Glossary for ISTAR Training Video

- **Assent**: verbal or written agreement from a minor or other individual who lacks the legal capacity to consent to participate in research

- **Certificate of Confidentiality**: issued from federal agencies to protect the privacy of research participants’ names and sensitive information when collected in research. A certificate of confidentiality protects against forced disclosure of identifying information through legal demands such as court orders or subpoenas

- **Confidentiality**: the way identifiable information will be collected, stored, and shared

- **Conflict of Interest in Research**: a situation in which financial or other personal considerations compromise, or have the appearance of compromising, an individual’s professional judgment in proposing, conducting, supervising or reporting research

- **Coded Specimens/Data**: data and/or specimens not collected for the current proposed research that have been labeled with a code linked to personal identifying information

- **Collaborative Review**: a review conducted jointly by two or more IRB

- **Collaborators**: researchers working together on a study

- **Consent**: process by which information is presented to enable individuals to decide whether or not to participate as research subjects. Informed consent must be written in “lay language” that is understandable to those being asked to participate. Content must include an explanation of a study’s purpose, the duration, a description of experimental procedures, alternatives, risks, and benefits

- **Contingency**: changes or modifications to the research application required by the IRB

- **Coordinating site**: in studies conducted at several sites/institutions, the coordinating site is responsible for managing, analyzing and disseminating study data

- **Deidentified/Anonymous**: data and/or specimens not labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information

- **Engaged**: determination that an institution or individual is involved in human subjects research and thus ethical and regulatory requirements for human subjects protections are applicable. Individuals/institutions are engaged if they obtain data about participants through intervention or interaction, obtain identifiable private information about participants, obtain consent informed consent from participants or receive a federal award to support research

- **Exempt Review**: type of review for studies that involve less than minimal risk to subjects and fall within categories established by federal regulations

- **Expedited Review**: type of review for studies that involve no greater than minimal risk to subjects and fall within categories established by federal regulations

- **Fetus**: product of conception from the time of implantation until delivery
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- **Full Committee Review**: type of review for studies that involve greater than minimal risk to subjects. Examples include clinical trials or studies that collect sensitive information such as domestic abuse research.

- **Grant/Contract Only**: type of submission for administrative approval of the grant or contract only. This option is for studies without immediate plan to use human subjects or for a grant that will fund several human subjects projects. However, this submission type is not to be used for human subjects research.

- **Health Insurance Portability and Accountability Act (HIPAA)**: contains provisions to protect the confidentiality and security of personally-identifiable health information that is collected, created.

- **Humanitarian Use Device (HUD)**: a device intended to benefit patients with a disease or condition that affects less than 4000 individual in the US per year. HUDS are not considered research by FDA but IRB review is required nonetheless.

- **Identifiable**: data and/or specimens labeled with personal identifying information.

- **Incidental Findings**: previously undiagnosed medical or psychiatric conditions that are discovered unintentionally and are unrelated to that medical or psychiatric condition which is the object of the research.

- **IRB Authorization Agreement**: an agreement between institutions that describes each institution’s responsibilities for IRB review and oversight of the research when one IRB relies on a review conducted by another IRB.

- **Minor**: person under 18 years of age. In California people less than 18 years of age can consent to medical care and research related to the prevention or treatment of pregnancy.

- **Neonate**: newborn human.

- **Normal Volunteer**: healthy volunteers who are used to study normal physiology and behavior (e.g. volunteers who do not have the condition under study in a particular research protocol).

- **Parental permission**: verbal or written agreement from a parent or guardian granted on behalf of a child to participate in research.

- **Pregnant Woman**: woman who exhibits any of the presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. Pregnancy encompasses the period of time from implantation until delivery.

- **Prisoner/Detainee**: an individual involuntarily confined or detained in a penal institution or any individual detained pending arraignment, trial, or sentencing.

- **Privacy**: a participant’s ability to control how other people see, touch, or obtain information about him/herself.

- **Prospective Study**: a study in which the data or specimens will be collected in the future. The data or specimens do not currently exist.
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- **Recruitment**: the process of finding and enrolling appropriate subjects into a study. The recruitment of subjects is considered to be the beginning of the informed consent process. The IRB must review and approve methods of recruitment and content of recruitment materials prior to use.

- **Retrospective Study**: a study in which the data or specimens already exist at the time the study is proposed. A typical retrospective study involves a review or analysis of previously collected information.

- **Research Protocol**: detailed plan for an activity to conduct research with human subjects.

- **Scientific merit**: scholarly rigor or worth.

- **Waiver of consent**: process in which the IRB determines that consent is not a reasonable requirement to protect subjects and an appropriate mechanism for protecting the subjects has been instituted.

- **Ward**: an individual, usually a child, for whom the court has appointed a guardian.