**IRB GLOSSARY**

**(Dated 01/21/2019)**

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# A

**Academic records:** Documentation of a student's achievement in school, college or university. (FERPA and PPRA regulations may apply.)

**Administrative closure:** Closure of a study that does not have IRB approval, due to: (1) a lapsed approval, or (2) a failure to respond to required modifications. Initiated by the Office of Research Compliance, not the researcher or the IRB.

**Adult:** A person who has attained the legal age of majority under the applicable law of the jurisdiction in which the research will be conducted.

**Adverse Event (AE):** Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease temporally associated with the subject's participation in the research, and does not imply any judgment about causality.

**Amendment:** Any changes to an IRB-approved study, such as procedures, purpose, subjects, recruiting materials, study staff, location, etc. Changes must be approved in advance by the IRB. See: Modification.

**Anonymous**: Data and/or specimens are anonymous if no one, not even the researcher, can connect the data or specimen to the individual who provided it either directly (e.g., name, address, ID#, etc.) or indirectly (e.g., linked code or other unique individual characteristics that might make it possible to identify an individual from a pool of subjects). Anonymous, confidential, and de-identified are not the same and cannot be used interchangeably. Video and voice recordings are not anonymous. Interview or survey data in which recorded demographic characteristics or descriptions of specific incidents could easily lead to the recognition of the individual respondent are not anonymous.

**Appeal:** Request for reconsideration of an IRB determination, including (but not limited to) decisions regarding approval status, conditions for approval, or non-compliance.

**Approval:** 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.

**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 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.

**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.

**Assent:** Agreement to participate in research expressed by an individual who cannot provide legally effective informed consent to participate on his/her own behalf (e.g., a child, adult with diminished capacity). **Note:** Failure to object does not constitute assent. [45 CFR § 46.402(b)]

**Autonomy:** An individual's right to consider alternatives, make choices, and act without undue influence or interference of others.

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# 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.

**Belmont Report:** A report that sets out basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978. See: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

**Beneficence:** An ethical principle from the Belmont Report that entails an obligation to protect persons from harm by maximizing possible benefits and minimizing possible risks of harm

**Benefit:** A valued or desired outcome; an advantage. Note: payments, gifts, course credit, etc., for research participation are not considered to be a benefit.

**Biological product:** Also: **biologic**. A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. (Biological products include, among other products, bacterial vaccines, allergenic extracts, gene therapy products, growth factors, cytokines, and monoclonal antibodies.)

**Biological specimen:** A physical sample used for analysis, for example: urine, hair saliva, blood, or other tissues.

**Biomedical Research**: Research that is conducted to contribute to an increased understanding of disease processes, new treatments and interventions, and the prevention and control of infectious and chronic diseases in clinical medicine and public health; and research involving human biological specimens (i.e. collecting or accessing tissues or genetic material for research purposes).

**Botanical**: A finished, labeled product that contains vegetable matter, which may include plant materials, algae, macroscopic fungi, or combinations of these. Depending in part on its intended use, a botanical product may be considered a food, drug, medical device, or cosmetic.

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# C

**Certificate of Confidentiality:** A certificate of confidentiality may be granted to protect identifiable study data from discovery pursuant to legal process. Certificates are issued by NIH and other Department of Health and Human Services (HHS) agencies to researchers to help protect the privacy of human subjects enrolled in sensitive, health-related research.

<http://grants.nih.gov/grants/policy/coc/index.htm>

**CFR:** Code of Federal Regulations

**Child: A** person who has 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.

**CITI:** meaning Collaborative Institutional Training Initiative. Baylor maintains an institutional subscription to CITI’s online training modules and requires completion of the appropriate training for all key personnel involved in human subjects research.

 **Clinical Investigation**: Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under Section 505(i) or 520(g) of the FDA Act, or is not subject to requirements for prior submission to the FDA under these sections of the FDA Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of Part 58 [of Title 21 of the CFR], regarding non- clinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for the purposes of FDA regulations. [21 CFR Section 50.3(c), 21 CFR 56.102(c)].

**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.

**Coded Data/Information**: Direct personal identifiers (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimen pertain 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:** In human subjects research, coercion occurs when an overt or implicit threat of harm (such as loss of services or access to programs to which the potential participant is otherwise entitled) is intentionally presented by one person to another in order to obtain compliance or research participation. This is often confused with undue influence. <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/>

**Cognitive Impairment:** Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Capacity for autonomy and voluntary participation is thus impaired. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative disease 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 interest.

**Co-investigator:** Researcher who works alongside the Principal Investigator or Lead Researcher. Co-Investigators can be delegated all of the duties of a Principal Investigator, but do not have final responsibility for the conduct of the study.

**Common Rule:** also known as the Federal Policy for the Protection of Human Subjects regulations governing research with human subjects, and adopted by many federal agencies; as stated in 45 CFR 46 (Subpart A) of the Code of Federal Regulations. The Common Rule was revised in 2018 with a compliance date of 01/21/19. The Common Rule in effect on and after 01/21/19 is commonly referred to as “2018 Requirements.” The Common Rule in effect prior to 01/21/19 is commonly referred to as “pre-2018 Requirements.” <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

**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. See: Incentive or Payment

**Competence:** Used as a legal term to indicate a person’s capacity to act on one’s own behalf; a person’s ability to understand information presented, to realize the consequences of acting (or not acting) on that information, and to make a choice.

**Confidentiality:** Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

**Conflict of Interest:** A conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. An apparent conflict of interest is one in which a reasonable person would think that the professional’s judgment is likely to be compromised. A potential conflict of interest involves a situation that may develop into an actual conflict of interest. It is important to note that a conflict of interest exists whether or not decisions are affected by a personal interest; a conflict of interest implies only the potential for bias, not a likelihood. It is also important to note that a conflict of interest is not considered misconduct in research, since the definition for misconduct is currently limited to fabrication, falsification, and plagiarism. See: Financial Conflict of Interest, Institutional Conflict of Interest, and Non-Financial Conflict of Interest.

**Consent Form:** Document describing the risks, benefits, and study procedures so that potential subjects can make an informed decision whether or not to participate in the research.

**Continuing Non-Compliance: (***See*: non-compliance) A pattern of non-compliance that:

* Suggests that non-compliance will continue, if there is no intervention, or,
* Increases the risk of serious non-compliance.

**Continuing Review:** the periodic review of a research study by an IRB to evaluate whether the study continues to meet organizational and regulatory requirements. Federal regulations stipulate that continuing review should be conducted at intervals appropriate to the level of risk involved in the study, and not less than once per year. [45 CFR 46.109(e)] [21 CFR 56.109(f)].

**Covered Entity:** A health plan, a health care clearinghouse or a health care provider that transmits any health information in electronic form in connection with a transaction for which HHS has adopted a standard. See: hybrid covered entity

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# 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 Board (DSMB):** An independent group of experts who monitor subject safety, study outcomes, and study progress while research is ongoing. May also be called a Data Monitoring Committee (DMC).

**Data and Safety Monitoring Plan (DSMP):** 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.

**Data Use Agreements (DUA)**: A legally binding agreement between two parties when data is being transferred from one party to the other. It describes any limitations on the use of the data as well as any confidentiality and access protections.

**Debriefing:** In the context of informed consent, the process of providing information to participants at the conclusion of study procedures. The intent of debriefing is to provide participants with previously undisclosed information, to make sure that they are fully informed about their experience, and to repair breaches in the informed consent process.

**Deception:** In the context of informed consent, the omission of relevant information and/or presentation of misleading information about a study.

**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 research purposes, 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).

**Department of Health and Human Services (HHS):** The United States government's principal agency for protecting the health of all Americans and providing essential human services. The department includes more than 300 programs, covering a wide spectrum of activities. <http://www.hhs.gov/>

**Dietary supplement:** Product taken by mouth that is intended to supplement the diet and that contains one or more dietary ingredients. The dietary ingredients in these products can include vitamins, minerals, herbs and other botanicals, amino acids, other dietary substances intended to supplement the diet, and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. Dietary supplements can be found in many forms such as tablets, capsules, softgels, liquids, or powders.

**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.

**Disapproval:** 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.

**Document Control:** The management of documents through the document life cycle to a much higher degree of reliability for security, version control, review cycle, visibility, availability and, most importantly, for a controlled reliable audit trail.

**Drug:** An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or an article (other than food) intended to affect the structure or any function of the body of man or other animals. (Note, however, that (1) a dietary supplement intended only to affect the structure or function of the body and not intended for a therapeutic purpose is not a drug and (2) a food used as such (i.e., primarily for its taste, aroma, or nutritive value) and not for a therapeutic purpose or to affect the structure or function of the body, other than by providing nutrition, is not a drug.)

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# E

**Emancipated Minor:** An emancipated minor is a child who is legally considered an adult.

**Emergency Research:** A limited class of research activities involving human subjects who are in need of emergency medical intervention but cannot provide legally effective informed consent. [21 CFR § 50.24]

**Emergency Use:** The one-time clinical use of an investigational drug or device with a patient in a life-threatening or seriously disabling situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval. [21 CFR § 50.23]

**Employee or Agent:** Refers to someone who: acts on behalf of an organization; exercises institutional authority or responsibility; or performs institutionally-designated activities.

**Engagement:** An institution becomes "engaged" in human subjects research when its employees or agents: (1) Intervene or interact with living individuals for research purposes; or (2) Obtain individually identifiable private information for research purposes; or (3) Have significant responsibility for design and conduct of the study. When an institution is a direct recipient of federal funding (prime awardee) for a human subjects research project, even if it conducts no work with human subjects itself, the institution is engaged. Whether an institution is engaged in research is addressed in detail in the OHRP memo "Engagement of Institutions in Research" http://www.hhs.gov/ohrp/policy/engage08.html

**Enrollment:**  A subject is considered to be enrolled in a study when he/she gives informed consent to participate. Accessing the identifiable information of an individual similarly counts as enrolling a subject.

**Equitable:** Fair or just; used in the context of selection of participants to indicate that the benefits and burdens of research are fairly distributed.

**Ethical Research:** Research that follows widely held guidelines about what is ethical, moral and responsible in research settings (e.g. not plagiarizing others’ work, not misreporting sources, not submitting questionable data, not destroying or concealing sources, etc.) and that considers its role in the broader community and the effect of its findings on the community.

**Exculpatory Language:** Language which has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.

**Exempt research:** Research that meets the definition of "human subjects research" but that is determined by the Office of Research Compliance to be exempt from the federal human subjects regulations because it involves no more than minimal risk to subjects and all of the proposed research activities fit within one or more of certain methodological categories under 45 CFR 46.104, 21 CFR 56.104, or Baylor policy. **Note:** Investigators cannot make the determination that their 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 or for IRB review.

**Expedited Review:** IRB review that is conducted by the IRB chair, or a designated voting member or group of voting members, rather than by the entire IRB. Federal rules permit (but do not require) expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. Expedited reviews apply the same criteria for IRB approval as reviews conducted by the full convened IRB.

**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*.*

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# F

**Family Educational Rights and Privacy Act (FERPA):** A Federal law that protects the privacy of student education records [20 U.S.C. § 1232g; 34 CFR Part 99]. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. See: http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html

**Family Member:** Any of the following legally competent persons: spouses, parents, children (including adopted children), brothers, sisters and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with a Human Subject is the equivalent of a family relationship. [21 CFR 50.3(m)].

**FDA:** The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. See: http://www.fda.gov

**FDA Regulations:** The rules set forth by the U.S. Department of Health and Human Services, Food and Drug Administration through Title 21 of the Code of Federal Regulations.

**Federalwide Assurance (FWA):** An assurance of compliance with applicable federal regulations for the protection of human subjects in all research conducted under the auspices of the institution holding the assurance and that is conducted or supported by any U.S. department or agency that has adopted the Common Rule.

**Financial Conflict of Interest:** A conflict of interest that involves financial relationships. **Note:** Financial interests include (but are not limited to) salary or other payments for services (e.g., consulting fees or honoraria), employment, equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). See: Conflict of Interest.

**Finder's Fee:** Compensation of any type (cash, office or medical supplies, educational stipends, gift certificates, priority in authorship listings, travel reimbursement, or anything else of value) to an individual made in exchange for referral or recruitment of a participant to a research study. Such payments, generally, are made to individuals in a position to identify potential participants that might qualify for enrollment into a study.

**Full Board Review:** Review of proposed research at a convened meeting of the IRB, at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in a nonscientific area [45 CFR § 46.109; 21 CFR § 56.108].

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# G

**Generalizable Knowledge:** Truths, facts, information or conclusions that are intended to apply more broadly beyond the individuals studied, or beyond a specific time and/or location, such as to other settings or circumstances. Note that the intent to publish is irrelevant. Has not been explicitly defined in federal regulations, but can be: a) applied to individuals outside the research sample; b) predictive of future events; or c) widely applied as theories or principles that enhance scientific or academic understanding; or d) create general explanations about all that has happened in the past.

**Good Clinical Practice (GCP):** An international quality standard for clinical care, including but not limited to clinical trials involving human subjects. The standard is provided by International Conference on Harmonisation (ICH/GCP). See: http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html

**Greater than Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. In the case of research involving prisoners "minimal risk" means that the probability and magnitude of physical or psychological harm are greater than that normally encountered in the daily lives, or in the routing medical, dental, or psychological examination of healthy persons."

**Guardian:** An individual who is authorized by court appointment to oversee and make decisions in the best interests of a child, or incapacitated adult. This may include consent to provide medical care or to participate in research activities as a human subject. A guardian is one type of legally authorized representative (LAR). See also: legally authorized representative

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# H

**Health Information:** any information, including genetic information, whether oral or recorded, in any form or medium that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care.

**Health Insurance Portability and Accountability Act of 1996 (HIPAA):** Contains provisions to protect the confidentiality and security of individually identifiable health care information about patients (Protected Health Information, or PHI) that arises in the course of providing health care in the United States. HIPAA applies only to covered entities within the jurisdiction of the United States. [45 CFR §§ 160, 164].

**HHS Regulations:** The HHS Regulations set forth the Federal Policy for the Protection of Human Subjects.

**HIPAA:** The Health Insurance Portability and Accountability Act of 1996.

**HIPAA Authorization:** The formal documentation of consent for release of protected health information by a covered entity, given by either the patient or a legally authorized representative. For the authorization to be valid, the elements specified by the regulations must be present. [45 CFR § 164.508].

**Human Subject:** Baylor applies 2 definitions of “human subject.”

* The HHS definition: A living individual about whom an investigator (whether professional or student) conducting research (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. [45 CFR Section 46.102(e)(1).]
* For research involving items regulated by the FDA, human subject is defined as: (1) Living individuals who are or who become a participant in research, either as a recipient of a test article or control. A subject may be either a healthy individual or a patient (have a medical condition or disease); or (2) Individuals on whose specimens an investigational device is used, even when the specimen is a "leftover" clinical specimen that is not individually identifiable. [21 CFR Section 50.3(g)]

**Humanitarian device exemption (HDE)**: Is a status granted by the FDA to devices intended for treatment or diagnosis of a disease or condition that affects fewer than 8,000 individuals in the United States per year. This status indicates that the FDA has granted an exemption from the effectiveness requirements of the Food, Drug, and Cosmetic Act. The device manufacturer is still required to provide sufficient information for the FDA to determine that the device does not pose unreasonable or significant risks and that the probable benefit outweighs the risks, in comparison to the probable risks and benefits of currently available devices or alternative forms of treatment. HDE status provides an incentive for the development of devices for use in limited populations.

**Humanitarian use device (HUD)**: A medical device (1) intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 8,000 individuals in the United States per year, and (2) that has been granted Humanitarian Device Exemption (HDE) status by the FDA. There are fewer FDA requirements for approval of these devices to encourage manufacturers' research and development of medical devices for use with limited populations.

**Hybrid covered entity**: HIPAA term for entities that have both covered and non-covered components.

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# I

**Identifiable biospecimen**: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

**Identifiable Private Information**: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**Identifier:** The term “identifier” refers to any information that could be used to match the collected data with the individual subject. Some examples are the subject’s full or partial name, initials, social security number, student ID, or a linked code.

**Impracticable:** Refers to practical barriers (not just inconvenience) to conducting aspects of the research. Consent may be impracticable when the group is very large or its members are deceased, geographically dispersed or difficult to track. Financial, human and other resources required to contact individuals and seek consent may impose undue hardship on the researcher. In some jurisdictions, privacy laws may preclude researchers from using personal information to contact individuals to seek their consent for secondary use of information.

**Incentive:** Something that motivates or encourages a person to participate in research. An incentive can be money, gift cards, merchandise, class credit, or some other gift or service.

**Individual Investigator Agreement (IIA):** This is a formal binding agreement signed by individuals who are collaborating on research conducted by an institution, but who themselves are not acting as employees or agents of an institution that has a FWA or that regularly conducts human subjects research. The agreement describes the expectations and responsibilities for the individual

**Individually Identifiable:** The identity of the participant is or may readily be ascertained by the investigator, or is associated with the information. Data which are either (a) directly connected to name/other identifiers, or (b) indirectly connected via a study number or other coding scheme. Even if neither condition applies, it might still be possible to infer identity via descriptors such as age, gender, ethnicity, etc. Note: This is different from the definition of "identifiable" in the HIPAA regulations about health care information. Information that is considered an "identifier" under HIPAA may not meet the federal human subjects definition of "identifiable." **See:** individually identifiable health information and protected health information.

**Individually identifiable health information:** As defined by the HIPAA regulations, this is a subset of health information, including demographic information collected from an individual, and;

1. Is created or received by a health care professional, health plan, employer, or health care clearinghouse; and
2. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and
3. That identifies the individual; or
4. With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

**IND:** See: Investigational New Drug

**Information Sheet:** Term for a document used to provide information to research participants when the requirement for written consent has been waived.

**Informed Consent:** A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

**Institutional Authorization Agreement:** With regard to any research that falls within the jurisdiction of the Baylor University (BU) IRB, the BU IRB reserves the right to defer to another appropriately constituted IRB for the review of the research. In the event of a deferral to another IRB, the BU IRB must enter into an Authorization Agreement with the other IRB. The Authorization Agreement must describe the research that it covers and provide that the IRB to which the BU IRB is deferring will provide the BU IRB with documentation or correspondence regarding that IRB’s review of the deferred research protocol, including copies of those portions of the reviewing IRB’s minutes that document that review or other action by the reviewing IRB.

**Institutional Biosafety Committee (IBC):** The IBC evaluates human gene transfer investigations focusing on public protection (i.e., research personnel, care givers, general public, etc.) This review complements IRB review; both are necessary prior to subject enrollment for this type of research.

**Institutional Conflict of Interest:** The financial interests of the institution or of an institutional official might affect or reasonably appear to affect institutional processes including the conduct, review, or oversight of human research. Institutional conflicts of interest may occur when one or more aspects of either internal relationships between different units within the university or external relationships between the university and other entities are incongruent with institutional core values, and result, or have the potential to result in choices or actions that are harmful to the missions, the obligations, or the values of the university. See: Conflict of Interest.

**Institutional Official:** An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in research.

**Institutional Review Board (IRB)**: A specially constituted review body established or designated by an entity to protect the rights and welfare of human subjects involved in research.

**Interaction:** Communication or interpersonal contact between an investigator and participant. Examples: questionnaires, interviews, surveys. May be by in-person, web-based, mail, e-mail, text, phone, social media, etc.

**Intervention:** Could include: a) physical procedures; b) social, psychological, or emotional manipulations, by which data are gathered; or c) manipulations of the subject or subject's environment performed for research purposes. "Environment" includes an individual's social and virtual environments as well as physical environment.

**Investigational Device Exemption (IDE):** Exemption from certain regulations found in the Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations [21 CFR 812.20].

**Investigational New Drug (IND):** An IND application is the document submitted to the FDA for permission to conduct a clinical study using a drug or biologic that is new or not approved for a given dosage, formulation, route, or indication. When the FDA approves an IND application, it assigns an IND number to the specific use of the item.

**Investigator**: An individual who conducts research. In the event of research conducted by a team of individuals, the responsible leader of that team.

**Investigator’s brochure (IB):** A comprehensive document summarizing the body of information about an investigational drug. The IB should include a brief description of the drug substance and formulation, a summary of the drug's pharmacological and toxicological effects, safety and effectiveness in humans, and possible risks and side effects based on prior experience with the drug under study or with related drugs.

**IRB Authorization Agreement (IAA):** 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. It normally authorizes one institution to provide IRB review for another.

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# J

**Journalism:** Includes activities focused on the collection, verification, and reporting of information or facts on current events, trends, newsworthy issues or stories about people or events, with no intent to develop or test a hypothesis.

**Justice:** An ethical principle in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly. Injustice occurs when benefits of research are denied to participating subjects or when burdens of research are imposed unduly.

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# K

**Key Personnel:** Individuals who participate in the design, conduct (including data analysis), or reporting of human subjects research. Includes: (1) individuals who recruit participants, obtain consent, interact with participants, or who collect and/or analyze identifiable study data; (2) individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested on the corresponding grant application/contract proposal.

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# L

**Legal Guardian:** See: Guardian.

**Legally Authorized Representative (LAR):** 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 research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research. The use of an LAR is normally associated with adults, not with children.

**Limited Data Set:** Protected Health Information (PHI) that excludes specific individual identifiers as described in HIPAA regulations.

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# M

**Material transfer agreement (MTA):** A contract that protects ownership of research materials transferred between research institutions or corporate entities. Examples include: cell lines, cultures, bacteria, nucleotides, proteins, transgenic animals, pharmaceuticals, and chemicals. Each exchange of research material requires an MTA.

**Medical device:** A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, orthopedic pins or other orthopedic equipment and therapeutic hypnosis recordings.

**Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. [45 CFR Section 46.102(j); 21 CFR Sections 50.3(k) & 56.102(i)].

* For ***Research*** involving ***Prisoners***, ***Minimal Risk*** is defined as 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 phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” is not interpreted to include the inherent risks certain categories of human subjects face in their everyday life (for example, in their work environment or through having a medical condition).

**Minor:** A person who has not attained the legal age of majority under the applicable law of the jurisdiction in which the research will be conducted. See: child.

**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. **Note:** A minor change does not increase risk more than minimally or add procedures in research categories other than those that qualify for expedited review.

**Modification:** Any changes to an IRB-approved study, such as procedures, purpose, subjects, recruiting materials, study staff, location, etc. Changes must be approved in advance by the IRB. See: Amendment.

**Modifications Required (to secure approval)**: 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, 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 called: contingent approval, approval with conditions.

**Monitor**: Responsible for overseeing the progress of a clinical trial and for ensuring that the study is conducted, recorded and reported according to the study protocol, standard operating procedures of the sponsor, Good Clinical Practice (GCP) and local regulatory requirements. Monitors are most commonly required in biomedical and sponsored research.

**Monitoring**: The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and participant protections.

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# N

**NIH:** National Institutes of Health See: http://www.nih.gov

**Non-Compliance:** A situation, event or process in human subjects research that is under the researcher's control and that is inconsistent with the following:

* The ethical principles of human subjects research as described in the Belmont Report;
* Federal, state, and/or local regulations applicable to human subjects research under the jurisdiction of the BU IRB;
* BU policies and procedures governing human subjects research; or
* The research activities as approved by the BU IRB, including any IRB requirements or determinations.

Non-compliance can include inquiries and complaints directed to the researcher that involve an allegation of non-compliance as defined here.

**Non-Disclosure Agreement:** A legal contract between at least two parties that outlines confidential materials, knowledge or information and prohibits divulgence of said information.

**Non-Financial Conflict of Interest:** A conflict of interest that involves non-financial interests, such as intellectual bias, academic activities, and scholarship. See: Conflict of Interest.

**Non-Significant Risk (NSR) Device Study:** A study of a device that does not meet the definition for a significant risk device. See: Significant Risk Device

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# O

**Obtaining:** Means receiving or accessing identifiable private information or identifiable specimens for researchpurposes.

**Office of Human Research Protections (OHRP):** The administrative agency that oversees the regulation of research involving human research subjects conducted or supported by the U.S. Department of Health and Human Services (HHS). <http://www.hhs.gov/ohrp/>

**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.

**Oral History:** The National Oral History Association (OHA) defines oral history as 'a method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life. Oral history is a recorded conversation about the past with named individuals in which knowledge about specific events and individual lives is narrated in story form and made available to the public through deposit in archives. Biographical in nature and historical in scope, the scholarly oral history interview is rooted in particular recollections about history based on the individual perspective of the narrator.

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# P

**Package insert:** Document that lists the most common adverse effects for an approved drug.

**Parent:** A child’s biological or adoptive mother or biological or adoptive father. [45 CFR § 46.402(d)]

**Participant**: See: Human subject.

**Payment**: A term used broadly in research referring to providing an incentive for study participation, for example: money, class credit, or gift cards.

**Performance Site:** The location where research is performed.

* A performance site becomes "engaged" in human subject's research when its employees or agents 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. Further, a performance site is considered to be "engaged" in human subjects' research when it receives a direct Federal award to support the research.
* A performance site is not engaged in human subjects research if its employees or agents do not 1) intervene or interact with living individuals for research purposes, and do not 2) obtain individually identifiable private information for research purposes.

See: Engagement.

**Permission:** The agreement of a parent(s) or legal guardian to the participation of his/her child or ward in research. [45 CFR § 46.402(c)]

**PHI**: See: Protected Health Information.

**Placebo:** A chemically inert substance (e.g., sugar pills) given to control groups as if it were the medicine or treatment for its psychologically suggestive effect; it is used in controlled trials to determine whether improvement and side effects may reflect imagination or anticipation rather than actual power of a drug or treatment.

**PPRA**: Protection of Pupil Rights Amendment. This federal law applies to all children not over age 21 who are in elementary or secondary programs and institutions that receive funding for any purpose (research or otherwise) from the U.S. Department of Education. It is intended to protect the rights of students and their parents in educational settings. Among other things, it requires researchers to obtain prior written consent from parents before conducting research activities with studies that involve eight sensitive areas (such as sex behavior or attitudes). See: <http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html>

**Premarket Approval (PMA):** Process of scientific and regulatory review by the FDA to ensure the safety and effectiveness of Class III devices.

**Principal Investigator:** The scientist or scholar with ultimate responsibility for the design and conduct of a research project.

**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)]. Alternatives may include: hospitals, alcohol/drug treatment facilities, work-release, or at-home detention programs.

**Privacy:** Privacy is about having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. It includes: a sense of being in control of access that others have to ourselves; a right to be protected; and is in the eye of the participant, not the researcher or the IRB. Privacy is about people; confidentiality is about data. See: confidentiality.

**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 that the individual can reasonably expect will not be made public. Examples of private information include medical or academic records or personal journals. Usually, if permission is required to obtain information, then the information is private. [45 CFR Section 46.102(e)(4)]. **Note**: There are numerous "gray" areas in distinguishing "private" from "non-private." For example, there are some situations that are best considered "semi-private." This may include some behaviors, communications, and interactions that occur in electronic or social media.

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

**Protected Health Information (PHI)**: Individually identifiable health information that is transmitted or maintained in any form or medium by a covered entity (a health plan, healthcare clearinghouse, health care provider that transmits healthcare information electronically), or its business associates, excluding certain educational and employment records. Examples include: physician / psychologist notes, test results, genetic information, medical conditions, diagnoses, treatments, and medications.

**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 participants and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

**Protocol Deviation**: A deviation is a departure from the IRB-approved protocol. Deviations may represent minor departures and/or non-compliance.

**Public Behavior:** Behavior occurring without the intervention of the researcher and generally open to view by any member of a community and/or which would not involve any special permission to observe (i.e., no reasonable expectation of privacy by those being observed), such as at a park, in a mall, at a movie theater, etc.

**Public Health Authority**: An agency or authority of the United States, a state, a territory,

a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

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# Q

**Quality Assurance (QA):** Planned activities implemented within a system to ensure that the system is producing the best possible results. Quality Assurance is not research when there are no intentions to contribute to generalizable knowledge. See: http://answers.hhs.gov/ohrp/categories/1569 See also: generalizable knowledge

**Quality Improvement (QI):** The use of planned activities or methods within a system to improve the effectiveness of said system. Quality Improvement is not research when there are no intentions to contribute to generalizable knowledge. See: http://answers.hhs.gov/ohrp/categories/1569 See also: generalizable knowledge

**Quorum:** The minimum number of members that must be present to conduct official IRB business including at least one member whose primary concerns are in a nonscientific area.

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# R

**Recruitment:** The practices or procedures used to find and 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 Bonus or Incentive:** Payment, merchandise, or other gift or service offered by a research sponsor as an incentive or reward to an organization, investigator, or key personnel conducting the research which is designed to accelerate recruitment and is tied to enrollment rate, timing, or numbers.

**Registry:** A list of names and contact information of people who are willing to be contacted about research related to a specific topic. A registry might include information that would assist in selecting candidates appropriate to recruit for a specific study.

**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.

**Research Misconduct:** Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

**Research Plan:** See: Protocol

**Researcher:** See: Investigator

**Respect for persons:** The principle that individual autonomy be respected and that persons with diminished autonomy be protected. See also: Belmont Report

**Risk:** The probability of harm or injury (physical, psychological, social, legal, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only “minimal risk.”

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# 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.

**Secondary Data Set:** Data that can be used in research and comes from public or private documents, including medical records, police reports, vital statistic records, student record.

**Semi-private Information:** A “gray” area in distinguishing “private” from “non-private.” For example, there are some situations that are best considered “semi-private.” This may include some behaviors, communications, and interactions that occur in electronic or social media. Also, a specific type of information may be considered private for one group of individuals but not for another. Generational age groups may have different views on what is private information.

**Sensitive Information:**  Sensitive information is information regarding sexual attitudes, preferences or practices; information relating to the use of alcohol, drugs or other addictive products; information regarding an individual’s psychological well-being or mental health; genetic information or tissue samples; or information that if released might be damaging to an individuals’ financial standing, employability or reputation within the community or might lead to social stigmatization or discrimination.

**Serious Adverse Event:** An adverse event that results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

**Serious non-compliance:** Non-compliance which could significantly:

* Increase the risks to, or jeopardize the safety, welfare, and/or rights of subjects or others, or,
* Decrease the potential benefits (including the scientific integrity of the research).

**Significant risk device**: Under 21 CFR 812.3(m), a significant risk device means an investigational device that presents a potential for serious risk to the health, safety, or welfare of a subject and is: intended as an implant; purported or represented to be for use supporting or sustaining human life; for a use of substantial importance in diagnosing, curing, mitigating, treating disease; or otherwise preventing impairment of human health.

**Social/Behavioral Research:** Research involving the study of social and behavioral human functioning at the individual, small group, institution, or community levels. The study of behavioral factors such as thought processes, personality and emotion; also, the study of social and environmental variables are examples. Methodologies include direct observation, interviews and surveys, etc.

**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.

**Study:** For human subjects purposes, a research protocol.

**Study Personnel**: See: Key Personnel

**Subject**: See: Human Subject

**Suspension:** An action initiated by the IRB or other officials of the organization to stop temporarily some or all research procedures pending future action by the IRB or by the Investigator or his/her study personnel.

**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.

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# T

**Tabled:** An IRB action that indicates that review could not be completed, usually due to: not enough information for the IRB to determine whether approval criteria are met; loss of quorum; or other administrative issues. Research tabled at a convened meeting will be reviewed at a future convened meeting.

**Termination:** An action initiated by the IRB or other officials of the organization to stop permanently some or all research procedures.

**Test article:** Any drug for human use, 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 Federal Food, Drug and Cosmetic Act or under sections 351 or 354-360F of the Public Health Service Act.

**Therapeutic Misconception:** The purpose of a clinical trial is to evaluate an experimental therapy or intervention, not to provide therapy. Clinical trial participants, hoping for therapeutic benefits, may not realize that research is aimed primarily at producing knowledge, or that elements of a clinical trial may interfere with their own health care. This failure to distinguish between research and usual clinical care may result in an underestimation of the risks or overestimation of the benefits of research participation.

**Third Party Subjects:** An informal name for living individuals about whom researchers obtain individually identifiable private information from someone else but who themselves have no interaction with the researcher. Third party subjects are considered to be human subjects.

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# U

**Unanticipated:** Has not been previously observed and/or described in the documents describing risks associated with the study.

**Unanticipated Problem Involving Risk to Subjects or Others** (**UP**): An unanticipated problem involving risk to human subjects or others, is one that (1) was unforeseen at the time of its occurrence, and (2) indicates that subjects or others are at an increased risk of harm.

**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. <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/>

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# V

**Violation:** Accidental or unintentional changes to or not compliant with the IRB approved protocol that affect the subject's rights, safety, welfare, and/or the integrity of the resultant data.

**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.

**Vulnerable Populations:** Groups of subjects who may be at higher risk for effects of undue influence or coercion on their decision about whether to participate in a research study, or who may be unable to understand the consenting process. Depending upon the circumstances, these groups may include individuals who are decision-impaired due to illness, injury or other conditions; students; employees; individuals who are unable to read; and non-English speakers or English as a second language speakers. The Office for Human Research Protections (OHRP) recognizes certain populations to be protected, and special considerations should be made when including these populations in research. These populations include:

* Pregnant Women, Human Fetuses, and Neonates
* Prisoners
* Children

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# W

**Waive/Waiver:** Forgo the requirement of a particular rule, regulation, or condition in a protocol and/or consent document.

**Ward**: Children who are legally under the care of a state or any other agency, institution, or entity.

**Written, or in writing:** Refers to writing on a tangible medium (e.g., paper) or in an electronic format.

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# X

# Y

# Z