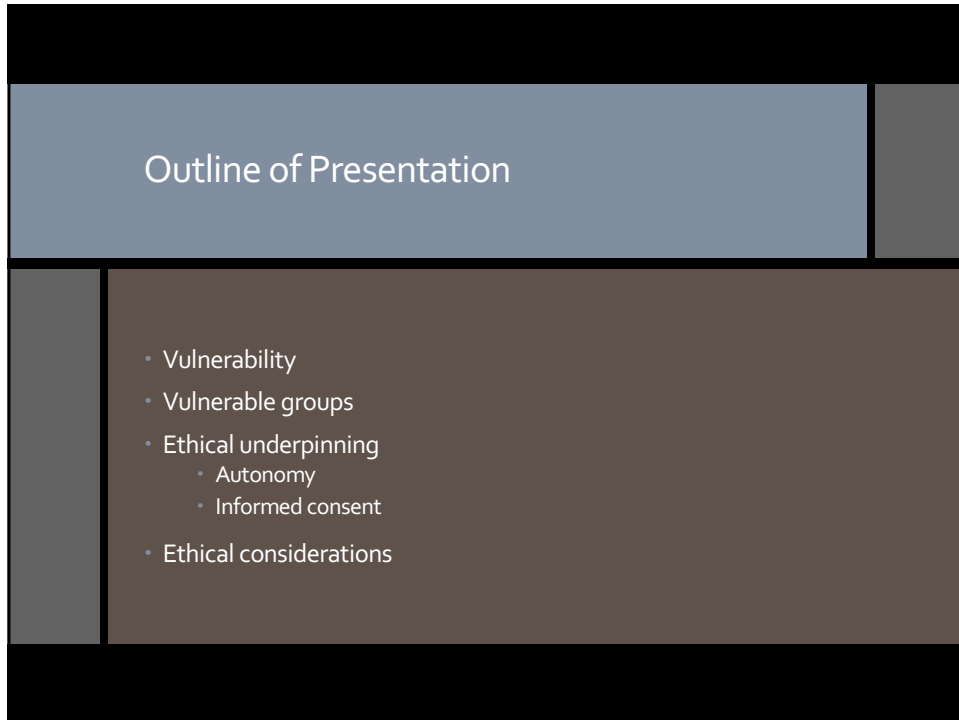




1



2

A presentation slide with a black header and footer. The main content area has a light blue background. The title "Outline of Presentation" is centered in white. Below the title, there is a list of topics in white text on a dark brown background.

Outline of Presentation

- Vulnerability
- Vulnerable groups
- Ethical underpinning
 - Autonomy
 - Informed consent
- Ethical considerations

3

A presentation slide with a dark grey background. On the left, there is a light blue trapezoidal shape containing the text "Shift in Research". To the right of this shape is a list of topics in white text.

Shift in Research

- Risk/ Benefit
- Risk of unethical research
 - Poor population
 - Low level of literacy
 - Acceptance of authority
 - Need for health services

4



The quality or state of being exposed to the possibility of being attacked or harmed, either physically or emotionally.



Vulnerability

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Vulnerability in the Research Ethics Context

- “a substantial incapacity to protect one’s own interests”



CIOMS 1993, 10

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Philosophical versus Political Vulnerability

Philosophical

- Persistent vulnerability as an essential feature of being human
- Inherently vulnerable
- Human condition is characterized by circumstantial fragility and weakness

Political

- Variable (or selective) vulnerability due to specific circumstances
- Those who are rendered vulnerable by their society
- Social and economic conditions make some people more exposed to threats and the possibility of harm than others, especially in developing countries
- Onora O'Neill, 1996:192

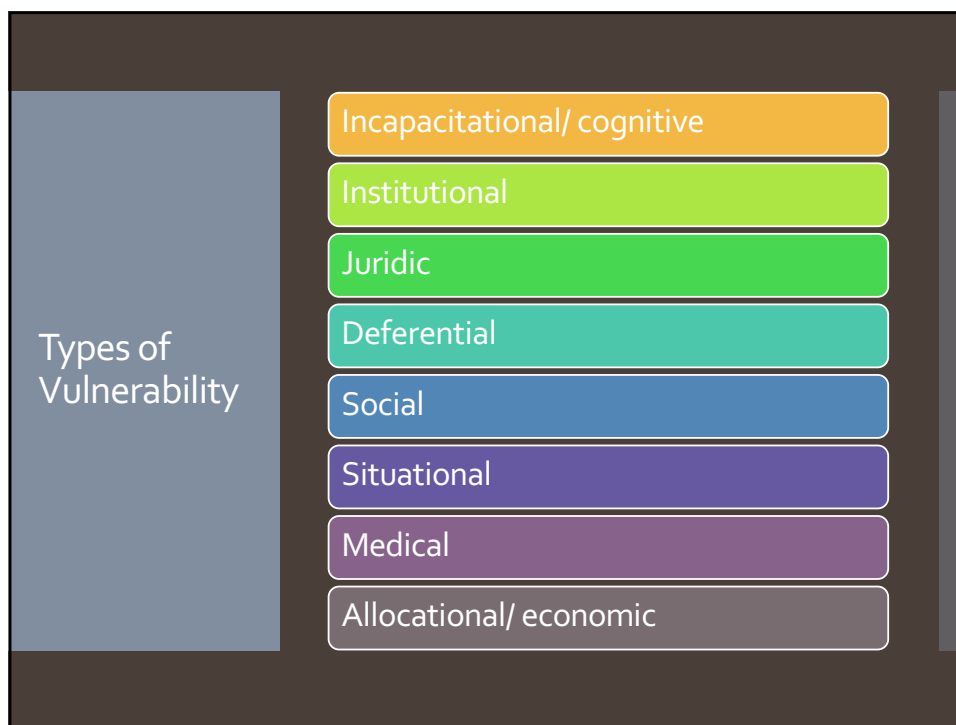
7

Two General Themes

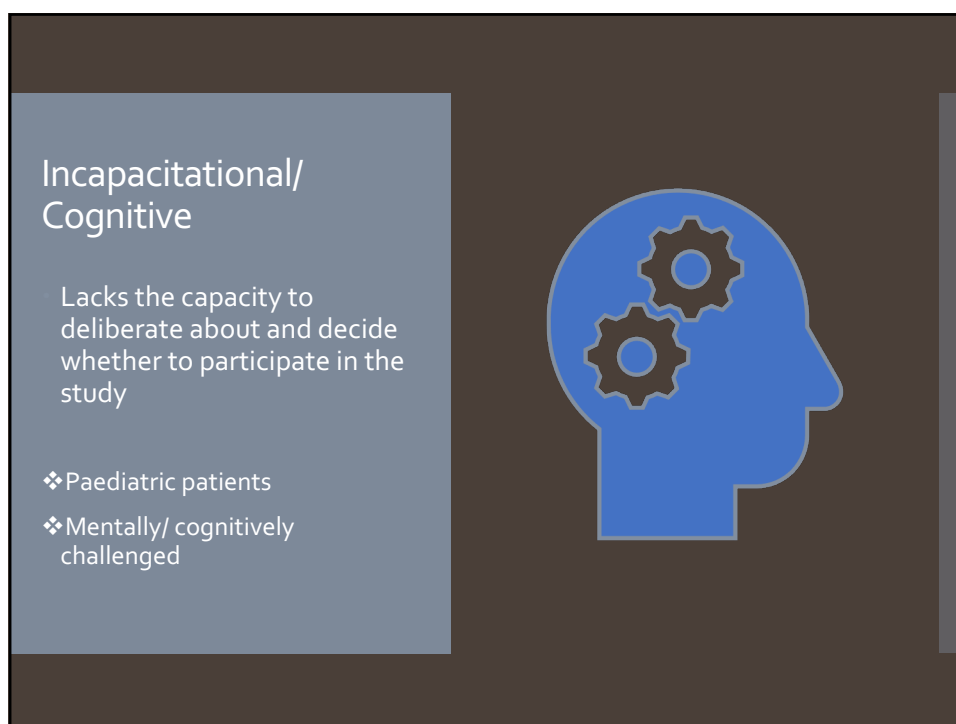
- Difficulty providing voluntary, informed consent arising from limitations in decision-making capacity or situational circumstances
- Especially at risk for exploitation, coercion & undue influence

Ethical and policy issues in research involving human participants: report and recommendations of the National Bioethics Advisory Commission. National Bioethics Advisory Commission. 2001

8



9



10

Institutional

Negatively impacts on the voluntary nature of decisions

- ❖ Students
- ❖ Old-age homes
- ❖ Incarcerated people



11

Juridic

Liability to the authority of others who may have an independent interest in participation in the study

- Minor – parent
- Adult child – parent (in some cultures)
- Wife – husband (in some cultures)
- Elderly parent – adult child



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Deferential

Given to patterns of deferential behaviour that may mask an underlying unwillingness to participate

- ❖ Child to parent
- ❖ Female to male
- ❖ Young to elder
- ❖ Deference to doctors



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Social

Belongs to a group whose rights and interests have been socially disvalued

- ❖ Racial/ ethnic minority
- ❖ Women
- ❖ Disabled



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Allocational/ Economic

Lacking in subjectively important social goods that will be provided as a consequence of participation in research

- ❖ Communities with limited access to health services
- ❖ Economically underdeveloped communities



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Sources of Vulnerability

Economic: status & geographic location

Health: age, functional or developmental status

Communication barriers

Vulnerability associated with position, race, ethnicity, sex, sexuality, etc.

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Vulnerable Groups

- Racial minorities
- Economically disadvantaged
- Very sick
- Institutionalized
 - Dependent status and their frequently compromised capacity for free consent
 - Easy to manipulate as a result of their illness or socioeconomic condition
 - May continually be sought as research subjects, owing to their ready availability in settings where research is conducted

THE BELMONT REPORT ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, 1979

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Other Vulnerable Groups

- Students
- Educationally disadvantages
- Children & adolescents
- Pregnant women
- Foetuses & neonates
- Incarcerated people
- Mental disabilities
- Substance use disorders
- Vulnerable communities

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Vulnerable Communities
UNAIDS
Definition

- Limited
 - Economic development
 - Human rights
 - Understanding of scientific research
 - Healthcare and treatment options
 - Individual informed consent

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Ethical Underpinning

Kant: all persons have unconditional moral worth & capacity to determine own destiny

Mill: all should be permitted to develop according to own personal convictions, as long as they do not interfere with a like expression of freedom by others

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African Moral Philosophers

Personhood


Ifeanyi Menkiti

Personhood is the sort of thing which has to be attained, and is attained in direct proportion as one participates in communal life through the discharge of the various obligations defined by one's stations

Kwame Anthony Appiah

"One is bound to be formed – morally, aesthetically, politically, religiously – by the range of lives one has known"

Godfrey Tangwa
Community




23

Metaphysical Concept of Autonomy

Normal choosers who act:

- Intentionally
- With understanding (by degree)
- Without controlling influence (by degree)



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Communal Concept of Autonomy

Capacity of autonomy is most valuable when used in relation to a community's values and instrumentally for making the proper choices that will promote one's own and the community's well-being

Social-moral thesis

Importance of how such freewill is used

How an individual's choices are guided by internalized communal values



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Informed Consent

■ Threshold Elements

- Competence
- Voluntariness

■ Information Elements

- Disclosure
- Recommendation
- Understanding

■ Consent Elements

- Decision
- Authorization

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Capacity to Give Consent

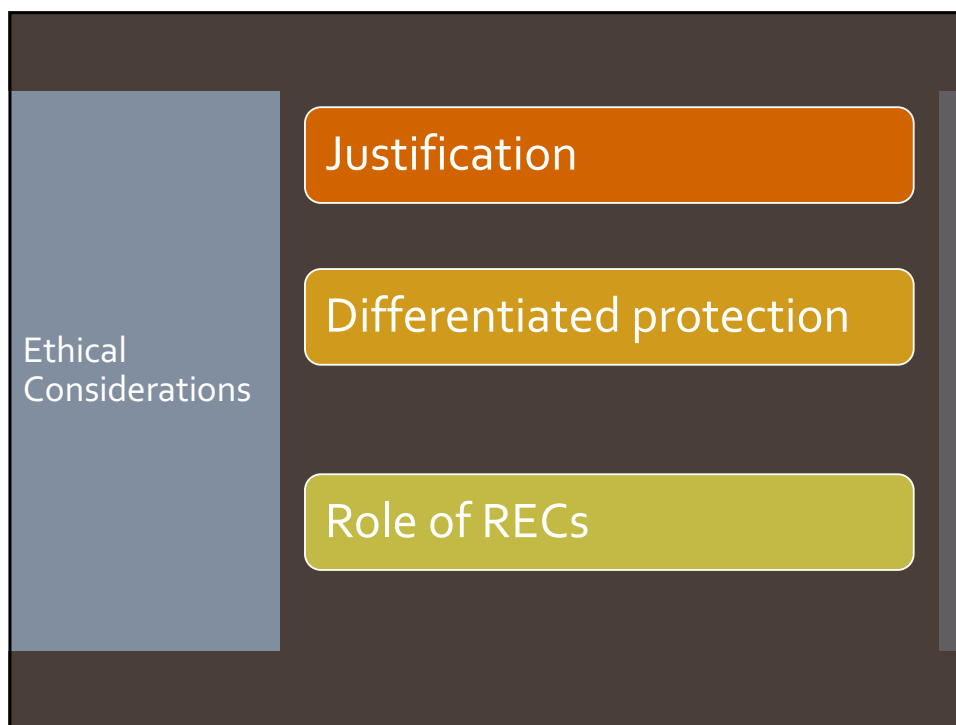
- Question of fact determined on case-by-case basis
- Even if a person has been declared legally incompetent, she may retain the capacity to make decisions
- Capacity to decide (understanding)
- Communicate the decision (language)

27

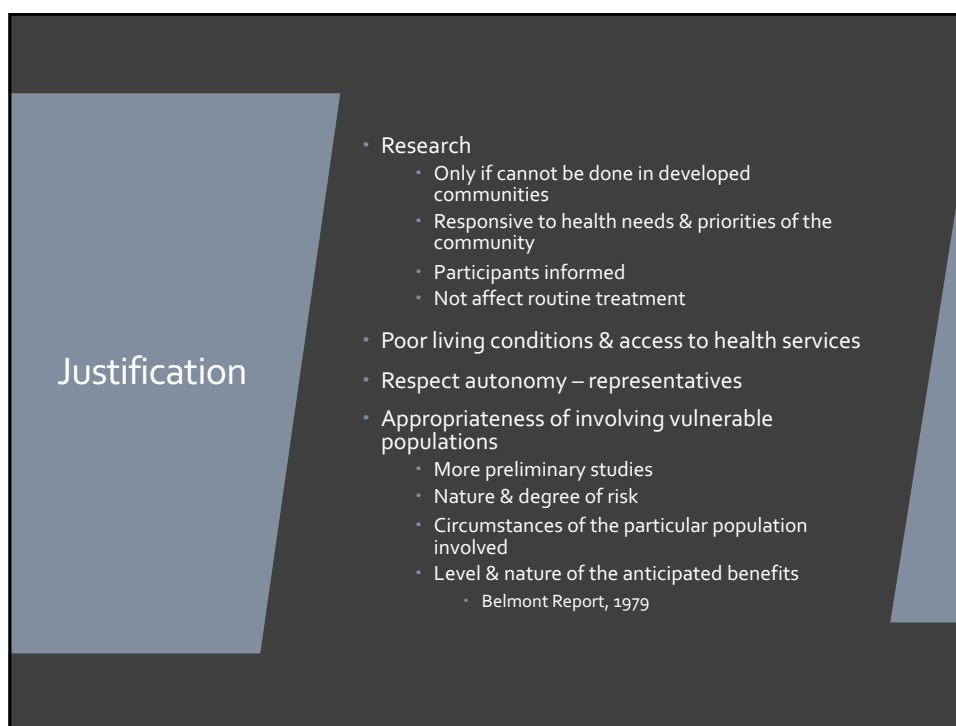
Proxy Decision Makers

- Clear and full justification in protocol
- Valid scientific hypotheses - reasonable possibility of more benefit than standard care
- Not contrary to medical interests
- No more risk of harm than inherent in the patient's condition or alternative methods of treatment
- Participant/ relatives/ legal representatives informed of research ASAP
 - Advised of right to withdraw

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Protection

- Additional safeguards to protect rights & welfare
 - Research should be responsive to the needs of the population
 - Stricter consent requirements
 - Limiting the risks of exposure

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Protection

- Protection most relevant where persons have individual incapacities or where autonomous decision-making ability is compromised
 - Limited paternalistic protection can be justified
- Less appropriate when vulnerability is related to social and economic conditions
 - Protection can easily become unduly paternalistic since nothing wrong with decision-making capacity of involved persons
 - Different kind of empowerment is needed
 - Affirmative action based on dignity, respect & social responsibility
 - Post-trial access and benefit-sharing
- 2 different regimes of protection
 - Equal protection for every human being as essentially vulnerable
 - Specific positive action
 - Remedial treatment and repair for specific susceptible persons

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Role of RECs

- Consider different types of vulnerability with due regard for the context
- Consent & power
 - Benefits & risks of gatekeepers' permission
- Sampling methodology
 - Equal opportunity
- Confidentiality & trust
 - Conflicting duties
- Empower participants in the research process
 - Feedback to participants
- Ancillary support

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Conclusion

"A man without ethics is a wild beast loosed upon this world" - Camus

An Ethics of Responsibility
Hans Jonas

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