Community Partner/Teacher Training

Developed for Community Partners and Teachers engaged in the conduct of experimental education intervention research with K-12 Students.

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Local Oversight

- Institutional Review Boards (IRB) review and provide oversight in order to protect the rights and welfare of research participants.
- This study is under the purview of the University of Kentucky (UK) IRB which is administered by the UK Office of Research Integrity (ORI).
- For questions, you may contact ORI at 859-257-9428 or toll free at 1-866-400-9428 or visit the website at www.research.uky.edu/ori.

Community Partners as Study Personnel

- Individuals in the community may partner with university researchers by helping with studies of importance to both parties.
- You may have agreed to help a researcher enroll participants, obtain consent, or collect information for the study.
- If so, you are considered study personnel and will be asked to complete human subject protection (HSP) training to inform you about the regulations and ethical standards that apply to research with humans.
- The researchers may have obtained IRB permission to use this module as HSP training or it may be a supplement to HSP training.

Respecting Participant Rights and Welfare

Research conducted with human volunteers is governed by federal regulations, ethical principles, and institutional policies.

Research regulations may use the term “human subject” but the common preferred term is “volunteers” or “participants”.

Training is required to help research personnel understand the rules related to human research and the safeguards to protect the rights, welfare, dignity, autonomy, and privacy of research participants.

This training has been condensed to focus on concepts that will apply to community partner’s specific role in the research.

Research Regulations

- Federal regulations define how human research should be conducted to respect the rights and welfare of human participants.

- Additional rules apply to research with children, which are considered under the regulations to be a vulnerable population.

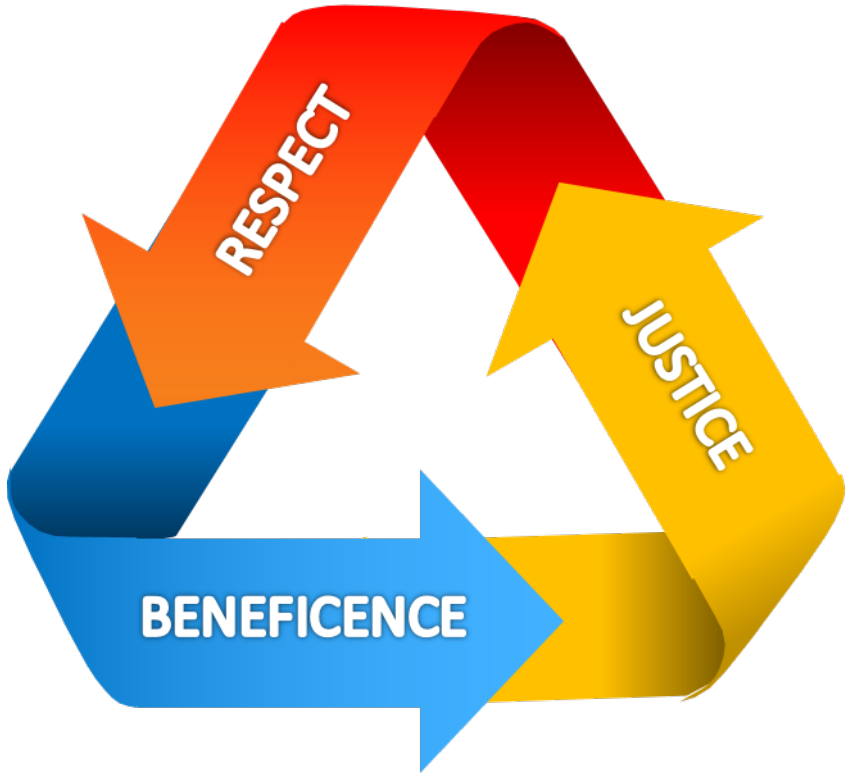
Professional and Ethical Research Codes & Principles guide the conduct of research.

They provide reference for interpretation where the regulations are silent.

Ethical Principles for Research

The Belmont Report issued by the National Commission outlines 3 ethical principles

- Respect for persons
- Beneficence
- Justice



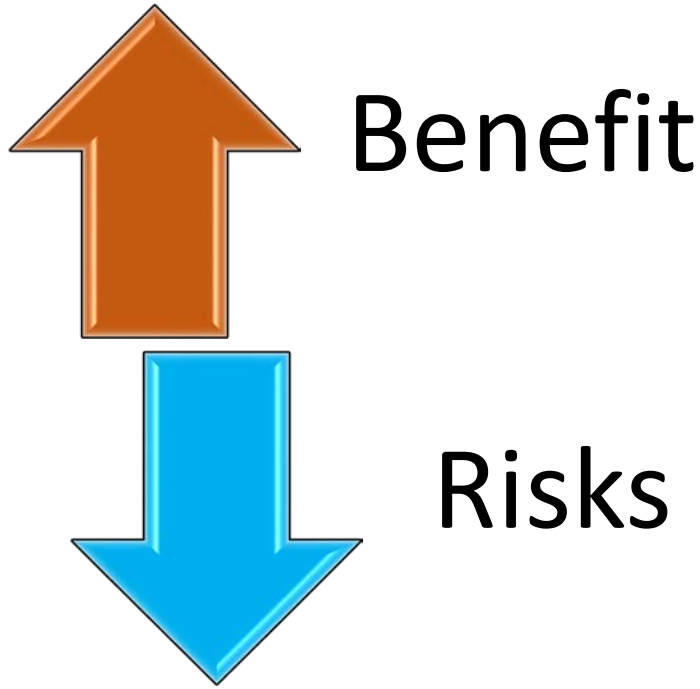
Source: The Belmont Report issued by the National Commission for the Protection of Human Research Participants of Biomedical and Behavioral Research, 1978.

Justice

- Choosing research participants fairly so that the benefits and burdens are shared equally
- People should not be targeted out of convenience or excluded out of convenience
- Research questions match needs of research participants

Beneficence

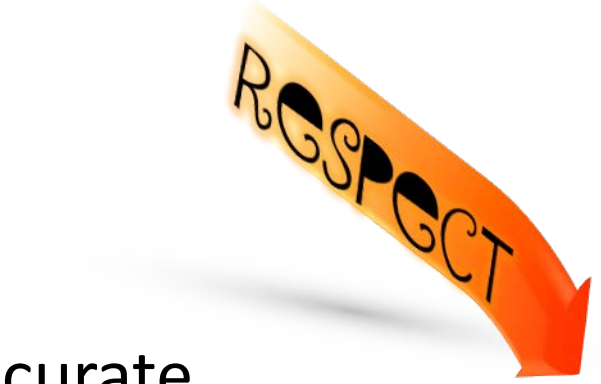
- Maximize benefits and minimize risks
- Protecting research participants from harm:
  - Physical (injury)
  - Social (embarrassment)
  - Psychological/emotional (upset)
- Enhance potential for gain



Beneficence

- Minimize the risk from a breach of confidentiality by using coded documents and securing research records with password protection or encryption.
- Minimize the risk from an invasion of privacy by not sharing information about a student's participation with anyone beyond the research team.

Respect



- People choose for themselves based on true and accurate information
- Agreement to participate must be freely and voluntarily given (voluntary informed consent, parental permission, and assent)
- Those with diminished capacity (vulnerable) require extra protections
- Respect involves accepting the individual's choice without question

Research with Children

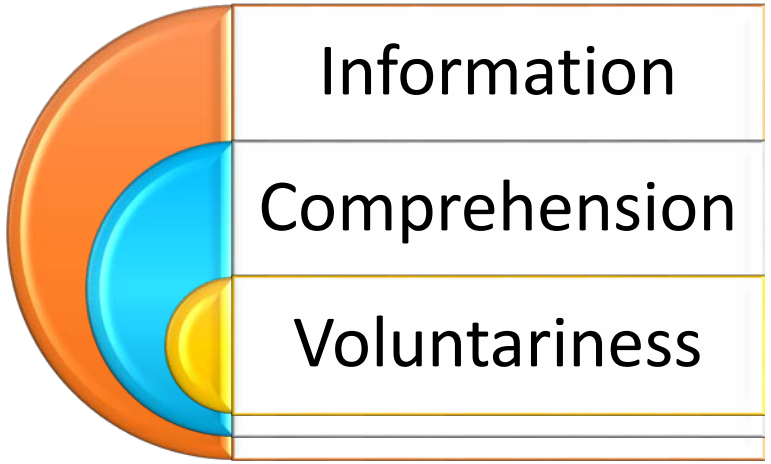
- Since children cannot provide legal informed consent, permission is obtained from at least one parent through an **Informed Consent Process**.
- Children 6 years or older are involved in the decision to participate through an **Assent Process**.
- Assent is an affirmative agreement to participate in research initially and throughout the study.

Key Components of Valid Informed Consent & Assent:

(1) Provide true and accurate information needed to make an informed decision;

(2) facilitating the understanding by using clear and simplified language and checking comprehension; and

(3) promoting the voluntary nature of the decision about whether or not to participate and freedom to choose to withdraw.



Voluntariness

Informed consent and assent are more than just a form obtained when enrolling research participants into a study. It is an ongoing process that involves continued communication between the research team, parent, and child.

Participants are informed that they may withdraw from participation at any time without fear of repercussion or being treated differently.

Children must not be forced to participate in a research intervention by anyone involved including parents, researchers, teachers, or peers.

Undue Influence affect on the Assent Process

- Even with a thorough consent and assent process, students in the elementary setting are susceptible to undue situational influence.

- Elementary students may:
  - view participation as required;
  - over-estimate potential benefits; or
  - feel pressure from others.

Potential Contributors to Undue Influence

- Teacher's are typically authority figures who should be obeyed.
- Opportunities to "choose" participation in an academic setting is rare. Choosing not to take part in a certain activity may be foreign to young students.
- Participation may be seen as an opportunity to win favor of a teacher or parent.
- Students may perceive that their grades would be affected by their participation; particularly when research involves pre or post-tests.

Practices to Promote Voluntariness Throughout the Research

To the extent allowed by the research plan, use terminology that differentiates the research project from the standard academic setting (i.e., “facilitator” or “group leader” instead of “teacher”; “participant” instead of “student”).

Reiterate that participation is voluntary and students will not get in trouble if they choose to withdraw or not take part.

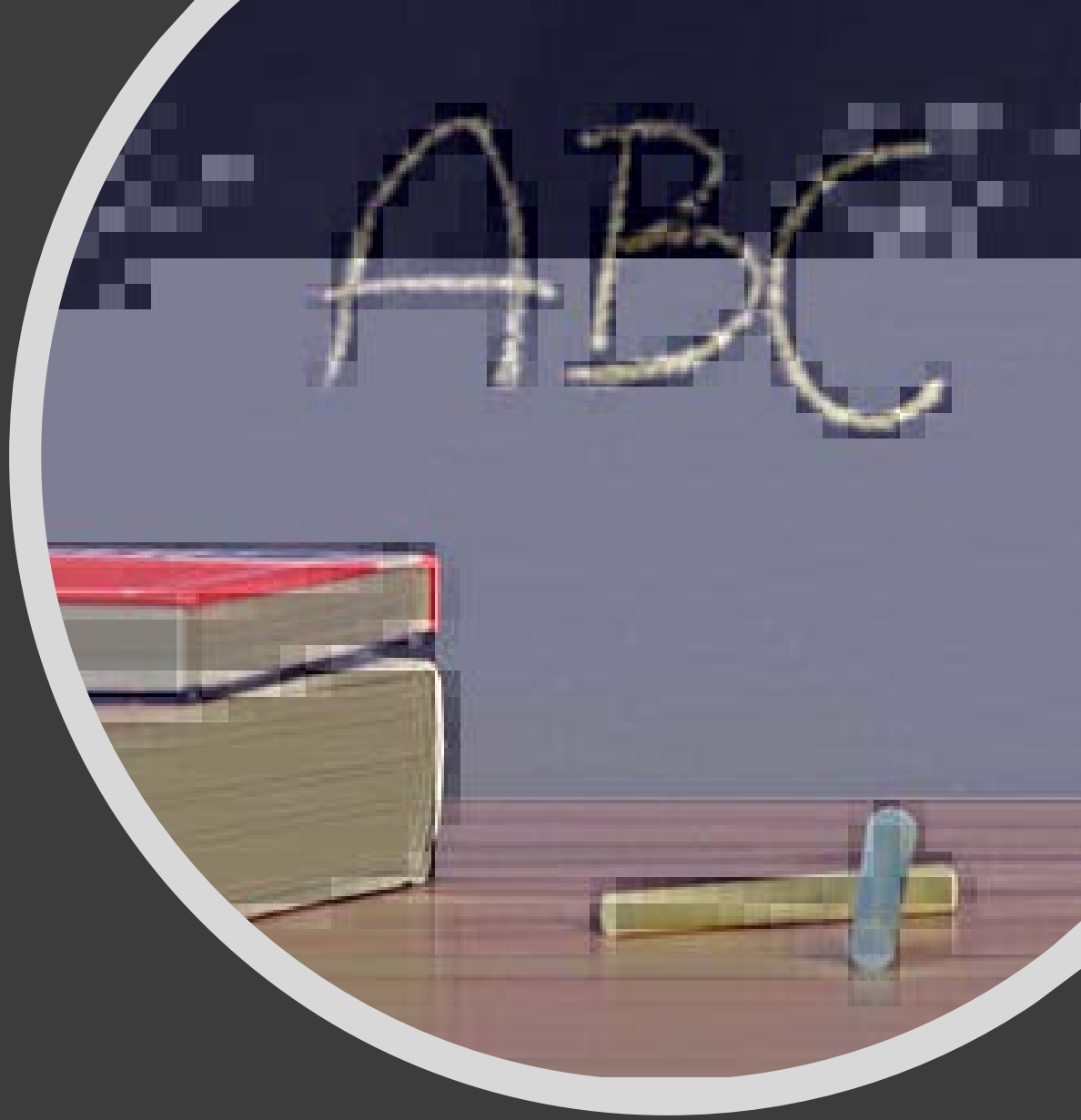
Remind parents that it is the child’s choice whether to participate, and that he/she should not be penalized for declining.

They should be allowed to sit out of an exercise or skip a question they are not comfortable answering. They cannot be penalized for lack of full participation. This is true even if the procedures or intervention is standard practice outside of the research.

Case- K- 12 curriculum intervention study

Parent A has signed consent giving parental permission for Elementary Student A to participate in a study that will implement and assess a new reading intervention. The intervention will be administered by a 3rd grade teacher and will take place 30 minutes after school, three days a week. The teacher is listed as study personnel and he has completed human subject protection training.

Student A provided verbal assent to participate in the study. At the third session, Student A complains of a head ache and is not actively participating in the scheduled activity. What should the teacher do?



Case- K- 12 curriculum intervention study

a. Let Student A skip the activity
b. Contact the researcher and ask if Student A can skip the activity
c. Remind Student A that he agreed to participate and encourage him to engage in the activity like all of the other students
d. Tell Student A that he must participate or he will have to leave the study

Correct answer – A

Assent is a minor's affirmative agreement to participate throughout the study. Research participation is voluntary. That means that participants may skip portions or stop participation altogether. This is irrespective of parental wishes or researcher requests.

When study personnel are in a position of authority, they should minimize undue influence or perceived coercion by reminding participants that continued participation is voluntary.

Ongoing Study Personnel Responsibilities

As research continues, the following must be reported to the IRB.
Be sure to communicate any of the following to a member of the study team:

- Requests to change the research (must be reviewed & approved by the IRB first)
- Progress and status of the project
- Unanticipated problems or harm (e.g., breach of confidentiality)
- When research procedures are not followed
- Participant complaints
- Instances where the rules aren't followed

How to contact the researchers or research study team:

Who to call with questions or concerns regarding participant rights/welfare:

References

- Community Partner Human Subjects Research Training, Harvard Catalyst | The Harvard Clinical and Translational Science Center January 2014, Version 1.0.
- University of Kentucky IRB Enrolling K-12 Students as Research Subjects https://www.research.uky.edu/uploads/ori-d790000-guidance-enrolling-k-12-students-research-subjects-pdf
- CIRTification Community Involvement in Research Training in Human Research Protections, Emily E. Anderson, The University of Illinois at Chicago Center for Clinical and Translational Science, http://www.ccts.uic.edu/content/cirtification.
- IRB Protocols in the School Setting: Five Critical Areas of Risk, July 05, 2016, Axiom Research Compliance.