

SHSU's IRB Glossary

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A

Adverse event (AE): Any undesirable and unintended (although not necessarily unexpected) effect occurring as a result of interventions, interactions, or collection of identifiable private information in research. In medical research, any untoward physical or psychological occurrence in research, including abnormal laboratory finding, symptom, or disease temporally associated with the use of (although not necessarily related to) a medical treatment or procedure. Adverse events involving drugs are also referred to as *adverse drug experiences*.

Affiliated: IRB membership status designating association with the university. **Note:** A member (or alternate) is considered to be affiliated if he/she or a member of his/her immediate family is a current or past (within the last 2 years): employee (full or part-time); clinical, adjunct, or visiting faculty member or instructor; paid or unpaid member of a university governing panel or board (not including the IRBs); healthcare provider holding credentials to practice at Ohio State; volunteer working at the university (unrelated to IRB service); or university consultant or advisor (paid or unpaid). An emeritus faculty or retired staff member is also considered to be affiliated if he/she has been retired or involved in paid or unpaid university activities (including research or service) within the last 2 years. Current undergraduate, graduate, and postdoctoral students are also considered to be affiliated, as described by IRB SOP.

Allegation of noncompliance: An unconfirmed report of noncompliance.

Alternate: An individual appointed to the IRB to serve in the same capacity as the specific IRB member(s) for whom the alternate is named, who substitutes for the member at convened meetings when the member is not in attendance. **Note:** IRB members and alternates have equal responsibilities in terms of required education, service, and participation.

Anonymous: Unidentified (i.e., personally identifiable information was not collected, or if collected, identifiers were not retained and cannot be retrieved); materials (e.g., data or specimens) that cannot be linked directly or indirectly by anyone to their source(s).

Appeal: Request for reconsideration of an IRB determination in research involving human subjects, including (but not limited to) decisions regarding approval status, conditions for approval, or noncompliance. **Note:** An appeal is reviewed by the convened IRB responsible for the determination being appealed; for a decision made by expedited review, the corresponding convened IRB may review the appeal. Also: request for reconsideration.

Approval Date: The first date that research can be performed (following notification from the IRB), consistent with federal regulations, state and local laws, and university policy. The

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approval date is the date that the research is approved by convened or expedited review, or if modifications are required (to secure approval), the date that modifications/conditions are met by the investigator. **See also Approval Period.**

Approval Period: For initial review, the interval that begins on the day research is approved by convened or expedited review, or if modifications are required (to secure approval), the date that modifications/conditions are met by the investigator. For continuing review, the interval that begins on the day research is re-approved (by convened or expedited review) or modifications are required. **Note:** An approval period for initial or continuing review may not be longer than one year.

Approved: An IRB action taken when the required determinations are made that allow research involving human subjects to proceed consistent with federal regulations, state and local laws, and university policy.

Assent: Agreement to participate in research expressed by an individual (e.g., a child) who cannot provide legally effective informed consent to participate on his/her own behalf. **Note:** Failure to object does not constitute assent.

Audit: A systematic review, inspection, or verification, typically conducted by an independent individual or group.

B

Bank: Also: **repository.** Collection of data and/or specimens obtained and stored for future research uses and/or distribution, including a collection not originally or primarily obtained for research purposes.

Biological product: Also: **biologic.** A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings. **Note:** Biological products also include immunoglobulin products, monoclonal antibodies, products containing cells or microorganisms, and most proteins intended for therapeutic use.

C

CITI: meaning Collaborative Institutional Training Initiative, this is SHSU's ethics training program that houses all required training for Human Subjects, Animal Subjects, COI, and RCR

Child/Children: Person(s) 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. For purposes of PHSC SOP, individuals under 18 years of age are considered children in Texas unless they meet the definition of emancipated minors.

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Course Project: student projects conducted to fulfill course requirements and are designed to teach students research methods. Because it is a classroom assignment, the individual faculty members and departments are responsible for overseeing the activities as defined below under faculty responsibilities. This means faculty and departments are responsible for ensuring that the students are adequately trained and that their planned research activities are designed with appropriate and adequate safeguards in place in order to ensure that the activities are within the scope of ethical conduct.

Coded: Direct personal identifiers have been removed (e.g., from data or specimens) and replaced with words, letters, figures, symbols, or a combination of these (not derived from or related to the personal information) for purposes of protecting the identity of the source(s), but the original identifiers are retained in such a way that they can still be traced back to the source(s). **Note:** A code is sometimes also referred to as a “key,” “link,” or “map.”

Coercion: Persuasion (i.e., of an unwilling person) to do or agree to something by using obvious or implied force or threats.

The Common Rule: also known as the Federal Policy for the Protection of Human Subjects, it is a rule of ethics regarding biomedical and behavioral research involving human subjects in the United States. These regulations govern all Institutional Review Boards for oversight of human subject research. As the basis for standard practice, SHSU’s IRB abides by Subparts A, B, C, and D of Title 45 CFR 46, which was adopted by the U.S. Department of Health and Human Services (DHHS) in 1991.

Compensation: Payment, merchandise, class credit, or other gift or service provided to research participants or their legally authorized representatives to reimburse them for their time, effort, and/or for any out-of-pocket expenses associated with research participation. **Note:** Compensation is sometimes distinguished from an **incentive** or **inducement**, which is generally thought of as a payment or other offering that is “over and above” reimbursement and intended to encourage research participation.

Confidentiality: In the context of human subjects research, the condition that results when data are maintained in a way that prevents inadvertent or inappropriate disclosure of participants’ identifiable information.

Conflict of Interest: A financial interest or other opportunity for tangible personal benefit of an individual or his/her immediate family that may exert a substantial and improper influence on the individual’s professional judgment in exercising any institutional duty or responsibility, including the review of research. **Note:** For IRB members and consultants, financial and non-financial interests/opportunities are included.

Continuing noncompliance: Noncompliance (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention. Examples of

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continuing noncompliance may include, but are not limited to the following: repeated failures to provide or review progress reports resulting in lapses of IRB approval, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

Convened IRB Review: Review of proposed human subjects research by an Institutional Review Board that meets the membership requirements specified in federal regulations regarding the number, qualifications, diversity, and affiliation of its members, at which a majority of the members are present including at least one member whose primary concerns are in nonscientific areas.

D

Data and Safety Monitoring: The process for reviewing data collected as research progresses to ensure the continued safety of current and future participants as well as the scientific validity and integrity of the research.

Data and Safety Monitoring Plan: The plan for reviewing research data to ensure the safety of participants and scientific validity of the research, including who will perform the monitoring, the type and frequency of review, and procedures for notifying appropriate entities (e.g., investigators, sponsor, etc.) of the results. **Note:** Monitoring performed by a data and safety monitoring board is one type of data and safety monitoring plan.

Deferred: An IRB action taken when the IRB cannot fully evaluate the research under review and make the determinations required for approval without modifications to the protocol and/or informed consent document, or submission of clarifications or additional materials prior to reconsideration of the research. **Note:** Convened IRB review of the investigator's response(s) is required.

De-identified: All direct personal identifiers are **permanently** removed (e.g., from data or specimens), **no code or key exists to link the materials** to their original source(s), and the remaining information cannot reasonably be used by anyone to identify the source(s). **Note:** For purposes of PHSC SOP, health information is de-identified when it does not contain any of the 18 identifiers specified by the HIPAA Privacy Rule at 45 CFR Part 164 (or has been determined to be de-identified by a statistician in accordance with the standards established by the Privacy Rule). For more information, including the list of identifiers that must be removed to de-identify health information, see [HIPAA and Human Subjects Research](#).

Diminished decision-making capacity: As it applies to informed consent, lacking the ability to provide valid informed consent to participate in research, e.g., as a result of trauma, intellectual disability, certain mental illnesses, cognitive impairment, or dementia. **Note:** Diminished decision-making capacity may be temporary, permanent, progressive, or fluctuating.

Directed (For-Cause) Audit/Review: An audit of research and/or investigators initiated at the request of the IRB or Institutional Official to obtain or verify information necessary to ensure

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compliance with regulations and institutional requirements and to inform decisions about the conduct of human subjects research and/or human subjects protection.

Disapproved: An IRB action taken when the determinations required for approval of research cannot be made, even with substantive clarifications or modifications to the protocol and/or informed consent process/document. **Note:** Research cannot be disapproved by expedited review.

E

Emancipated Minors: For purposes of PHSC SOP, the following persons under the legal age of 18, who because of their unique circumstances have the legal rights of adults, including the right to consent to treatments or procedures involved in research:

- Persons under the age of 18 on active duty in the military
- Married persons under 18 years of age.

Note: Pregnancy or childbirth outside of marriage does not emancipate a minor in Texas.

Engaged: Involved in human subjects research in such a way (or to the extent) that the ethical and regulatory requirements for human subjects protection are applicable. An individual (or organization) becomes engaged in human subjects research when for the purposes of non-exempt research the individual (or organization's employee or agent) obtains any of the following:

- Data about research participants through intervention or interaction
- Identifiable private information about research participants
- Informed consent of research participants.

Note: An organization is also engaged in human subjects research whenever it receives a direct federal award to support the research.

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.

Exempt research: Research that involves human subjects that is not subject to regulations requiring IRB review and approval. Categories of research activities that may be determined to be exempt from review by the IRB are defined by federal regulations and university policy.

Note: Investigators performing exempt research must comply with the requirements of the PHSC even when the research is exempt.

Exempt Review: Research that involves human subjects that is not subject to regulations requiring IRB review and approval. Categories of research activities that may be determined to be exempt from review by the IRB are defined by federal. For this type of review, ORSP's RCC

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has been designated by the SHSU IRB Chair to make those decisions about what can be exempted from IRB review. **Note:** Investigators performing exempt research must comply with the requirements of the PHSC/IRB even when the research is exempt.

Existing: Available or “on the shelf” (e.g., data, specimens) at the time the research is submitted for a determination of whether the research is exempt.

Expedited IRB Reviewer: The IRB Chair and those experienced IRB members designated by the Chair who may perform some or all types of expedited reviews.

Expedited Review: Process by which designated IRB members, on behalf of the full IRB, approve a limited class of research activities through reviews conducted outside of the convened IRB meeting. The ORSP’s RCC distributes a PI’s IRB application, which includes all supplementary material to a single IRB reviewer designated by ORSP’s RCC (on behalf of the IRB Chair).

Experienced IRB Member: An IRB member determined by the IRB Chair to be qualified to perform reviews using expedited procedures. The following criteria are considered when determining whether an IRB member is experienced: length of IRB service, training regarding expedited review procedures, research experience/expertise, and/or work with the research participants being studied.

Expiration Date: The date that the IRB’s approval of research has lapsed and research can no longer be performed. **Note:** An expiration date may not be longer than one year from the date the approval period begins.

External event: An event occurring in research at a site(s) other than SHSU, over which another (non-SHSU) IRB has jurisdiction.

F

Family Member: For purposes of the waiver of informed consent for emergency research, any one of the following legally competent persons: spouse, parent, child (including an adopted child), brother, sister, spouse of a brother or sister, and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

Federalwide Assurance: also referred to as FWA, it is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by Health and Human Services (HHS) or other federal departments and agencies that have adopted the Common Rule. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR 46, as well as the Terms of Assurance.

Financial Conflict of Interest: An interest of an individual (or his/her immediate family) of monetary value that would reasonably appear to be affected by the research or an individual’s

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interest in any entity whose financial interests would reasonably appear to be affected by the research. **Note:** Financial interests include (but are not limited to) salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

Finding of noncompliance: An occurrence or determination of noncompliance that does not require further confirmation or investigation (e.g., failure to respond to the IRB within established deadlines, allegation of noncompliance determined by the IRB to be true).

G

Generalizable Knowledge: Information from which one may infer a general conclusion; knowledge brought into general use or that can be applied to a wider or different range of circumstances. For example, publication and presentation are typical methods used to disseminate research findings, thereby contributing to “generalizable knowledge.” However, not all information that is published or presented represents generalizable knowledge. Generalizable knowledge is also interpreted to include data intended for general use, regardless of its eventual distribution or acceptance.

Guardian: An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. In Ohio, a guardian may be a grandparent, other family member, or other person, association, or agency other than the biological or adoptive parents who has been formally appointed as a guardian or legal representative by a court to care for a child, including to consent on behalf of a child to general medical care. **Note:** Grandparents or other family members who are not formally appointed as guardians or legal representatives by a court generally do not have the authority to provide consent on behalf of a child without consent by the child’s parents.

H

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.

I

Immediate Family: For purposes of the IRB Committee membership requirements, an IRB member or consultant’s spouse or domestic partner and dependent children.

Individual Investigator Agreement: A written agreement between an organization and a collaborating external investigator who will be engaged in the organization’s non-exempt human subjects research that describes each party’s responsibilities for research conduct and oversight.

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Individually Identifiable: The identity of the participant is or may readily be ascertained by the investigator or the investigator's staff, or is associated with the information. **Note:** Individually identifiable for the purposes of HRPP policy may be similar to, but is not the same as, individually identifiable health information or protected health information as defined by the HIPAA Privacy Rule at 45 CFR Part 160. Limited data sets released from data repositories with IRB approval to release such data sets are not considered to be individually identifiable.

Informed Consent: Agreement to participate in research expressed by an individual (or his/her legally authorized representative) authorized under applicable law to make such decisions, based on sufficient information (e.g., regarding possible risks and benefits of the research) and adequate opportunity to consider voluntary participation. Also: legally effective informed consent.

Initial Review: a PI's original application submitted to the IRB for its initial review; if modifications to the application are requested, it is no longer "initial review;" it is then referred to as a Response to Modifications submission.

Interaction: Communication or interpersonal contact between an investigator and participant.

Internal event: An event occurring in SHSU research at a site(s) under the SHSU IRB's jurisdiction.

Intervention: Physical procedure by which data are gathered, or manipulation of the participant or the participant's environment for research purposes.

IRB Amendment [Changes to Research]: this application form should be completed if there are Significant Changes to your IRB protocol and ONLY AFTER your initial IRB application has been approved; Note: When submitting an amendment(s) in conjunction with an application for continuing review, only the relevant appendices are required. No Amendment is needed.

IRB Authorization Agreement: A written agreement between organizations collaborating in non-exempt human subjects research that describes each organization's responsibilities for IRB review and oversight of the research.

IRB Continuing Review (IRB CR): this application form should be completed ONLY AFTER your initial IRB has been approved and you require an extension for continued data collection and/or analysis; Note: When submitting an amendment(s) in conjunction with an application for CR, only the relevant appendices are required. No Amendment is needed.

J

K

L

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Legally Authorized Representative: An individual, 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. For purposes of the IRB SOP, the following are recognized in Texas as legally authorized representatives:

- Persons appointed as health care agents under an Texas Durable Power of Attorney for Health Care
- Court-appointed guardians
- Next of kin in the following order: spouse, adult child, parent, and adult sibling.

Limited Data Set: Health information that excludes certain direct identifiers, but may include city, state, and ZIP code; elements of date; and other numbers, characteristics, or codes that cannot be used to identify an individual or the individual's relatives, employers, or household members. **Note:** Limited data sets may be used or disclosed for purposes of research with a data use agreement as described by the HIPAA Privacy Rule at 45 CFR Part 164. For more information, including the list of identifiers that must be removed from health information in a limited data set, see [HIPAA and Human Subjects Research](#).

M

Minimal Risk: The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental, or psychological examination of healthy persons. *Note: The regulatory definition of "minimal risk" for research involving prisoners differs from the definition of minimal risk for research involving participants who are not prisoners.*

Minor Changes: Changes to research that in the judgment of the IRB do not affect assessment of the risks and benefits of the study by substantially altering any of the following: research aims or methodology, nature of subject participation, level of risk, proposed benefits, participant population, qualifications of the research team, or the facilities available to support the safe conduct of the research. For specific examples of changes that may be considered minor (and may be reviewed using expedited procedures), see [IRB SOP 3, Attachment 1](#). **Note:** A minor change does not increase risk more than minimally or add procedures in research categories other than those that qualify for expedited initial review.

Modifications Required: An IRB action that specifies conditions under which research can be approved, pending the following: confirmation of specific understandings by the IRB about how the research will be conducted, submission of additional documentation, precise language changes to the protocol and/or informed consent document(s), and/or substantive changes to documents with specific parameters the changes must satisfy. **Note:** Verification that the investigator's response(s) satisfies the conditions for approval set by the IRB may be performed by the IRB Chair and/or other designated individual(s). Also: contingent approval, approval with conditions.

N

Noncompliance: Failure (intentional or unintentional) to comply with applicable federal regulations, state or local laws, the requirements or determinations of the IRB, or university policy regarding research involving human subjects. Noncompliance can result from action or omission. Noncompliance may be non-serious (minor) or serious, and may also be continuing.

Non-Financial Conflict of Interest: An interest other than monetary of an individual (or his/her immediate family) in the design, conduct, or reporting of the research or other interest that competes with an IRB member's (or consultant's) obligation to protect research participants and potentially compromises the objectivity and credibility of the research review process.

Non-Scientist: An individual appointed to the IRB who (due to training, background, and/or occupation) is inclined to view research activities from the standpoint of someone outside the scientific or scholarly discipline of the IRB on which he/she serves.

Non-serious or minor noncompliance: Noncompliance that does not increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human research protection program. Examples of minor noncompliance may include, but are not limited to the following: lapses in continuing IRB approval, failure to obtain exempt determination before exempt research involving human subjects is conducted, minor changes in or deviations from an approved protocol, or administrative errors.

O

ORSP: standing for the Office of Research & Sponsored Programs, it is the office at SHSU that houses the support system for all compliance-related matters

Off-Site Research: Human subjects research sponsored or performed at a location/site that is not owned by or under the direct control of the organization responsible for the research.

Organizational Conflict of Interest (OCOI): A situation in which the financial investments or holdings of an organization (including licenses, royalties, intellectual property rights, patents, certain gifts) or the personal financial interests or holdings of a key leader might affect or reasonably appear to affect organizational processes for the design, conduct, reporting, review, or oversight of human subjects research.

P

Parent: A child's biological or adoptive mother or biological or adoptive father.

Parental Permission: The agreement of a parent(s) or legal guardian to the participation of his/her child or ward in research.

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PHSC Policies and Procedures: Policies and procedures of the Office of Research and the IRB that apply to the conduct, review, and oversight of human subjects research and describe the roles and responsibilities of those involved in these activities.

Policy: Formal statement of principles on which action(s) for a specific issue are based.

Pre-review: The process performed by ORSP's RCC to determine that a submission for IRB review is complete, including the required materials, and that institutional requirements, such as completion of human subjects protection education (i.e., CITI training) and conflict of interest (COI) disclosure, have been met.

Principal Investigator: When the University accepts a grant or contract from an external sponsor, the University assumes responsibility for the proper performance of the stated project, for the fiscal management of the funds received, and for accountability to the sponsor. Because the institutional responsibility for meeting these obligations is vested in the PI, only individuals in the categories shown below are authorized to be PIs or Co-PIs for sponsored projects:

- Tenure or tenure-track faculty (Professor, Associate Professor, and Assistant Professor);
- Research Faculty;
- Directors, Research Scientists, Research Associates, and certain Research Staff
- Individuals who have been authorized by written permission of the Associate Vice President.
- In rare instances others may be authorized, but only with the prior written approval of the ORSP.

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 which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing ([45 CFR 46.303\(c\)](#)).

Privacy: The state of being free from the observation, intrusion, or attention of others.

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 that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Examples of private information include medical or academic records or personal journals.

Procedure: A series of actions conducted in a certain order or manner; operational method by which policy is put into practice.

Q

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Quorum: one more than 50% of the Regular members of the IRB, including at least one member whose primary concerns are in a nonscientific area (aka, nonscientist).

R

RCC: meaning Research Compliance Coordinator, it is the position at ORSP responsible for all compliance-related matters, such as coordinating activities for the IRB, IACUC, and other compliance committees.

Recruiting Methods: Materials, compensation, and other practices or procedures used to inform potential participants about research. **Note:** Methods for recruiting research participants are generally distinguished from those of marketing, advertising, or public relations' efforts, which have promoting a product, service, or idea as goals.

Recruitment Incentive: Payment, merchandise, or other gift or service offered by a sponsor as an incentive or reward to an organization, investigator, or key personnel conducting research designed to accelerate recruitment that is tied to enrollment rate, timing, or numbers.

Recruitment Materials: Announcements; advertisements; flyers; posters; scripts for telephone or other oral communication; letters or email messages; bulletin board tear-offs; Internet postings; newspaper, radio, television, or video broadcasts, or other media used to attract potential participants for research.

Repository: Also: **bank.** Collection of data and/or specimens obtained and stored for future research uses and/or distribution, including a collection not originally or primarily obtained for research purposes.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

S

Sample: See also: **specimen.** Human biological material, including solid material (e.g., tissue, organs) body fluid (e.g., blood, urine, saliva, semen, cerebrospinal fluid), and cells.

Serious noncompliance: Noncompliance that has the potential to increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human research protection program. Examples of serious noncompliance may include, but are not limited to the following: conducting or continuing non-exempt human subjects research without IRB approval; lack of legally effective informed consent from research participants; failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or inappropriate oversight of the research to ensure the safety of human subjects and the integrity of the research/data.

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Specimen: See also: **sample.** Human biological material, including solid material (e.g., tissue, organs) body fluid (e.g., blood, urine, saliva, semen, cerebrospinal fluid), and cells.

Subpart A: also referred to as The Common Rule of the DHHS, it is the baseline standard of ethics by which any government-funded research in the U.S. is held, and nearly all academic institutions hold their researchers to these statements of rights regardless of funding. This federal policy now applies to approximately 17 federal agencies or departments.

Subpart B: The Common Rule includes additional protections for certain vulnerable research subjects. This Subpart provides additional protections for pregnant women, in vitro fertilization, and fetuses.

Subpart C: The Common Rule includes additional protections for certain vulnerable research subjects. This Subpart contains additional protections for prisoners.

Subpart D: The Common Rule includes additional protections for certain vulnerable research subjects. This Subpart provides additional protections for children.

Suspension: An action taken by the IRB Chair or convened IRB to withdraw approval for some research activities, temporarily or permanently, or all research activities temporarily, short of permanently withdrawing approval for all research activities. The Institutional Official may also suspend research on an urgent basis. **Note:** Similar actions taken by investigators or sponsors to stop research activities are not suspensions as described by IRB SOP.

Systematic Investigation: A planned scientific or scholarly activity involving qualitative or quantitative data collection and/or data analysis that sets forth an objective(s) and a set of procedures intended to reach the objective(s), i.e., to acquire knowledge, develop a theory, or answer a question.

T

Tabled: An IRB “action” that indicates that review was not initiated or was not completed, resulting in postponement of IRB review, usually due to loss of quorum or other administrative issue. Research tabled at a convened meeting will be reviewed at a future convened meeting.

Termination: An action taken by the convened IRBs to permanently withdraw approval for all research activities (except for those follow-up procedures that may be necessary to protect the health and/or welfare of participants). **Note:** Similar actions taken by investigators or sponsors to stop research activities are not terminations as described by IRB SOP.

U

Unanticipated problems involving risks to subjects or others: Unforeseen events (given the nature of the research procedures and subject population) that suggest subjects, research staff, or

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others are placed at greater risk by the research than previously expected. Unanticipated problems involving risks to subjects or others may be medical or non-medical in nature, and include – but are not limited to – *serious, unexpected, and related adverse drug events* and *unanticipated adverse device effects*.

Undue Influence: Excessive or inappropriate reward or other incentive in which a person is induced to act otherwise than by his/her own free will or without adequate consideration of the consequences.

V

W

X

Y

Z