are In addition to the Common Rule & Subparts B, C, D* | Department of Defense | DOD Directive 3216.02 | Research conducted or supported by the Department of Defense |
| 10 U.S.C. 980 | Research conducted or supported by the Department of Defense AND that involves “experimental subjects” as defined by DOD |
| 24 U.S.C. 30 | Research conducted or supported by the Department of Defense AND that involves payment to donors of blood for persons undergoing treatment at government expense |
| **Navy research**  *Usually funded through ONR Office of Naval Research*  *These are in addition to the Common Rule; Subparts B, C, D; and DOD regs* | Department of the Navy | SECNAVINST 3900.39D | Research conducted or supported by the Department of Navy |
| **Air Force research**  *These are in addition to the Common Rule; Subparts B, C, D; and DOD regs* | Department of the Air Force | Air Force Instruction 40-402 | Research conducted or supported by the Department of the Air Force |
| **DOJ**  ***Department of Justice***  *These are in addition to the original Common Rule (Subpart A)* | Department of Justice | 28 CFR 22 “Confidentiality of Identifiable Research Information”  28 CFR 46 “Protection of Human Subjects” [original version of Common Rule] | Research conducted or supported by the Department of Justice  *Examples: National Institute of Justice, Bureau of Prisons* |
| **Bureau of Prisons**  *These are in addition to the original Common Rule (Subpart A) and the DOJ regs* | Bureau of Prisons (a component of the Department of Justice) | 28 CFR 512 | Research conducted or supported by the Bureau of Prisons, including any research that is conducted in a BOP facility or that involves BOP personnel regardless of whether the involvement meets the definition of “engagement” |
| **EPA**  ***Environmental Protection Agency***  *This is in addition to the Common Rule (Subpart A)* | Environmental Protection Agency | 40 CFR 26 all Subparts | Research conducted or supported by the Environmental Protection Agency |
| **Energy**  ***Department of Energy***  *This is in addition to the Common Rule (Subpart A)* | Department of Energy | DoE Order 443.1C  DoE Order 206.1 | Research conducted or supported by the Department of Energy |

| **State of Washington** | | | |
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| **Informal name** | **Government entity** | **Regulatory citation** | **Human subjects research that is governed by it** |
| **Washington PHI**  *State HIPAA law* | State of Washington | RCW 70.02 | Research involving the access to, obtaining of, or use of Personal Health Information from a covered entity (though the law does not use this term) in Washington State  Per legal opinions provided to HSD, fulfillment of the HIPAA regulatory criteria for granting a waiver of Authorization also fulfils the requirements for a waiver of authorization that is specified in RCW 70.02.  *“Covered entity” generally means: healthcare organization, healthcare provider, health insurance / billing companies* |
| **LAR in Washington State** | State of Washington | RCW 7.70.065 | Identifies who can act as a legally authorized representative (LAR) for the purpose of obtaining consent. Per state legal opinion, this law may be applied to research consent. Revised in 2019 to expand the list of who can serve as a LAR. |
| **WA state definition of age of majority** | State of Washington | RCW 26.28.020 | The age at which someone is capable of providing legally effective consent |
| **WA state exceptions to standard age of majority** | State of Washington | RCW 70.24.110 | Research in Washington State that focuses on the **diagnosis or treatment of sexually transmitted disease.** Must involve the actual diagnosis or treatment, not just analyses of records. |
| RCW 9.02.100(1) | Research involves **choosing or refusing abortion services**. Must be more than just analyses of records. |
| RCW 9.02.100(2) | Research involves **choosing or refusing birth control services**. Must be more than just analyses of records. |
| State V. Koome, 84 Wn 2d 901 (1975) | Research involving the **receipt of prenatal care services**. Must be more than just analyses of records. |
| RCW 71.34.530 | Research that focuses on the **provision of outpatient mental health care**. Must involve the actual provision of outpatient mental health care, not just analyses of records. |
| RCW 71.34.500, 510 | Research focusing on the **provision of inpatient mental health care**. Must involve the actual provision of inpatient mental health care by a certified program, not just analyses of records. Parent(s) must be notified within 24 hours after admission. |
| RCW 70.96A.235 | Research in which **outpatient treatment in chemical dependency or substance abuse programs** is provided as a focus of the research. Programs must be certified by a state department. Child must meet definition of a “child in need of services” at RCW 13.32A.030(5). |
| RCW 71.34.500. 510 | Research in which inpatient treatment in a substance use disorder treatment program is provided as a focus of the research. Programs must be certified by a state department. Parent(s) must be notified within 24 hours after admission. |
| RCW 26.28.020 | **Impact of marriage upon the age of majority**: A minor who is married to a person of full age is considered to be of full age. |
| RCW 13.64 | **Definition of emancipated minor** |
| RCW 26.50.020 | Research that may provide **relief from domestic violence** to an individual or to the individual’s minor family or household members |
| **Notifiable conditions in WA** | State of Washington | WAC 246-101 | Research that may learn about or diagnose a condition and disease on the Washington State [list of notifiable conditions](http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/ListofNotifiableConditions) AND with a study team member who is considered a mandatory reporter per this state law. Review [GUIDANCE Mandatory State Reporting](https://www.washington.edu/research/policies/guidance-mandatory-state-reporting-2/). |
| **Mandated reporting of adult abuse or neglect in WA** | State of Washington | RCW 74.34 | Research that may identify reasonable cause to believe that a vulnerable adult in Washington State has suffered abuse or neglect AND with a study team member who is considered a mandatory reporter per this state law. Review [GUIDANCE Mandatory State Reporting](https://www.washington.edu/research/policies/guidance-mandatory-state-reporting-2/). |
| **Mandated reporting of child abuse or neglect in WA** | State of Washington | RCW 26.44.030  RCW 288.10.486 | Research that may identify reasonable cause to believe that a child in Washington State has suffered abuse or neglect AND that has a study team member who is considered a mandatory reporter by these state laws. Review [GUIDANCE Mandatory State Reporting](https://www.washington.edu/research/policies/guidance-mandatory-state-reporting-2/). |
| **Reporting privacy breaches in WA** | State of Washington | RCW 42.56.590 | Research for which there is a breach of data maintained in Washington State and where the breach involves:   * First name (or initial of first name) and last name in combination with any one or more of a long list of data elements specified in the law * User name or email address in combination with a password or security questions and answers that would permit access to an online account * Any of the data elements or any combination of the data elements described in the law without the consumer's first name or first initial and last name if:   + Encryption, redaction, or other methods have not rendered the data element or combination of data elements unusable; and   + The data element or combination of data elements would enable a person to commit identity theft against a consumer |
| **Recording private communications** | State of Washington | RCW 9.73.030 | Research that involves recording of private audio communications of subjects in Washington State |
| **Electronic signatures** | State of Washington | RCW 1.80 | Research requiring documentation of consent and for which an electronic signature will be obtained. Review[GUIDANCE Consent Approvable Methods for Obtaining Electronic Signature](https://www.washington.edu/research/hsd/guidance/consent/#10e). |

**Table 2. Some regulations that are commonly mistaken as involving HSD or the IRB.**

| **Federal** | | | |
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| **Informal name** | **Government entity** | **Regulatory citation** | **Human subjects research that is governed by it** |
| **FERPA**  *Family Education Rights and Privacy Act* | Department of Education | 34 CFR 99 | Applies to all research involving (or conducted by) an entity that receives funding (for any purpose, not just research) from the Department of Education |
| **PPRA**  *Protection of Pupil Rights Amendment* | Department of Education | 34 CFR 98 | Applies to all research involving (or conducted by) an entity that receives funding (for any purpose, not just research) from the Department of Education |
| **COPPA**  *Children’s Online Privacy Protection Rule* | Federal Trade Commission | 16 CFR 312 | Websites or online services directed to children under 13 years of age or that involves websites or online services that have actual knowledge that they are collection personal information online from a child under 13 years of age. Applicability to research is not clear. |
| **CLIA**  *Clinical Laboratory Improvement Amendments* | Center for Medicaid & Medicare Services (part of the Department of Health & Human Services) | 42 CFR 493 | CLIA governs laboratories that return of clinically-actionable information to patients |
| **EU GDPR**  European Union General Data Protection Rule | European Union | Official Journal of the European Union OJ L 119, 04.05.2016 | Research that collects data from persons while they are residing in the European Union |

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| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.0 | 04.25.2024 | 04.25.2024 | Add reference to OHRP webpage listing Common Rule signatories |
| 1.9 | 01.04.2024 | 01.04.2024 | Remove references to retired content |
| 1.8 | 03.02.2023 | 03.02.2023 | Update references to DoE regulations; minor updates to CoC section; add NIH DMS policy; note legal opinion about the relationship between RCW 70.02 and HIPAA |
| 1.7 | 04.29.2021 | 04.29.2021 | Add reference to new NIH notice regarding fetal tissue regulation |
| 1.6 | 10.15.2020 | 10.15.2020 | Add reference to Chapter 57, Laws of 2020 – electronic signature requirements |
| Previous verisons |  |  | For older versions: HSD Staff – refer to the SharePoint Document Library; Others - contact [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu).” |

**Keywords:** Regulations