Travis hirschi social bond theory

Sociology

Protected* Populations – Examples include, but are not limited to: Children/Minors (under the age of 18) (Exception – projects conducted in established or commonly accepted educational settings involving normal educational practices. Contact IRB office for guidance.) Prisoners (now includes non-publicly available secondary data) Pregnant women Fetuses and products of labor and delivery

People with diminished capacity to give consent Mentally or physically challenged individuals *Sensitive Information – Examples include, but are not limited to: Information relating to an individual’s psychological well being or mentalhealthInformation relating to sexual attitudes, preferences, or practices Information relating to the use of alcohol or drugs Information relating to illegal behavior

Information that if released could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual’s financial standing, employability, or reputation Information that would normally be recorded in a patient’s medical record and the disclosure could reasonably lead todiscrimination, stigmatization, etc. There are several categories of protected subjects. Children - Subpart D of the federal regulations protecting human subjects, incorporated in Georgetown's policies, provides additional protections for children.

Research with children as subjects can be exempt in only two instances: {text: list-item} {text: list-item} Prisoners - Subpart C to the governing regulations provides additional safeguards for prisoners as research subjects. Essentially, the regulations are designed to discourage the use of prisoners

as subjects unless the research will materially affect the lives of prisoners. They are not, in other words, to be used as a captive population. An IRB that reviews a protocol with prisoners as subjects must have a prisoner representative on the committee. 3. A.

Children Children are considered to be protected because their youth may make full understanding of the risks and benefits of a study impossible, making them unable to make a truly informed decision. Recognizing that regulations may vary from state to state and country to country, the IRB defines a child as any individual under the age of 18. If a study will occur in an area where different legal definitions exist, the researcher should incorporate this information into the proposal if he or she is seeking a waiver of requirements for this protected population.

If the subjects of a study will be children, the researcher is expected torespecteach child as an autonomous being. Consequently, the researcher must secure the assent of each child as well as the consent of the child’s parents / guardians or legal representatives. If a child cannot read, the consent process will need to be adapted to provide the information orally. Documentation of the child’s assent and the consent of parents or guardians must follow the guidelines for informed consent.

Each class of subjects that one might consider to be incompetent, such as young children, should be considered on their own terms. “ Respect” requires giving them the opportunity to choose whether to participate to the extent they are able to make a decision. Researchers are not required to obtain a child’s assent if the child is incapable of providing it. Each individual

child’s ability to assent must be determined. In other words, researchers cannot assume that all children below a certain age are unable to assent.

Even a very young child may be capable of understanding what is proposed and thus can agree or decline to participate. In rare instances, a child’s assent may not be required if the intervention or procedure is likely to benefit the well-being of the child directly and is available only in the context of the research. This situation occurs most frequently in biomedical research. In determining whether children are capable of assenting, the IRB will take into account the ages, maturity, and psychological state of the children involved.

This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. When interacting with children, use language the child can understand and present concepts in a way the child can grasp. Researchers should also take care that the child does not feel pressured by the researcher as an adult (authority figure) or by the child’s parent, guardian, or legal representative—other authority figures.

In studies that involve more than minimal risk, obtain consent from both parents, if possible. (See “ Studies with *Children*—More than Minimal Risk. ") For minimal risk studies, consent from one parent is sufficient. Consent from one parent is also permitted if a parent is deceased, unknown, incompetent, or not reasonably available, or if one parent has legalresponsibilityfor the care and custody of the child. In the absence of a

parent or parents able to give consent, consent may be given by a child’s legal guardian or legal representative.

Children who are wards of the state or of any agency, institution, or other entity may participate in research only if the study (1) is related to the children’s status as wards, or (2) will be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards (that is, the fact that an individual subject is a ward is incidental). In these situations, researchers must provide for the appointment of an advocate for each child who is a ward.

The advocate is in addition to the child’s guardian or legal representative, and he or she must have the background and experience necessary to act in the best interests of the child for the duration of the child’s participation in the research. An individual may serve as advocate for more than one child; the advocate may not be associated in any way with the proposed research, the researcher(s), or the child’s guardian organization. (See 45CFR46, Subpart D.)