Definitions

1. ADVERSE EVENT

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research (whether or not considered related to the subject's participation in the research). Adverse events encompass both physical and psychological harms. They occur primarily in the context of biomedical research, although they may occur in the context of social and behavioral research.

2. ANONYMITY:

In the context of these guidelines, "anonymity" means that no one, including the researcher(s), knows the identity of the participant. No identification of subjects should be possible by the procedures employed or by the information solicited. (For example, a mailed or on-line survey where no names or signatures are obtained, where no identifying code is used, where question responses will not reveal identities, and where the subject group is sufficiently large to avoid inadvertent or inferred identification.)

3. ASSENT:

A minor's (under 18 years of age in the state of Arkansas) affirmative agreement to participate in research after receiving an adequate explanation. The absence of a child's objection does not constitute assent.

4. CERTIFICATION:

If a funding or sponsoring agency of research requires certification that research proposals are appropriately reviewed and approved by a University IRB, it is the responsibility of the investigator to obtain and complete all appropriate documents.

5. CHILDREN (Also, MINORS):

Federal regulations define children as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." In the state of Arkansas, children/minors are identified as individuals under 18 years of age.

6. CODED:

When (1) identifying information that would enable the researcher to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced by a letter, number, symbol, or combination thereof, and (2) a key to deciphering the

code exists, thereby enabling the linkage of the individual's identity to the private information or specimens.

7. CONFIDENTIALITY:

Treating a subject's private information, disclosed to the researcher(s) during data collection, such that further disclosure or release of the information will not occur without the subject's express written authorization. Provisions for confidentiality must be made when the identity of subjects is known by name, by specific data, or by appearance.

8. INFORMED CONSENT:

Ethical and professional codes governing the use of human subjects in research mandate that no research involving human subjects be undertaken without the informed and voluntary (e.g., free from force, fraud, duress, or any other form of restraint or coercion) consent of the human subject, or the consent of his or her authorized representative if the subject lacks the capacity to consent. Informed consent is an ongoing process through the duration of the research.

9. DEBRIEFING:

Giving subjects previously undisclosed information about the research project following completion of their participation in research. (This usage, occurring within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

10. DECEPTION:

Whenever information about an activity is deliberately withheld from subject participants. (In some research, fully informed consent may itself have injurious effects on the subject, or may invalidate the experiment, as in the use of placebos or double blind studies.) Studies involving deception always require full board review.

11. ENGAGED INSTITUTION:

An organization/institution is considered engaged in human research when its employees or agents, for the purposes of non-exempt research projects obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; (3) the informed consent of human subjects for the research; or (4) when the institution receives a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by a subcontractor (i.e., employees or agents of another institution).

12. INDIVIDUAL IDENTIFIERS:

[See also **NON-IDENTIFIABLE/DEIDENTIFIED DATA**] 18 personal identifiers of human subjects as defined by HIPAA:

- Names;
- All geographical subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and equivalent geocodes, except for the initial three digits of a ZIP code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000;
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- Phone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social Security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data).

13. INCOMPETENT:

In the context of the human subjects review process, an individual who is unqualified to give or incapable of giving informed consent. (May refer to a minor, an adult declared legally incompetent, or an adult whose competency may be questioned because of an illness or an unusual circumstance.)

14. INTERMEDIARY:

An impartial individual or organization that in another capacity has contact with a prospective subject population and that cooperates with a researcher by obtaining consent from prospective subjects for the release of their names, addresses, or telephone numbers to the investigator. The intermediary should avoid seeming to endorse a particular research activity.

15. INVESTIGATOR:

The primary researcher who assumes the responsibility of the protection of human subjects. (When the PI is a master or doctoral student, the faculty advisor is ethically and legally responsible for all research activities.)

16. MINIMAL RISK:

The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

17. NON-IDENTIFIABLE DATA / DE-IDENTIFIED:

Where no information or code exists to link an individual to private information or specimens; or where information has been stripped of all 18 personal identifiers as defined by HIPPA [see **INDIVIDUAL IDENTIFIERS**].

18. PERSONAL AND (POTENTIALLY) SENSITIVE:

Examples include, but are not limited to: information about sexual attitudes, preferences, practices; the use of alcohol, drugs, or other addictive products; information that could damage an individual's financial standing, employability, or reputation within the community; information in a subject's medical record that could lead to social stigmatization or discrimination; information about a subject's psychological well-being or mental healthcare; and/or other records, such as medical, academic, photographic, audio tapes, and videotapes. **NOTE: according to Federal regulations, "sensitive" means that -- if disclosed and linked to the participant -- data could potentially cause economic, social, psychological, or other damage, or put the participant at risk for criminal or civil liability.**

19. 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, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

20. RIGHT TO PRIVACY:

The right of individuals to decide for themselves how much they will share with others regarding their thoughts, feelings, and facts of their personal lives.

21. RISK:

In some medical and behavioral science research projects, certain procedures may induce a potentially harmful altered physical state or condition for the subject participant. (For example: removal of organs or tissues for study, reference, transplantation, or banking; administration of drugs or radiation; use of indwelling catheters or electrodes; requirement of strenuous physical exercise; and subjection to deceit, public embarrassment, or humiliation.) In other research protocols, including social or behavioral studies, no immediate physical or psychological risk to the subject may be apparent (e.g., personality inventories, interviews, questionnaires, observations, photographs, tapes, records, and stored data). However, some of these procedures may involve varying degrees of discomfort, harassment, or invasion of privacy, or constitute a threat to the subject's dignity, all of which pose another type of risk.

22. SCIENTIFIC MERIT:

In general, it is not the charge of the IRB to comment upon the scientific merit of proposals submitted for review, except where merit cannot be established by another entity. The exception, however, is where the scientific merit of the research, or lack thereof, increases either the risks to the subject (directly or indirectly) or the research burden to be borne by the subject. In such cases, the investigator may be referred to his/her advisor (in the case of a student) or to institutional experts for further guidance.

23. SUBJECT ADVOCATE:

An individual who participates in the consent process on behalf of an adult subject who has not been declared legally incompetent, but whose ability to give informed consent is in question. The subject advocate should be a family member, a close friend, or someone who knows the subject well enough to attest to the subject's probable agreement to participate.

24. UMBRELLA PROTOCOL:

An umbrella protocol (or program protocol) is the set of materials and procedures related to a group of research projects conducted in a single lab, program, or department. The research protocol submitted with an umbrella IRB application describes the general types of materials and procedures that will be used in the lab, program, or department. Specific materials and procedures must be added individually to the umbrella protocol before they are implemented.