The importance of upholding ethical standards in the research environment

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Define tomorrow.

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MISUSE OF THE HAVASUPAI BLOOD SAMPLES

- https://www.nytimes.com/video/us/1247467672743/blood-journey.html

UPHOLDING THE STANDARDS OF RESEARCH ETHICS IN RESEARCH

- Community participation or collaborative partnership
- Social value: relevance of research to local health needs & expectations
- Scientific validity
- Qualification of researchers
- Participant selection process
- Acceptable balance of risks and potential benefits
- Informed Consent
- Fair compensation / reimbursement
- Privacy and confidentiality
- Researcher conflict of interest
- Scientific integrity
- Ongoing respect of research participants and collaborating communities

Image: https://www.dreamstime.com/photos-images/decision-making.html

COMMUNITY PARTICIPATION OR COLLABORATIVE PARTNERSHIP

- **Ensuring that the research is responsive to the health needs of the community to be involved**.

This means that the importance of a problem and the setting of priorities for research will be determined in partnership with local communities.

- **Ensuring that successful interventions are reasonably made available to the community.**

This requires the sponsor of the research to initiate a negotiation with stakeholders in the host country, representatives of the communities from which participants are drawn and non-governmental organizations such as health advocacy groups to determine the practical implications of making the products of research available to the local community.

- **Developing local capacities.**
- **Ensuring that the participants and communities receive benefits.**

Reference: Ezekiel E.J., Wendler D., Killen J., Grady C., 2004.

SOCIAL VALUE: RELEVANCE OF RESEARCH TO LOCAL HEALTH NEEDS & EXPECTATIONS

- **Justification of the use of human participants in the study**

Researchers must convince the REC of the importance of the study objectives for the society

- **Research have social value if the research question have potential benefits for the individuals and or/community where the research takes place.**

- **Student work does not always generate new knowledge or original work– benefit in education and training – implication of direct relevance to their community and society after completing their training.**

SCIENTIFIC VALIDITY

- **Research that is deemed to lack scientific validity is considered unethical since such research would not allow for meaningful conclusions, while unnecessarily exposing participants to risks of inconvenience, or even of harm.**

  This contravenes the overarching principle of respect for persons and human dignity and wastes society's resources.

- Regardless of who performs the evaluation, ultimately the responsibility to ensure that an appropriate scientific evaluation is performed on all research projects involving humans is that of the REC.

Reference: WMA: Declaration of Helsinki 2013, Para. 21, 22

RESEARCHER COMPETENCE

- **Is the researcher qualified?**

Important for the safety of the participants & to ensure the project will be conducted appropriately and lead to results and accrue the benefits a set out in the objectives and rationale of the study.

- **Conflict of Interest:**

Actual, perceived or potential conflicts of interest needs to be assessed.

Examples:

REC should be provided with details on budgets, commercial interests, contractual relationships, third party agreements and other relevant information.

PARTICIPANT SELECTION PROCESS

- **Applying the principle of justice**

The selection of research participants must be fair.

- **RECs need to ensure that**

The choice of the study population is based on scientific considerations, minimizes risk, and involves the participation of the targeted community.

Individuals and or communities who share in the risks of the research participation also share in the benefits.

ACCEPTABLE BALANCE OF RISKS AND POTENTIAL BENEFITS

- **Principles of doing good (Beneficence)**

- **What are the potential benefits?**

Physical (better health)

Psychological (participating in the development of knowledge)

Social benefits (new drug formulation; new scientific knowledge

Economic benefits (free access to drugs or profits)

Benefits can be direct or indirect.

ACCEPTABLE BALANCE OF RISKS AND POTENTIAL BENEFITS- CONTINUE

- **Principles of not doing harm (non-maleficence)**
- **What are the risks raised by a study?**

A risk is the potential for harm to occur:

Physical (injury, illness, disability, side effects)

Psychological (anxiety, emotional distress, reactivation of trauma, embarrassment)

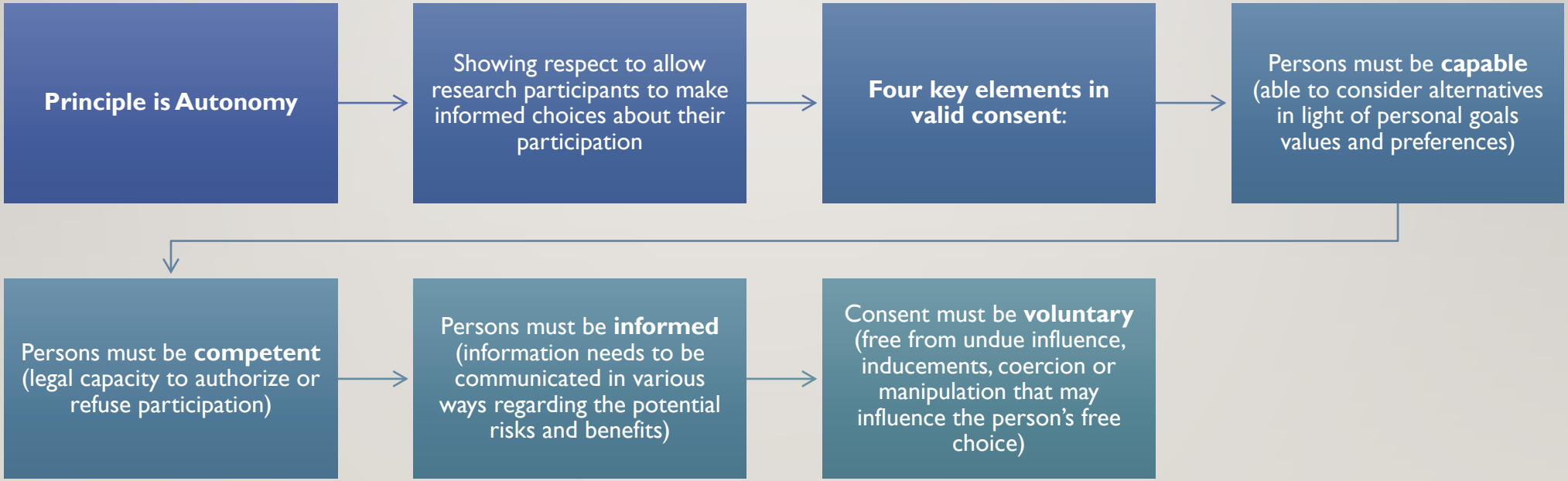
Social (stigma, breach of confidentiality)

Economic (loss of income due to time away from work, loss of job)

- Asymmetry between who bears risks and who bears benefits

Reference: WMA Declaration of Helsinki, 2008, Par. 21, 27and 32

INFORMED CONSENT



PRINCIPLES OF ETHICS THAT FACILITATE PROTECTION OF HUMAN RIGHTS AND DIGNITY

- Justify the inclusion of humans in research
- Ensure scientific value and validity
- Bring about more good, than harm
- Promote interest of humans before sciences or society
- Ensure voluntary participation – autonomy in choosing to take risks of the research
- Distribute the risks and potential benefits of research fairly
- Showing ongoing respect for persons
- Uphold transparency during the research process

Thank you!

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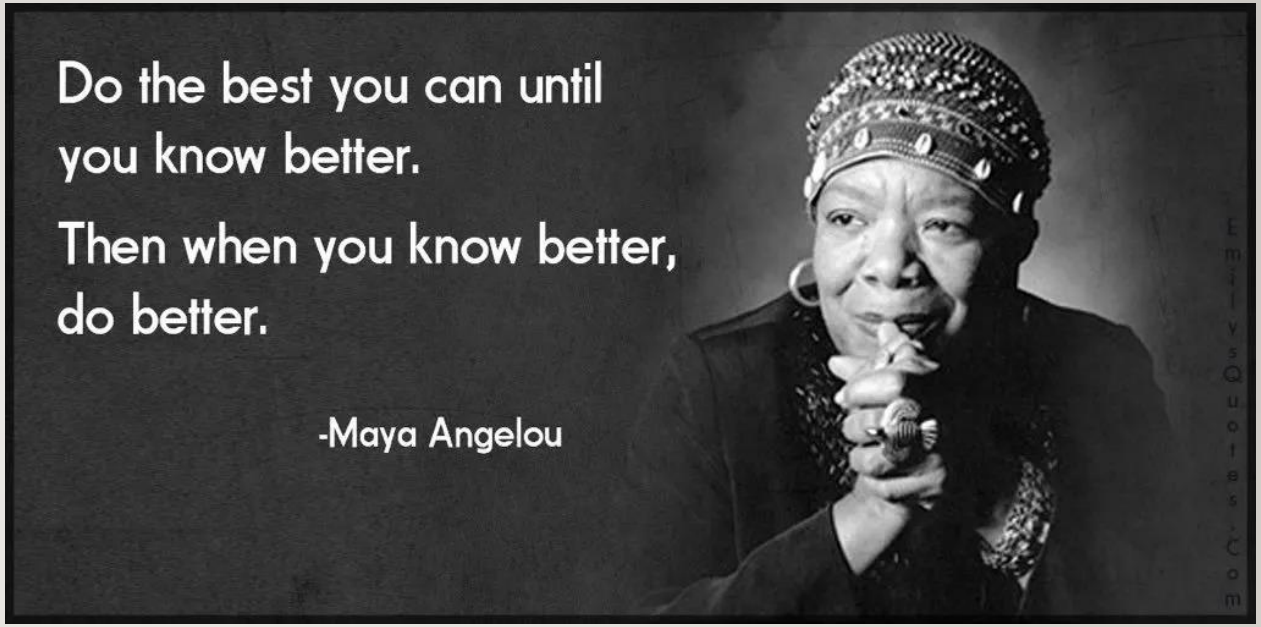

https://phenomenal-e.com/2019/08/04/when-you-know-better-you-do-better/

Reference:
Module 1: Introduction to Research Ethics
(https://elearning.trree.org/)