		SOP
Department	**Title**	**Dates**
Research Integrity and Protection	Definitions	Effective: 5/31/2018
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PURPOSE

This SOP establishes the definitions used by the Ascension Wisconsin Human Research Protection Program.

SCOPE:

This SOP applies to all personnel who conduct research involving human subjects, or assist in the performance of such research activities, where that research is performed at or under the auspices of any Ascension Wisconsin system hospital or subsidiary ministry (Ministry) covered by the Ascension Wisconsin Federalwide Assurance for the Protection of Human Subjects. For the purposes of this and all SOPs under the Ascension Wisconsin Human Research Protection Program, the term "research involving human subjects" shall be interpreted to include any research-related procedure conducted at the ministry or any ministry-controlled facility.

DEFINITIONS:

1. **Adverse Event (AE)** Any unfavorable or unintended event, including abnormal laboratory findings, symptom or disease, or death associated with the research or the use of a medical investigational test article. An AE in research may occur even in the absence of any error or protocol deviation and does not necessarily have to be caused by any identifiable aspect of the research.
2. **Advocate** An individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the research. The Advocate is not associated in any way (except in her/his role as advocate or member of the IRB) with the research, the investigators, or the guardian.
3. **Amendment** A modification or change to the IRB approved protocol, study instruments, consent form or other study materials. No changes may be made to the approved research plan without first submitting a request to the IRB and obtaining the IRB's approval, unless there is need to eliminate an immediate hazard facing the subject as outlined in 45 CFR 46.103(b)(4). Amendments may be considered minor or significant. A minor amendment is one that would not materially affect an assignment of the risks and benefits of the study or does not substantially change the specific aims or the design of the study. A significant amendment is one that is not minor and requires review by the convened board.
4. **Anonymity** Pertains to the information that an individual has disclosed in a study with the expectation that the information has no identifiers linked to the participant and therefore cannot in any way be traced to the participant. "Anonymity" and "confidentiality" do not have the same meaning and are not interchangeable
5. **Assent** Agreement by an individual not competent to give legally valid informed consent (i.e. a child or cognitively impaired person). Ex: to obtain consent for research involving a child between the ages of 7 and 18, an assent form written in language understandable to the child is signed by the child, and a separate Child Consent form is read and signed by the parent(s) or legally authorized representative allowing the child to participate.

6. **Assurance of Compliance** (Human Subjects) or Federalwide Assurance: A legally binding written document that commits an institution to complying with the Federal Policy (Common Rule) and other applicable Federal and VA standards for the protection of human subjects.

7. **Authorization** Document designating permission. The HIPAA Privacy Rule requires authorization or waiver of authorization for the use or disclosure of identifiable health information for research (among other activities).

8. **Authorization Agreement** Also called a Reliance Agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating institution relying on the ethical review.

9. **Autonomy** Also known as "Respect for Persons", this ethical principal, established by the Belmont Report, means individuals are to be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.

10. **Belmont Report** The 1979 report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled, "The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (accessible at: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm).

11. **Beneficence** This ethical principal, established by the Belmont Report, means individuals are to be treated in an ethical manner by respecting their decisions, protecting them from harm, and striving to secure their well-being. Two general rules are complementary expressions of beneficent actions: (1) do no harm, and (2) maximize possible benefits and minimize possible harms.

12. **Biological Specimen** A sample that originated from an organ system of a human.

13. **Centers for Medicare and Medicaid Services ("CMS")** The agency within the Department of Health and Human Services ("HHS"). CMS has authority over the two largest Federal health care programs, Medicare and Medicaid under unified leadership.

14. **Certification** The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

15. **Children** Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In Wisconsin, "children" are generally those persons under the age of 18 years. In Wisconsin, emancipated minors are not subject to Subpart D of 45 CFR 46 and are consented as adults. Emancipated minors include individuals under 18 years of age who are or have been married. [Wis. Stat. 880.04(1), 54.46(6)]. In Wisconsin, non-emancipated minors may consent to certain treatment or procedures without parental permission.

16. **Clinical Research** Any activity that represents "research" that involves "human subjects", as those terms are defined by the Common Rule or by the Food and Drug Administration (FDA). For the purposes of this Policy, the terms "Human Subject Research", "Research Involving Human Subjects", "Clinical Investigation", "Clinical Study", and similar phrases are considered to be synonyms for the term "Clinical Research".

17. **Clinical Trial** 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.

18. **Coercion** Pertaining to unacceptable participant recruitment methods which involve duress, undue inducement or indirect pressure. One example of an environment conducive to coercion involves the recruitment of employees by their employer for human participant research.

19. **Cognitively Impaired** Having either a psychiatric or a developmental disorder that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

20. **Collaborative Study** A study in which two or more institutions coordinate, with each institution completing a portion of the research activities outlined in a specific protocol

21. **Common Rule** Also known as 45 CFR 46. Outlines requirements of federally supported research with regards to human subject protections, and places the responsibility of these protections on institutions, their Institutional Review Boards, and investigators.

22. **Confidentiality** Refers to data (e.g. identifiable information about a person) and about agreements and procedures for limiting the access of others to that data. Methods to protect confidentiality should be described both to the IRB (via the study application) and to subjects (via the informed consent process). There can be many different methods employed to protect confidentiality, including making efforts to store and dispose of data securely, sharing data appropriately, obtaining Certificates of Confidentiality, etc. Confidentiality expectations may differ for quantitative vs. qualitative research.

23. **Conflicting Interest** An individual involved in research review is automatically considered to have a conflicting interest when the individual or the individual's spouse, domestic partner, children, and dependents have any of the following interests in the sponsor, product, or service being tested, or competitor of the sponsor held by the individual or individual's immediate family: 1) Involvement in the design, conduct, or reporting of the research; 2) Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds; 3) Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research; 4) Proprietary interest Related to the Research including, but not limited to, a patent, trademark, copyright or licensing agreement; 5) Board or executive relationship, regardless of compensation; 6) Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teach hospital, or medical center; or, 7) Any other reason for which the individual believes that he or she cannot be independent.

24. **Consent Capacity** describes an adult's ability to understand information relevant to making an informed, voluntary decision to participate in research. Several kinds of information are relevant to such decisions, including the purpose of the study, its experimental nature, risks and anticipated benefits, the right to withdraw, alternatives to participation, confidentiality protections, and the safeguards used to minimize risks.

25. **Covered Entity** A facility that conducts health care operations involving the creation and transmission of Protected Health Information (PHI). As set forth in the St. Vincent Health HIPAA Privacy Compliance Policy, the majority of the SVH System Hospitals, SVH System Subsidiaries and SVH Subsidiary Organizations are Covered Entities under HIPAA.

26. **Declaration of Helsinki** A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries (revisions 1975, 1989.)

27. **Decision-Making Capacity** Refers to a potential participant's ability to make a meaningful decision about whether or not to participate. Decision-making capacity is protocol-specific and situation-specific. Thus a human subject may have capacity to consent to a low-risk research protocol in usual circumstances, but not have the capacity to consent to a high-risk protocol when he or she is confused or under duress.

28. **Deidentified** Under the HIPAA Privacy Rule, data are deidentified if either (1) an experienced expert determines that the risk that certain information could be used to identify an individual is "very small" and documents and justifies the determination, or (2) the data do not include any of the following eighteen identifiers (of the individual or his/her relatives, household members, or employers) which could be used alone or in combination with other information to identify the subject:

    - names,
    - geographic subdivisions smaller than a state (including zip code),
    - all elements of dates except year (unless the subject is greater than 89 years old),
    - telephone numbers,
    - FAX numbers,
    - email address,
    - Social Security numbers,
    - medical record numbers,

- health plan beneficiary numbers,
- account numbers,
- certificate/license numbers,
- vehicle identifiers including license plates, device identifiers and serial numbers,
- URLs,
- internet protocol addresses,
- biometric identifiers,
- full face photos and comparable images,
- and any unique identifying number, characteristic or code;

Note that even if these identifiers are removed, the Privacy Rule states that information will be considered identifiable if the covered entity knows that the identity of the person may still be determined.

29. **Designated Reviewer** The IRB chair or an experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews.

30. **Diminished Capacity** May be due to psychiatric, organic, developmental, or other disorders that affect cognitive or emotional functions. Other individuals who may be considered decisionally impaired with limited decision-making ability are persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps. Investigators must take special care to consider issues such as the selection of human subjects, privacy and confidentiality, coercion and undue influence, and the risks versus the benefits.

31. **Disclosure** The release, transfer, access to, or divulging of identifiable health information to anyone outside of the covered entity.

32. **Exculpatory Language** As it applies to informed consent, any written or verbal communication through which a research participant (or his/her legally authorized representative) is asked to waive or appear to waive any of the participant's legal rights or to release (or appear to release) the investigator, sponsor, or institution or its agents from liability for negligence.

33. **Exempt Review Category** Research activities in which the only involvement of human subjects will be in one or more of the categories delineated as exempt in 45 CFR 46.101.

34. **Expedited Review Category** Research activities that (1) present no more than minimal risks to human subjects, and (2) involve only procedures listed in one or more of the categories detailed in 45 CFR 46.110 and 46 FR 8392.

35. **Expiration Date** The first date that the protocol is no longer approved. The date after the end date of the approval period.

36. **Federalwide Assurance (FWA)** See Assurance of Compliance.

37. **Fetus** The product of conception from fertilization until delivery.

38. **Fiscal Intermediary ("FI")** The business entity contracted by CMS to process claims and perform bill processing functions and benefit payment functions for Part A Medicare claims for hospitals.

39. **Full Board review** Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

40. **Guardian** An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. In Wisconsin a "Guardian" of a minor means having the duty and authority to act in the best interests of the minor, subject to residual parental rights and responsibilities, to make important decisions in matters having a permanent effect on the life and development of the minor and to be concerned with his or her general welfare. (s. 48.02 (8)) Under Wisconsin law, in addition to a parent, a court-appointed "guardian" for an unemancipated child under the age of 18 has the authority to consent to major medical, psychiatric and surgical treatment. [Wis. Stat. 48.023(1)].

41. **Guidance** Written discussion of issues. Guidance may be free-standing documents or may be embedded within a Standard Operating Procedure (SOP). When embedded within a SOP, guidance is clearly labelled as "guidance". Guidance enhances policies and procedures by providing additional information about specific ethical or regulatory issues.
42. **HIPAA** The Health Insurance Portability and Accountability Act of 1996. HIPAA is a federal law that was designed to allow portability of health insurance between jobs. In addition, it required the creation of a federal law to protect personally identifiable health information; if that did not occur by a specific date (which it did not), HIPAA directed the Department of Health and Human Services (DHHS) to issue federal regulations with the same purpose. DHHS has issued HIPAA privacy regulations (the HIPAA Privacy Rule) as well as other regulations under HIPAA. The full text of the HIPAA regulations is available at: http://www.hhs.gov/ocr/hipaa.
43. **Human Subject**
    - As defined by the Common Rule, the term Human Subject means a living individual about whom an investigator conducting research obtains (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
    - As defined by the FDA at 21 CFR 50.3(g), the term Human Subject means an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.
44. **Humanitarian Use Device (HUD)** a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 8,000 individuals in the United States per year.
45. **Identifiable Biospecimen** A biospecimen for which the identity or the subject is or may be ascertained by the Investigator or associated with the biospecimen.
46. **Identifiable Private Information** Private Information for which the identity of the individual is or may readily be ascertained by the Investigator or associated with the information.
47. **Immediate Family** Spouse, domestic partner, and dependent children
48. **Institutional Official (IO)** A high-level institutional official who has the authority to represent the institution named on a Federalwide Assurance (FWA), as well as the institutional components listed in the FWA. The individual should be at a level of responsibility that would allow authorization of necessary administrative or legal action should that be required. The IO is the Signatory Official on the Federalwide Assurance and must assure that human subjects research to which the FWA applies is conducted in accordance with the terms of the FWA.
49. **Institutional Profile** A record of information an institution keeps about another collaborating institution/organization for one or more Collaborate Studies or Multi-Site Studies
50. **Intervention** Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the Human Subject or the Human Subject's environment that are performed for research purposes.
51. **Interaction** Communication or interpersonal contact between an Investigator and a Human Subject.
52. **Investigational device exemption ("IDE")** Approval by the Food and Drug Administration (FDA) to allow the investigational device to be used in a clinical study to collect safety and effectiveness data required to support a Pre-market Approval application or a Premarket Notification [510(k)] submission to FDA.
53. **Investigational New Drug ("IND")** Application required by the FDA before clinical trials of a new drug or new biological agent may be initiated.
54. **Investigator:** The person responsible for the conduct of the Clinical Research. If the Clinical Research is conducted by a team of individuals, the investigator is the responsible leader of the team and may be called the Principal Investigator.
55. **Informed Consent** Required by the Common Rule. Refers to the requirement that all researchers explain the purposes, risks, benefits, confidentiality protections, and other relevant aspects of a research study to potential human subjects so that they may make an informed decision regarding their participation in the research. IRBs

review the informed consent process and form documenting the consent to ensure compliance with research regulations and policies.

56. **Institutional Review Board (IRB)** A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

57. **Justice** This ethical principal, established by the Belmont Report, means the benefits and burdens of research are to be shared fairly.

58. **Legally Authorized Representative** A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

59. **Limited Data Set** Set of data that may be used for research, public health or health care operations without an authorization or waiver of authorization. The limited data set is defined as PHI that excludes the following direct identifiers of the individual or of relatives, employers or household members of the individual.

    All identifiers must be removed (see "deidentified" for a list) EXCEPT for the following, which may remain on the disclosed:

    - dates such as admission, discharge, service, DOB, DOD;
    - city, state, five digit or more zip code; and
    - ages in years, months or days or hours.

    A covered entity must enter into a data use agreement with the recipient of a limited data set.

60. **Minimal Risk** The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

61. **Minimum Necessary Standard** A HIPAA standard requiring that when protected health information is used or disclosed, only the information that is needed for the immediate use or disclosure should be made available by the health care provider or other covered entity. This standard applies to all research involving the use of PHI, including protocols involving the use of a limited data set and/or a waiver of authorization, and for reviews preparatory to research.

62. **Multi-Site Study** A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.

63. **Neonate** A newborn; especially a child less than one month.

64. **New Drug Application ("NDA")** Vehicle through which drug sponsor formally proposes that FDA approve a new pharmaceutical for sale and marketing in the U.S. Data gathered during animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA.

65. **Non-Compliance** Failure to follow the federal regulations; state and local laws; institutional policies governing human subject research; or the requirements or determinations of the IRB.

    - **Continuing Non-Compliance** A pattern of Non-Compliance:
        - that suggests the likelihood that, without intervention, instances of Non-Compliance will recur, or
        - a repeated unwillingness to comply, or
        - a persistent lack of knowledge of how to comply.

    - **Serious Non-Compliance** Non-Compliance such that the failure to comply could:
        - adversely affect the rights, safety, or welfare of a human subject, or
        - place a human subject at increased risk of harm, or
        - cause harm to a human subject, or
        - affect a human subject's willingness to participate in research, or
        - damage or compromise the scientific integrity of research data.

66. **Participating Site (pSite)** An institution that participates in a Single IRB (sIRB) Study.

67. **Pregnancy** Encompasses the period of time from fertilization until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

68. **Prisoner** Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Parolees who are detained in residential treatment (i.e. residing in a treatment center) as a condition of parole (which is an alternative to incarceration) are Prisoners, for purposes of research taking place within that facility.

69. **Privacy** Refers to individuals and to their interest in controlling access of others to themselves. Individuals have an interest in controlling the time, place, and nature of the information they give to others and controlling the information or experiences that are proffered to them. Privacy considerations can be affected by gender, ethnicity, age, socioeconomic status, education, ability level, health status, relationship to researcher, legal status, etc.

70. **Privacy Board** A group of individuals responsible for the review and approval of requests for the use or disclosure of PHI for research purposes.

71. **Private Information** Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

72. **Proband** In relation to genetic study of biological specimens, a proband is an individual being studied or reported on. A proband is usually the first affected individual in a family who brings a genetic disorder to the attention of the medical community.

73. **Prospective study** Study designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

74. **Protected Health Information (PHI)** Individually identifiable health information transmitted or maintained in any form.

75. **Protocol** The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

76. **Protocol Deviation** Any departure from the defined procedures and treatment plans as outlined in the protocol version approved by the IRB. A protocol deviation occurs when there is an inconsistency in a research study between the protocol that has been reviewed and approved by the IRB and the actual activities being done. Protocol deviations may be minor or major:

    - **Minor Protocol Deviation:** Any difference or departure in the conduct of a study from the criteria and/or procedures prescribed in the IRB approved protocol which does not affect the participant's rights, safety, welfare, and/or the integrity of the study and resultant data. Deviations may result from action or inaction of the participant, investigator, or staff. A minor deviation:
        - Has no substantive effect on the risks to research participants;
        - Has no substantive effect on the value of the data collected (i.e., the deviation does not confound the scientific analysis of the results);
        - Does not result from willful or knowing misconduct on the part of the investigator(s), and;
        - Does not result in or require any substantive action to be taken or result in any change to the subject's condition or status (i.e., does not affect the subject's participation in any way, does not result in a

change to the subject's emotional or clinical condition, does not cause an adverse experience or require a change to the clinical care of the subject, etc).

- **Major Protocol Deviation:** Any difference or departure from the criteria and/or procedures prescribed in the IRB approved protocol that affects the participant's rights, safety, or welfare; increases the risk/benefit ration; or, compromises the integrity of the study's data. A major deviation:
  - Results in or requires substantive action be taken or results in a change to the subject condition/status;
  - Harms or poses a significant risk of substantive harm to research participants;
  - Damages the scientific integrity of the data collected for the study;
  - Results from willful or knowing misconduct on the part of the investigator(s);
  - Involves serious or continuing noncompliance with federal, state, or local research regulations;
  - Includes repeated minor protocol deviations from the same investigator/research staff; or
  - Includes a failure to follow action ordered to correct minor protocol deviations.

77. **Research**
    - As defined by the Common Rule at 45 CFR 46.102(d), the term Research means a systematic investigation involving Human Subjects, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
    - As defined by the FDA at 21 CFR 50.3(c), the term Research means an experiment that involves a test article and one or more human subjects
78. **Retrospective study** Research conducted by reviewing records from the past or by obtaining information about past events elicited through interviews or surveys.
79. **Single IRB (sIRB) Study** A study in which two or more institutions (participating sites, or pSites) coordinate to complete the research activities, but all institutions rely on a single institution's/organization's IRB for ethical review. The reviewing IRB may or may not be affiliated with any of the pSites.
80. **Suspension of IRB Approval** An action of the IRB, IRB designee, Intsitutional Official, or designee of the Intsitutional Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review. This action may be reportable to federal agencies.
81. **Termination of IRB Approval** An action of the IRB, IRB designee, Intsitutional Official, or designee of the Intsitutional Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review. This action may be reportable to federal agencies.
82. **Test Article** Any drug (including a biological product for human use), medical device for human use, human food additive, color, additive, electronic product, or any other article subject to regulation under the jurisdiction of the FDA.
83. **Unanticipated Problem Involving Risks to Subjects or Others ("Unanticipated Problem")** Any event that is 1) unexpected in nature, severity, or frequency; 2) related or possibly related to participation in the research; and 3) places subjects or others at a greater risk of harm than was previously known or recognized.
84. **Undue Influence** Excessive or inappropriate reward or other incentive in which a person is induced to act otherwise than by their own free will or without adequate consideration of the consequences.
85. **Use** The sharing of individually identifiable health information within a covered entity.
86. **Viable** As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of Subparts A and D of 45 CFR 46.
87. **Vulnerable Populations** Pregnant females, fetuses, neonates, children, prisoners, and the cognitively impaired.
88. **Voluntary** Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

89. **Waiver of Authorization** Under limited circumstances, a waiver of the requirement for authorization for use or disclosure of private health information may be obtained from the IRB by the researcher. A waiver of authorization can be approved only if specific criteria have been met.

90. **Ward** A child who is placed in the legal custody of the State or other agency, institution or entity, consistent with applicable Federal, State and local law. 21 CFR 50.3(q). This definition includes children placed in foster care.

REFERENCES

- 45 CFR 46
- 21 CFR 50
- 21 CFR 56
- 21 CFR 312
- 21 CFR 812

RELATED MATERIAL

None

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	12/5/2017	New- Initial Integration Update	J. Blundon
02	11/8/2018	Added definition of Amendment; Minor formatting/editing corrections	J. Blundon-Kirchen