Ethical Issues in Developmental Disability Research

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Overview

1. Introductions
2. Historical context of human experimentation
3. International and national response
4. Research with people with developmental disabilities

Introductions


NBA WORLD
BULLS


L'Arche
Clinton, Iowa
we are one family

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With People with Developmental Disabilities on Health and Safety

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Historical Context of Human Experimentation

Historical Context

- Nazi Medical War Crimes
- The Tuskegee Syphilis Study
- The Willowbrook Study
- The Human Radiation Experiments
- Prisoner Experiments
- The Tea Room Experiments

Willowbrook (1956 – 1971)

- New York state institution for children with developmental disabilities
- Studied the natural history of hepatitis
- Infected children with hepatitis (fed with stool extracts; injections)
- Families could bypass waitlist for admittance by agreeing to participate in the research
- Parents not well informed of risks

The Human Radiation Experiments (1944 – 1974)

- Variety of studies
- Atomic Energy Commission & Quaker Oats Company
- Examine mineral absorption
- Children with developmental disabilities living in institutions (Massachusetts)
- Gave trace amounts of radiation in breakfast cereal
- Parents deceived on the purpose/risks (“science club”)

Common Factors

- “Participants'” belonging to marginalized groups (decreased social value)
- “Participants” embedded in coercive contexts
- “Participants” with limited capacity to understand information and act upon a decision
- Convenience samples
- Deception
- Little to no prospect of personal or social benefit

Legacies of Exploitation

- Regulation of human experimentation
- Suspicion/distrust of researchers

International and National Response

Correcting the Problem

- **International**
  - The Nuremberg Code (1949)
  - The Declaration of Helsinki (1964)
- **National**
  - The Belmont Report (1979)
  - The Common Rule (1991)
  - Institutional Review Boards (IRB)

The Nuremberg Code (1949)

- War Crimes Tribunal
- **First set of principles** for human research ethics (medical researchers)
- **Voluntary** consent
- **Avoid unnecessary suffering** and injury
- **Minimize risks**
- Permissible to **withdraw** during participation

The Declaration of Helsinki (1964)

- World Medical Association
- **Extended Nuremberg principles**
- Added considerations for **clinical research** (patient-physician relationship)
- Made **surrogate consent permissible** (*with the caveat that these groups only be included in research when the research is necessary to promote the health of the population and cannot be performed with legally competent individuals*)
- Independent oversight committees (1975 revision)
- Most recent revision in 2008

The Belmont Report (1979)

- ***National Commission for the Protection of Human Subjects in Biomedical or Behavioral Research*** established by Congress in 1974
- Articulated **ethical principles** to guide human research (including behavioral research)
  - Respect for Persons
  - Beneficence
  - Justice

Respect for Persons

- Treat individuals as **autonomous** agents
  - Capable of deliberation
  - Able to act on decision

- Provide **additional protections** to persons with diminished autonomy (social, cognitive)

Beneficence

- Maximize possible **benefits**
- Minimize possible **harms**

Justice

- Distribute the risks and benefits of research **fairly**

- **Scientific justification** for the inclusion or exclusion of any group

Common Rule (45 CFR 46; 1991)

- **Codified** the Belmont Principles
- Applies to **federally funded research** (many institutions apply to all research)
- Special provisions for research involving **vulnerable populations**:
  1. Neonates, fetuses and pregnant women (Subpart B)
  2. Prisoners (Subpart C)
  3. Children (Subpart D)

Institutional Review Boards (IRB)

- Scientists, non-scientists, non-institutional affiliates, and, if applicable, a prisoner representative who **independently review** research to ensure that researchers safeguard the **rights and welfare** of individuals participating in research

Definitions

- **Research**: A **systematic** investigation designed to discover or contribute to a body of **generalizable** knowledge

- **Human Participant**: **Living individual** about whom a researcher obtains:
  - **Identifiable** private information
  - Data from **intervention or interaction** with the individual

Minimal Risk

- The probability and magnitude of harm or discomfort anticipated in the research are **not greater** in and of themselves than those **ordinarily encountered in daily life** or during the performance of routine physical or psychological examinations or tests.

IRB Review

- **Exemption**: Normal educational practices, surveys, interviews, public observations, extant data, public benefits/services, public officials
- **Expedited**: No more than minimal risk; clinical studies, some blood samples, noninvasive biological specimens, routine clinical practice, data collected for nonresearch purposes, recorded data, surveys, interviews, oral histories, program evaluation; minor changes to approved protocols
- **Full**: Greater than minimal risk; classified populations
- **Continuing Review**: minimally annual review

Informed Consent

- Informed consent is an **ongoing process**
- Participation is **voluntary**
- Documents and explanation use **plain language** (6th grade reading level) and explain any technical terms in lay terms
- Conduct in a language in which the individual is proficient

Informed Consent

- **Purpose** of the research
- Research **procedures** and **duration**
- Reason for **selection**
- Participation is **voluntary**
- **Risks** and **benefits**
- **Alternatives** to participation
- **Confidentiality**
- **Incentive/compensation**
- Investigator and HSP **contact information**

Informed Consent

- **Waiver or Alteration**
  - Study of public benefits/services
  - No more than minimal risk
  - Practicality of conducting without waiver
  - Impact on participants' rights and welfare
- **Waiver of documentation**
  - Only link to participant identity
  - No more than minimal risk

Risks

- **Types**
  - Physical
  - Psychological
  - Social
  - Legal
  - Economic
- **Sources**

Privacy and confidentiality

- **Privacy:** Having control over the extent, timing and circumstances of sharing information about oneself
- **Confidentiality:** Not disclosing private information to outside parties
- **Anonymity:** Information collected cannot be linked to an individual
- **HIPAA**: Protected Health Information (PHI)

Benefits

- **Direct** (personal)
  - Insight into self, learning
  - Treatment
  - Satisfaction with contribution to science
  - *Compensation is NOT a benefit*
- **Indirect** (social)
  - Scientific knowledge that will benefit others

Protections

- Investigator training
- Surrogate consent
- Informed consent witnesses
- Identification numbers
- Storage of data (electronic and hard files)
- Debriefing
- Referrals and resources
- Data monitoring board
- Certificate of Confidentiality

Risk-Benefit Analysis

- What are the risks?
- What are the benefits?
- What protections are in place?
- Are the risks reasonable in light of the benefits?

Selection of Participants

- Equitable selection of participants
- ***Inclusion*** of vulnerable and minority groups (access)

Proposed Revisions to Regulations

1. Refinement of risk-based framework
2. Single IRB review for multi-site research
3. Improvements to consent forms and process
4. Mandatory data security standards
5. Improvements to data collection and analysis of unanticipated and adverse events
6. Extension of regulations to all research
7. Improved harmonization of regulations and agency guidance

http://www.hhs.gov/news/press/2011pres/07/20110722a.html

Other Relevant Guidance

- *Research Involving Individuals with Questionable Capacity to Consent: Points to Consider* (National Institutes of Health, 2009)
  - More on this later!

Other Relevant Guidance

- **Professional associations**
  - Ethical Principles of Psychologists and Code of Conduct (APA)
  - Guiding Principles for Evaluators (AEA)
- **Institutional policies** ("mental disorders", "mental disabilities", "cognitive disabilities", "questionable capacity")

IRB Review – Tips for Success

- IRB as a **floor**, not a ceiling
- **Interactive** review – talk with IRB administrator/chair/member
- Consider and discuss the **importance of including** people with developmental disabilities in research
  - Do not use the presence of disability to preclude research participation
- Obtain **sample research materials** and IRB applications
- **Involve** people with developmental disabilities in designing and carrying research (more on this to come)

Research with People with Developmental Disabilities

Developmental Disabilities Research

- How do we pursue the ***safe, respectful inclusion*** of people with developmental disabilities in research?

- Key issues/considerations
  - Exploitation → Protection (exclusion) → Access
  - Social and scientific consequences
  - Voice, paternalism, representation
  - Balance autonomy with protections
  - Research that serves people with developmental disabilities
  - Diversity of people with developmental disabilities (intersectionality)

Disability Rights and Research Ethics

- Disability rights movement → civil rights
- *Nothing About Us Without Us* → Direct involvement by people with disabilities in things that impact their lives
- Human rights framework (dignity and respect)
- Social model, strengths-based
- Accommodations and supports
- People with developmental disabilities as direct respondents
  - Proxy report (answering for other) → Bias, validity concerns
  - Representative of proxy not of people with developmental disabilities

(Over)exclusion from Research

- Exclusion from research appropriate when all avenues to facilitate inclusion have been exhausted

Addressing the Needs of People with Developmental Disabilities with/in Research

- Is research grounded in disability rights principles?
- Why is inclusion important?
- Does research address the needs of people with developmental disabilities?

Knowledge and Power

- Research findings (knowledge) can influence
  - Decision-making
  - What is brought to the table to decide on
  - What is in the public consciousness
- Decisions about research agenda, funding, dissemination
- Research impacts policy; policy impacts research; both impact lives

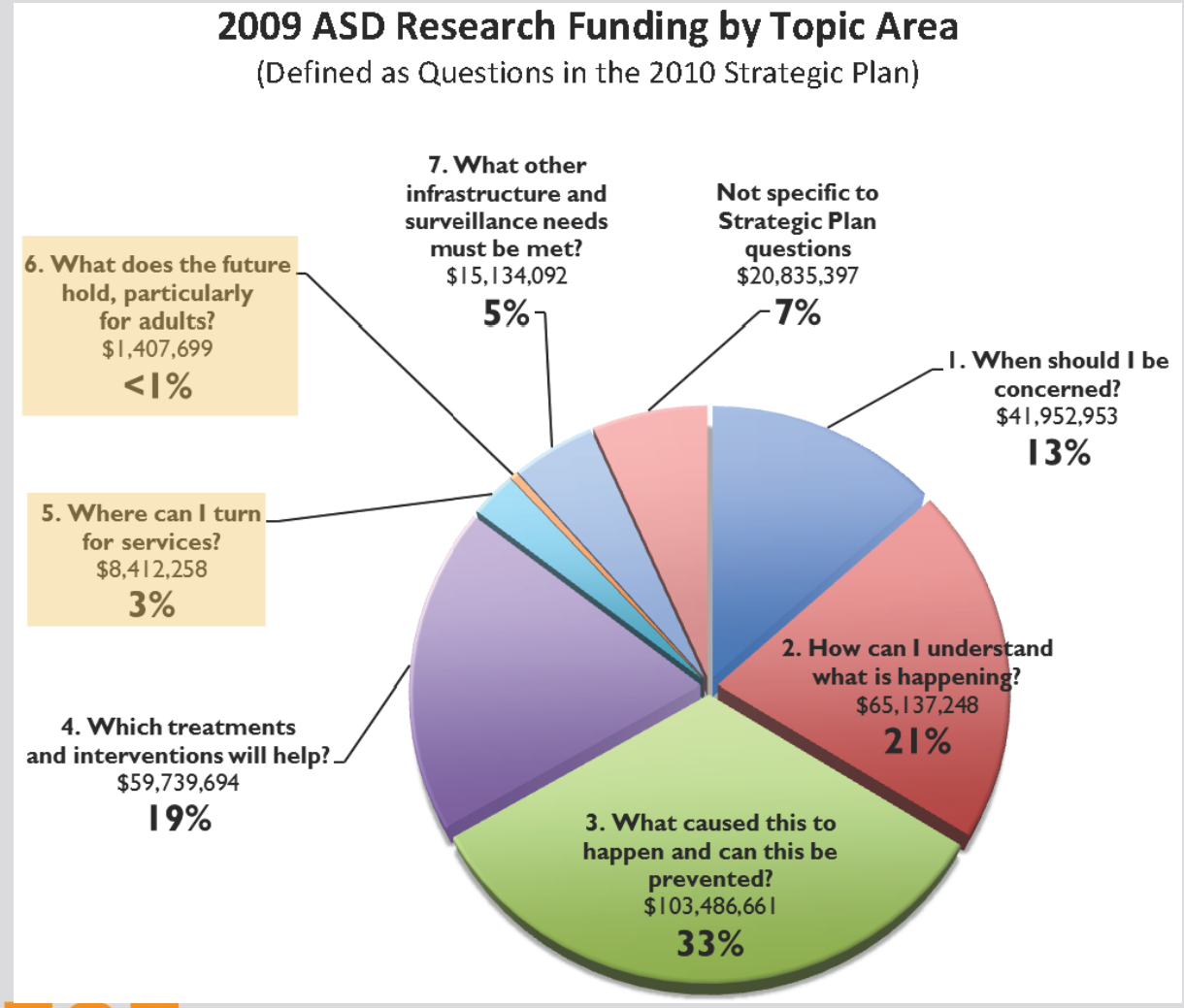
People with Developmental Disabilities are Frequently Excluded from:

- Grant review boards
- Advisory boards that decide research direction
- Participation in public policy
- Legitimacy as “experts”

People with Developmental Disabilities as Stakeholders

- Self-advocates may be under-represented in
  - Academia
  - Public office
  - Summits/seminars soliciting info regarding developmental disabilities
- Parents and professionals are not substitutes for self-advocates

Priority Mismatch Outcome



Ethical Issues with Interventions

- Many interventions conducted on children
- Long term effects of “normalizing”?
- Interventions with problematic methods (e.g., aversives)
- IRBs and researchers may be more likely to overlook these types of issues

Addressing the Needs of People with Developmental Disabilities with/in Research

- Pursue research that is **worthwhile and meets the needs** of PWDD
  - Relevant questions
  - Desired interventions
- Promote direct and indirect **benefits**
  - New opportunities, personal growth
  - More influence on policy, research, society

Facilitate by Involving People with Developmental Disabilities

- On grant review panels
- On research-related advisory boards
- In developmental disability policy
- As stakeholders with an important and legitimate perspective
- As researchers! (hold that thought)

Respectful Research

- **Strengths-based approach**
- Quality of **relationships (trust)**
  - Display and earn trust
  - Develop personal relationships
  - Clarify relationships (nature, duration)
  - Show positive regard (treat adults as adults)
  - Be honest, respectful, nice, friendly
  - Demonstrate patience
  - Encourage, but don't be pushy

Respectful Research

- Offer and uphold **confidentiality**
- Secure **privacy** in data collection
- Allow for **self-expression** (open-ended, interviews)
- Provide **compensation** for participation
- Make participant **comfortable** (refreshments)
- Give/send **thank you notes**
- Stay in **contact** (results, future studies)

Respectful Research

- Opportunities for **feedback** on dissemination materials
- Respectful **language** in dissemination materials
- **Accessible** dissemination materials and venues
- Attend to impact on **society**
  - Decreasing / not perpetuating stigma
  - Improving lives and communities

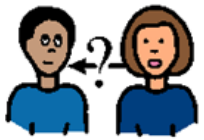
Respectful Research is Accessible Research

- **Remove barriers, provide supports** (anticipate, individualized, funding)
- Accessible locations (accessible, reliable, affordable transportation)
- Varied recruitment (preferences, accessible, trust)
- Specific information on where to go, who to contact (pictures)
- Invite/offer support provider if desired (trust, confidentiality, coercion)
- Accommodations for one participant may not be the needed accommodations for another participant (flexible)

Accessible Research

- Avoid lengthy surveys (respondent burden, fatigue)
- Accessible materials (plain language, picture boards, asynchronous communication)
- Read materials out loud
- Assistance with paperwork
- Demonstrate procedures
- Anticipate varied accommodation needs (ASL, large print)

Participating in Research – Meeting Schedule

When?	**Meeting #1: Informed Consent** Learn about research project Talk about risks and benefits of participating Ask questions you have about the project	
When?	**Meeting #2: Individual Interview** Tell us about your experiences in research studies Tell us what you think about you being in research studies	
When?	**Meeting #3: Group Interview** Hear about what you and other people said about being in research Tell us new thoughts you have about being in research studies	

Then, you will be finished with our project. You will go back to your normal life, and we will go back to ours. We will be so grateful to you for sharing your thoughts with us!

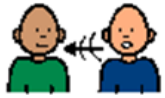
What will happen if you decide to participate in the research?

One-on-one interview

May last up to two hours

No right or wrong answers

Interested in **your opinion**



Audio-recorded

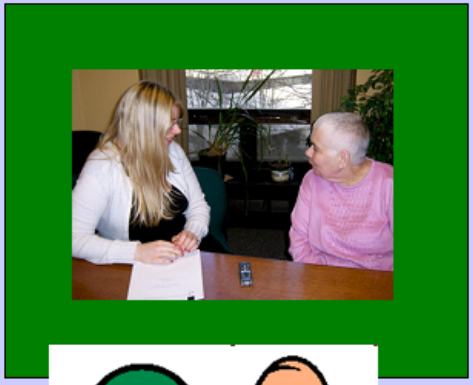
Then...

We **type** everything you said onto a **page**

Do you have any questions?

Participating in Research
Individual Interview Consent Form
02/2008
v. 2

Informed Consent – Your Choices



Yes

No

I don't know...

Participating in Research – Your Options

At any time, you may…

Stop for today

Take a break

Keep going

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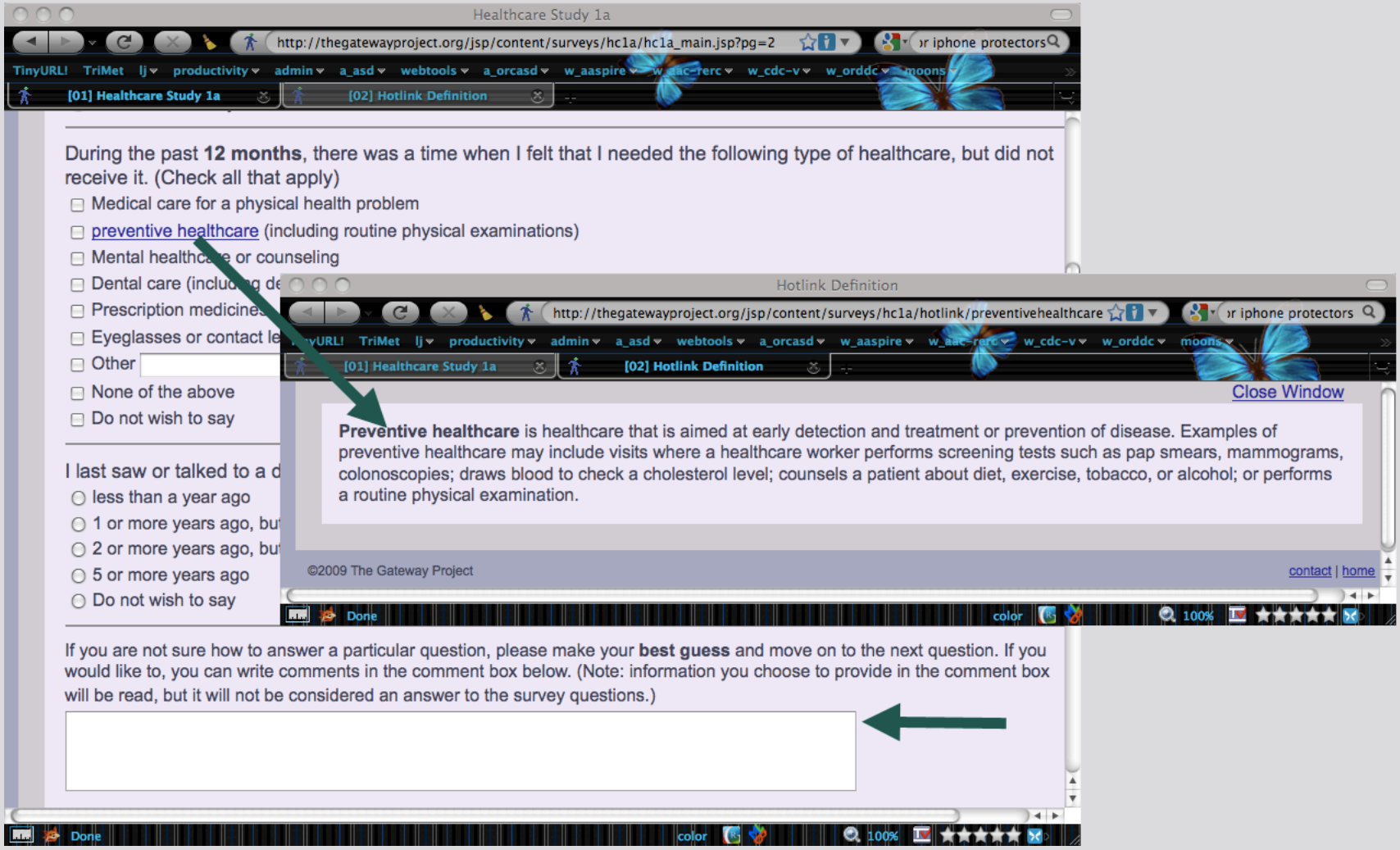
Healthcare Study 1a
http://thegatewayproject.org/jsp/content/surveys/hc1a/hc1a_main.jsp?pg=2
[01] Healthcare Study 1a
[02] Hotlink Definition
During the past 12 months, there was a time when I felt that I needed the following type of healthcare, but did not receive it. (Check all that apply)
Medical care for a physical health problem
preventive healthcare (including routine physical examinations)
Mental healthcare or counseling
Dental care
Prescription medicines
Eyeglasses or contact le
Other
None of the above
Do not wish to say
I last saw or talked to a d
less than a year ago
1 or more years ago, bu
2 or more years ago, bu
5 or more years ago
Do not wish to say
Hotlink Definition
http://thegatewayproject.org/jsp/content/surveys/hc1a/hotlink/preventivehealthcare
Close Window
Preventive healthcare is healthcare that is aimed at early detection and treatment or prevention of disease. Examples of preventive healthcare may include visits where a healthcare worker performs screening tests such as pap smears, mammograms, colonoscopies; draws blood to check a cholesterol level; counsels a patient about diet, exercise, tobacco, or alcohol; or performs a routine physical examination.
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contact | home
If you are not sure how to answer a particular question, please make your best guess and move on to the next question. If you would like to, you can write comments in the comment box below. (Note: information you choose to provide in the comment box will be read, but it will not be considered an answer to the survey questions.)
Done
100%

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Original

7. Someone to confide in or talk to about yourself or your problems.

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

---

New

7. How often do you have someone with whom you can share personal information about yourself or your problems?

None of the time | A little of the time | Some of the time | Most of the time | All of the time

Informed, Voluntary Consent

- **Consent Capacity**: ability to understand key information about a research study
  - Varies with research context (complexity, continuum)
  - Participant-research fit → modifications to enhance consent capacity
  - Nonverbals cues
  - Waiting periods
- **Assessment** of consent capacity
  - When is diminished capacity, impaired capacity?
  - Ask participants to describe research in own words (key elements)
  - Standardized approaches (problematic focus on cognitive abilities, impractical)
  - Coercion

Informed, Voluntary Consent

- Guardianship: Legally authorized representatives
- Permission/assent
- De-couple capacity from autonomy
- Address person with developmental disability directly and involve them in decision-making
- Decision of person with developmental disability is final (one caveat)
- Watch for coercion

Improving Ethics with Participatory Approaches to Research

- Direct response to ethical issues faced by minorities in research
- Includes
  - Participatory Action Research (PAR)
  - Community Based Participatory Research (CBPR)
  - Other “flavors”

Participatory Approaches to Research

- Change the relationship between members of a minority community and scientists
- “Subjects” become a part of the research team
- Involve an equitable exchange of power and expertise
- Can be used with any research methodology

Participatory Approaches to Research

- Can be used:
  - For the purpose of action
  - To support policy or systems change
  - To improve community conditions
  - To conduct research desired by a minority community
  - With any domain of inquiry, including “basic” research
- Can be conducted with people with developmental disabilities

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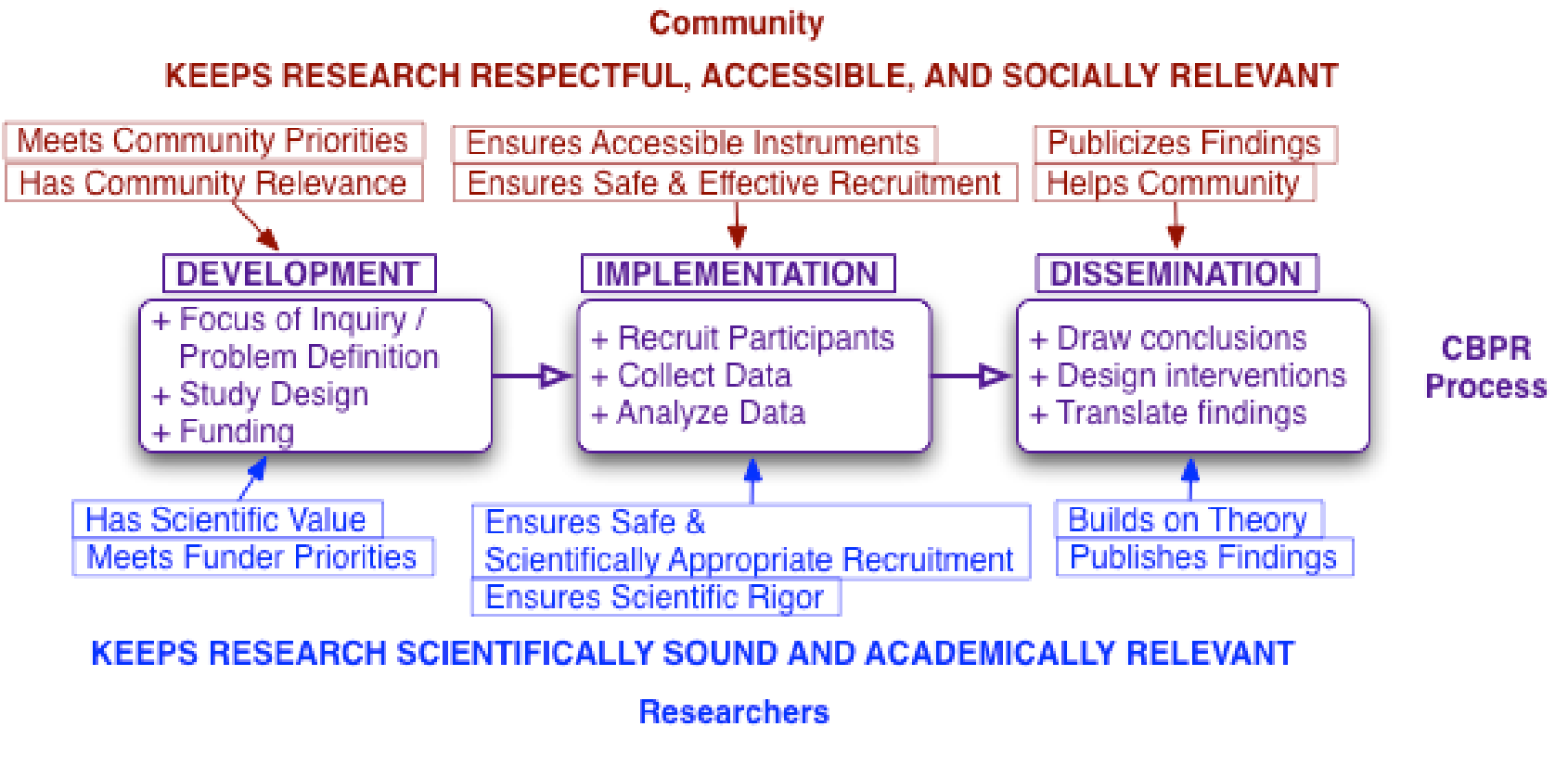
One Model of CBPR



Ethical Concerns with Participatory Research

- Compensation of community members
- Sharing power
- Tokenism
- Representativeness of co-researchers
- “But anyone who can be a co-researcher isn’t disabled enough to have a *REAL* developmental disability!”

Ethical (and other) Bonuses with Participatory Research

- Equitable inclusion
- Relevant questions and desired interventions
- Respectful research
- Civil rights framing
- Accessible study materials (including consents!)
- Personal and community benefits
- *Better science!*

Conclusions

- Infuse **disability rights** principles into the conduct of research
- Strive to **include** people with developmental disabilities in research (respondents, co-researchers)
- Attend to those who provide **informal and formal support** to people with developmental disabilities
  - Facilitate inclusion, exclusion, coercion
- Engage in **reflexive practice**

Discussion

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