ANONYMOUS:

Subjects' identities are unknown to the investigator, not requested, and not given. If the only time the investigator asks for a name is for a signature on a consent form, the investigator should use request a waiver of written documentation of consent, to preserve anonymity.The IRB is able to grant these waivers under certain circumstances.

ASSENT:

Agreement by subjects not competent to give legally valid informed consent (e.g., children or cognitively impaired people) to participate in a study.

ASSURANCE:

CERTIFICATE OF CONFIDENTIALITY:

A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Any research project that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for Certificate. For more information: http://grants.nih.gov/grants/policy/coc/index.htm

CERTIFICATION:

Official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

CHILDREN:

Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted.

COGNITIVELY I

CONTINUING REVIEW:

If data gathering continues for more than 12 months, federal regulations require that the project be subject to a "continuing review." Researchers should use the WIU IRB Review and Monitoring26 0 Td (")Tjdd (")ulr

- services, or concepts where it is not the intention to share the results beyond WSU or any agency supporting the research
- classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the WSU community

GUARDIAN:

An individual who is authorized under applicable state or local law to give permission on behalf of a child or cognitively impaired individual to general medical care.

HIPPA:

Health Insurance Portability and Accountability Act (HIPPA) of 1996 that protects certain health information. The Privacy Rule was issued to protect the privacy of health information that identifies individuals who are living or deceased.

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INTENTIONALLY IDENTIFIED:

Subjects' names are identified in connection with the data when the research results are presented to the public. This procedure is common for journalistic or historic interview studies, where subjects are public figures or in oral histories. In these cases, the investigator should seek explicit consent from the subjects for the use of their names in connection with their data.

INTERACTION:

Includes communication or interpersonal contact between investigator and subject.

INTERVENTION:

Includes both physical procedures by which data is gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

IRB APPROVAL:

The determination by the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and other Institutional and federal requirements.

MINIMAL RISK:

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

ORAL HISTORY:

Tape-recorded historical information obtained in interviews concerning personal experiences and recollections. Often, the intention is that these tapes become available to the public at a specified future time in order to convey historical insight.

NONAFFILIATED MEMBER:

Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (*e.g.*, minister, business person, attorney, teacher, homemaker).

PERMISSION:

The agreement of parent(s) or guardian to the participation of their child or ward in research.

PERSONALLY IDENTIFIABLE HEALTH INFORMATION:

Health or medical data or information that can be linked manifestly or inferentially to an individual.

POPULATION:

A group of people in society meeting certain criteria to be eligible as subjects in a project's protocol.

PRINCIPAL INVESTIGATOR:

The individual with primary responsibility for the design and conduct of a research study.

PRISONER:

An individual involuntarily confined in a penal institution, including persons: (1) sentenced (p)Tj (e)Tj 1.19 0 Td (n)Tj 0.19 0 Td ae

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PROTECTED HEALTH INFORMATION:

individually identifiable Health information recorded in any form or medium that 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 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.

PROTOCOL:

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

PUBLICLY AVAILABLE DAT A:

SIGNIFICANT RISK:

A study's design that presents a potential for serious risk to the health, safety or welfare of the subjects.

SUBSTANCE ABUSE:

Substance abuse refers to the use of substances when said use is causing detriment to the individual's physical health or causes the user legal, social, financial or other problems, up to, and including, endangering their lives or the lives of others. Substance abuse is not specific to illegal substances. Substance abuse also includes the abuse of legal substances which are legitimately purchased or prescribed.

SYSTEMATIC:

Step-by-step, methodical procedure presented or formulated as a coherent body of ideas or principles.

VOLUNTARY:

Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (and/or to continue to participate) in a research activity.

VULNERABLE POPULATIONS:

Refers to subjects such as children, prisoners, pregnant women, persons with disabilities, economically or educationally disadvantaged persons, or any other population that may b3 0yTd 0 Td ( )T(n)Tj -0.02 Tc 04 0 .52 -1Tw 1.26 0