Unit 12

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| Ethics of clinical research  It is important to understand that a number of internationally recognized codes of ethics have been developed since World War II to ensure the protection of human subjects in biomedical research. They include:   * The Nuremberg Code, 1947 * Declaration of Helsinki, 1964 (last amended in October 2013) * The Belmont Report, 1979 * The CIOMS Guidelines, 1982 (last amended in 2002) * Ethical considerations in HIV prevention trials: UNAIDS and WHO Guidance Document (updated in 2021) https://www.unaids.org/en/resources/documents/2021/ethical-considerations-in-hiv-prevention-trials   All ethical guidelines for the protection of humans in research have at their core three main principles of **autonomy, beneficence** and **justice**. |

# Autonomy – respect for persons

"The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated so as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him [or her] to make an understanding and enlightened decision." —The Nuremberg Code

# Beneficence – benefits outweigh risks

"Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of scientific literature." —Declaration of Helsinki

"Any experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary by nature." —The Nuremberg Code

# Justice – selection of subjects is equitable

"The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g. welfare patients, particular racial and ethnic minorities, or groups confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied" —The Belmont Report

# Some ethical issues related to HIV vaccine research

* Culturally sensitive informed consent
* Development of vaccines that address the needs of the populations most vulnerable to infection
* Potential for imbalance of power when vaccines are developed in one country and tested in another
* Possibility for social and psychological harm to participants in an HIV related trial
* Availability of a licensed product to trial participants and populations at high risk for infection when one becomes available.
* Choice of study populations for all phases of clinical development
* Level of care given for adverse reactions to an experimental HIV vaccine during a trial
* Influence of benefits from study participation; are the benefits coercive?
* Availability of interventions for risk reduction
* Level of care and treatment for HIV/AIDS provided to participants who become infected through risky behavior during the trial.

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| Please consult the HVTN website for more information and resources regarding Ethics and HIV vaccine Clinical Trials.  http://www.hvtn.org/en/science/hiv-vaccine-basics/ethics-hiv-vaccine-trials.html |