Working with participants

History: Declaration of Helsinki (1964)
- Nuremberg Code + medical research with therapeutic intent (World Medical Association)

History: National Research Act of 1974
- Established “National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research”
- Required establishment of IRBs at institutions receiving the Department of Health and Human Services funding for human subjects research

History: Belmont Report (1979) – Govt of USA
- Established the basis for the ethical principles upon which federal regulations for protection of human subjects are based

Research oversight\(^1\) is needed
- Too many clinical trial blunders
- The future impact of such issues as cloning, gene therapy, genetic engineering, etc. is unknown.

History: Nuremberg Code
- Informed consent is essential.
- Research should be based on prior animal work.
- The risks should be justified by the anticipated benefits.
- Only qualified scientists must conduct research.
- Physical and mental suffering must be avoided.
- Research in which death or disabling injury is expected should not be conducted.

\(^1\) a system for addressing questions of potential risk through guidelines, regulations or other structures

The Institutional Review Board

Mandated for all institutions conducting human research.
- Any study intended to result in publication or public presentation, including classroom projects.
- Any activity resulting in publication or public presentation, even if it involves only review of existing data that was collected with no intent to publish.
- Any use of an investigational drug or device.

Exempt \(\Rightarrow\) non research
- Employee evaluation, program evaluation, quality assurance, or other situations where such evaluation is not designed to lead to generalizable knowledge

The Institutional Review Board

Roles and responsibility.
- Review research plan to be sure it meets criteria in Federal regulations
- Confirm there are no unreasonable risks
- Conduct continuing review
- Assess suspected or alleged protocol violations.

Authority
- Approve, disapprove, or terminate all research.
- Require modifications to protocols.
- Require that information the IRB deems necessary is provided to participants.
- Require documentation of informed consent, or allow waiver of consent.

Types of IRB Review

Full board review
- For research involving risk of physical or psychological harm greater than that encountered in daily life, particularly research involving deception, stress, or manipulation
- Research with vulnerable population

Expedited review
- Collection of data through noninvasive procedures, such as weight, blood pressure, flexibility testing, etc
- Materials (data, documents, records, or specimens) that are collected solely for non-research purposes.

Administrative review
- Research conducted in accepted educational settings
- Research involving only observation of public behavior
- Research involving only surveys or interviews
What to submit to IRB
► Protocol statement (What is to be done.)
► Consent forms OR
► Assent forms (for children 7-17 years old)
► All personnel involved and their qualifications
► Location for study
► Special populations, if any
► Data collection method – a copy of the questions might be needed
► Recruitment ads
► Source of funding
► Payment to subjects
► Costs to subjects
► Benefits to subjects
► Risks and discomforts
► Confidentiality – how confidentiality will be maintained for records, videotapes, audiotapes, and how records will be destroyed at end of study.

Recruitment
► Add recruiting time and expenses
► Make key contacts → difficult to open communication otherwise
► Check ethical issues
► Conduct preliminary tests early → some people might need way more extra time that you had anticipated
► Plan higher expenses (transport cost, a carer, etc)
► Consider their needs (wheelchair access, blind-friendly environment, etc)
► Plan time for participants to become comfortable and familiar with the environment
► Be ready to do some work at participants’ home
► Make sure all materials are available in necessary formats.

Preparing the Study
► Include consent forms with the materials sent ahead of time (ask which format)
► Use a checklist to ensure that you have anticipated any potential barriers → evaluate the accessibility of potential locations
► Schedule a walkthrough by a person with similar accessibility needs
► Be familiar with the Assistive Technology the participants need to use → Schedule time to set up and test AT
► Make sure everybody involved in the session are properly trained on issues associated with dealing with persons with special needs → training can take a while

At the Session
► Don’t make assumptions
► Ask before you help – general rule, be courteous, but NOT condescending
► Speak normally unless requested otherwise
► Avoid potentially offensive terms or euphemisms → ‘mentally different’, ‘physically inconvenienced’, or ‘physically challenged’
► Make everybody that will be there aware that there will be session with people with disabilities
► Practice “not staring” → or apologize in advance
► Don’t pause (or “errrr…..”) to avoid certain words
► Be aware of personal space
► Don’t interact with a service animal
► Don’t act like a carer
► Consider how you would introduce yourself and explain the protocol to the participants

Terms to use
► Person-first terms i.e. ‘a person with wheelchair’ NOT ‘a wheelchair-bound person’
► Person (with a) or (has sustained) or (with and acquired) brain injury
► Person [living] with AIDS/HIV
► Down syndrome NOT ‘mongoloids’
► Cleft lip NOT ‘hare lip’
► Non-disabled NOT ‘normal’, ‘able-bodied’ or ‘healthy’
► Stroke survivor NOT ‘stroke victim’
► People with disabilities NOT ‘the disabled’ or ‘handicapped people’ → people with disabilities are not generic
► Mature or older person NOT ‘the elderly’
► Person with epilepsy or seizure disorder NOT ‘epileptic’

Specific Consideration for Working with Persons who are Blind or VI
► Introduce yourself as you approach the participant
► Introduce others who are in the room.
► Describe the setting to the participant, including the position of the video camera.
► Tell the participant when you or others enter or leave the room.
► Give directions about where to be seated. Ask the participant if he or she would like to be guided to the chair.
► Offer your elbow to lead the participant. Don’t grab the participant’s arm, hand, or cane.
► Tell the participant where there is room for the service animal.
### Specific Consideration for Working with Persons with Communication Impairment
- Admit if you don't understand, ask them to repeat
- Don't speak slowly unless requested
- Some prefer to write their communications down on paper – be patient
- Some will require communication aid (AAC) – understand how this system works
- Be flexible – you may need to change to yes/no or binary option in communicating
- Be careful before “filling-in the gaps”
- Wait for the response longer than you normally would, they might take more time formulating answers

### Specific Consideration for Working with People who are deaf or HI
- Get the participant’s attention before talking. Touch the person gently on the shoulder or arm.
- Take turns talking. A person who speechreads might miss information if two or more people talk at the same time.
- Face the participant while speaking, and speak at eye level.
- Clarify to the interpreter the importance of translating questions and answers exactly.
- Don't speak too loud. Some hearing aid and cochlear implant users are especially sensitive to loudness.
- Offer to write down what you are saying

### Specific Consideration for Working with People with Physical Impairments
- Do not move mobility aids. Some people are uncomfortable if the aids are out of reach.
- Remember seating for a personal attendant if needed.
- Have a clipboard available to hold the consent form and instruction sheet.
- Remember space for a wheelchair, a cane or other mobility aids.
- Offer to write down their answers (but be careful how you ask).
- Some may have difficulty getting in and out of soft and low seating. Provide upright, rigid seating (or better, adjustable)

### Specific Consideration for Children
- Arrange furniture so that children are not directly facing the video camera and one-way mirror
- Timetable a session of max 1 hr (30 min for pre-schoolers) and integrate play in breaks
- Check whether you need parents to sign consent form (most likely yes)
- Children up to 7 or 8-years-old will need a tester in the room with them for reassurance.
- If a parent will be present in the room, explain to the parent to minimise interaction with her children
- use phrases such as “Now I need you to...” or “Let’s do this...” or “It’s time to...”

### Specific Consideration for Older Adults
- They often arrive early (as they are retired), make sure somebody is around
- They often come with their spouses, anticipate space for spouses.
- They often do best in the morning, avoid scheduling late evening appts.
- They don't like driving at rush hour (if they drive at all), don’t schedule too close to rush hour.
- Remind them very close to the appt date what to bring (e.g. reading glasses), place and time.
- They often assume food is provided, inform them if that is not the case (so they can bring some, especially for long sessions).
- They often deviate with long stories about their offspring. Be tactful to keep them on track (they might leave if feeling offended).
- Some older women are very sensitive of smells, or if somebody shows the sign of illness.