Consent for Vulnerable Populations in Research

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What is Informed Consent

Informed consent is an active process of communication between the researcher and the prospective participant

The process leads to the participant's voluntary agreement (or disagreement) to participate in the study

Elements of Informed Consent

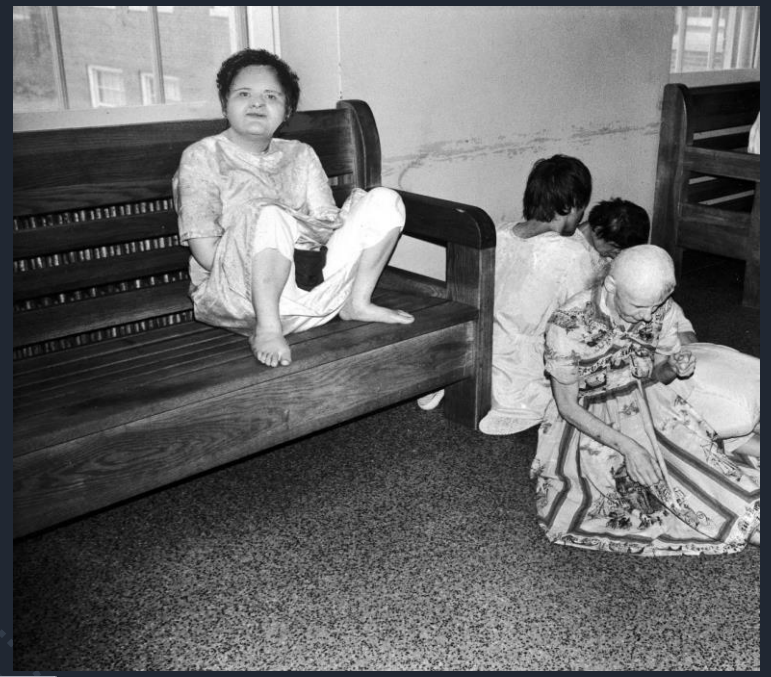
Information disclosure, voluntarism, and decision-making capacity

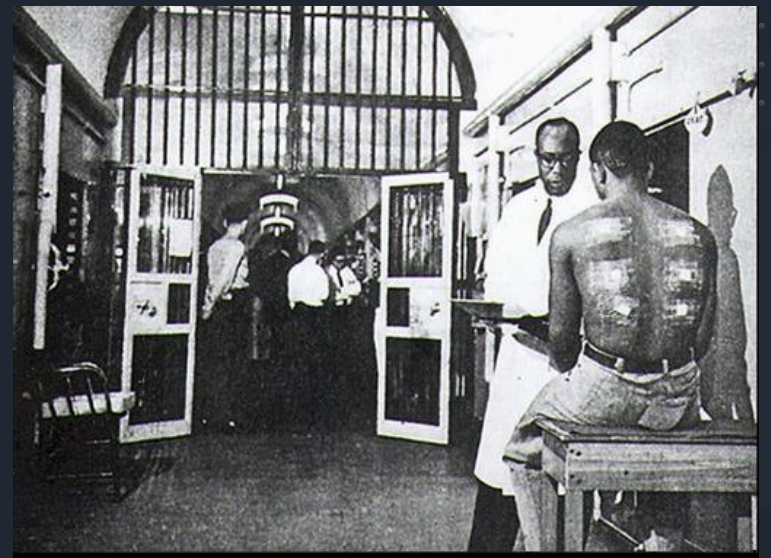
- Information disclosure means that all critical information about a research study is completely disclosed.
- Voluntarism means that the consent process should be free of any undue influence.
- Decision-making capacity means that the subject can fully understand the nature of the research study, including the risks and benefits involved.

Why Informed Consent is Important?

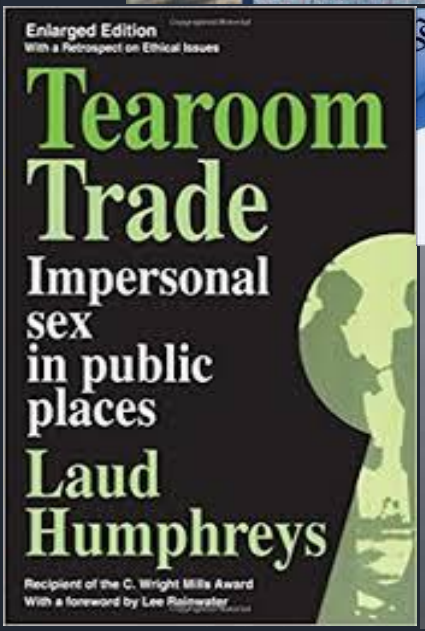
Informed consent reflects the fundamental principle of respect for persons

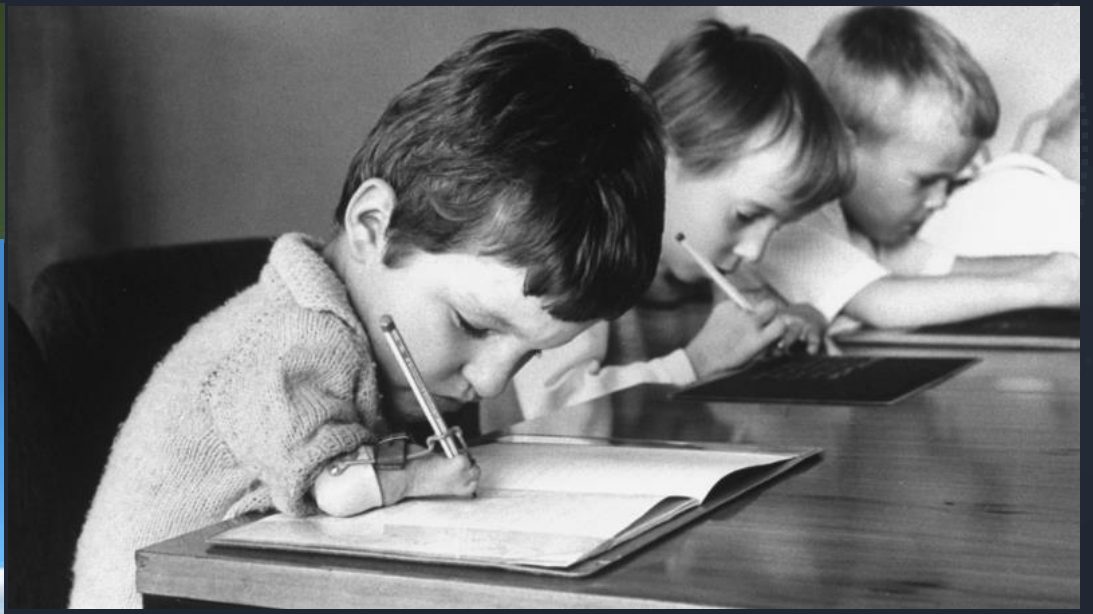
Informed consent recognizes personal autonomy and the moral right of every individual to decide what shall or shall not happen to them





In this Feb, 1966 photo, Solomon McBride, second right, a medical administrator in Holmesburg Prison's human research, questions a test subject at the facility in Philadelphia. The prison used inmates extensively for medical experiments. (AP Photo/The Urban Archives - Temple University)





U.S. Department of
Health and Human Services
Enhancing the health and well-being of all Americans

To prevent abuses, the United States government codified the requirement to obtain informed consent in the regulations protecting human research subjects

45 CFR 46

45 CFR 46.116 – General Requirements for Informed Consent

Informed consent must be obtained from each human subject prior to their participation in research.

Additional safeguards must be included to protect the rights and welfare of all subjects that are likely to be vulnerable to coercion or undue influence.

Vulnerable Populations

A “vulnerable participant” is any individual who lacks the ability to fully consent to participate in a study

Vulnerable Populations

Subpart B — Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Subpart C — Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Subpart D — Additional Protections for Children Involved as Subjects in Research

Vulnerable Populations

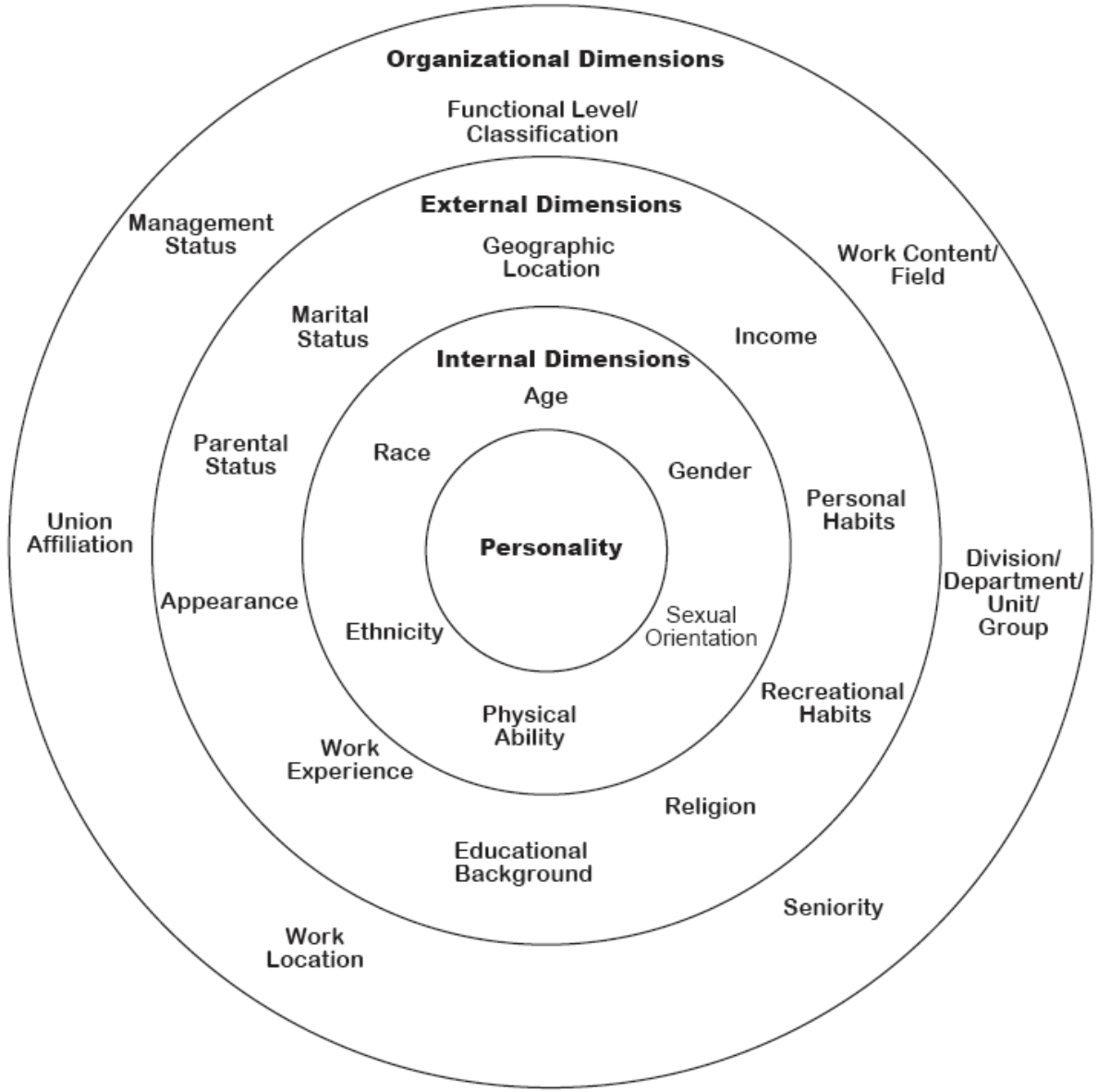
Persons with diminished mental capacity

Educationally disadvantaged

Economically disadvantaged

Marginalized populations

Levels of Diversity



Adapted from:
Gardenswartz and Rowe 1994
Diverse Teams at Work: Capitalizing on the Power of Diversity

Consent for Vulnerable Populations

Investigators should consider the needs of vulnerable populations and demonstrate sensitivity to those needs

The consent process should be appropriate to the population

Considerations for vulnerable populations

- Safeguard against exploitation
  - Incentives should not be exploitive
- Provide resources for support
  - Vulnerable populations may require additional resources
- Be intentional with study design
  - Be aware of intersectionality
  - Anticipate issues
  - Consult with community leaders

Resources

Consent Templates -

There is often a wide range of research activities and research participants, and one consent form may not be appropriate for all purposes. Depending on your needs, you may choose from the templates below.

Written Informed Consent Form

Short Consent Form for On-line Surveys

Verbal Consent Script

Additional Language for Consent Forms

Instructions for Consent Forms

Want More Information About IRB?

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