

Researching Vulnerable Groups



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AIM & OBJECTIVES

-
- to discuss the concept of vulnerability in research ethics.
 - to discuss how the risks and benefits of researching vulnerable groups are appropriately balanced and justified.
 - to review ethics application forms.



Research & Ethical Standards

Guidance

Oversight of research proposal

Research Ethics Boards

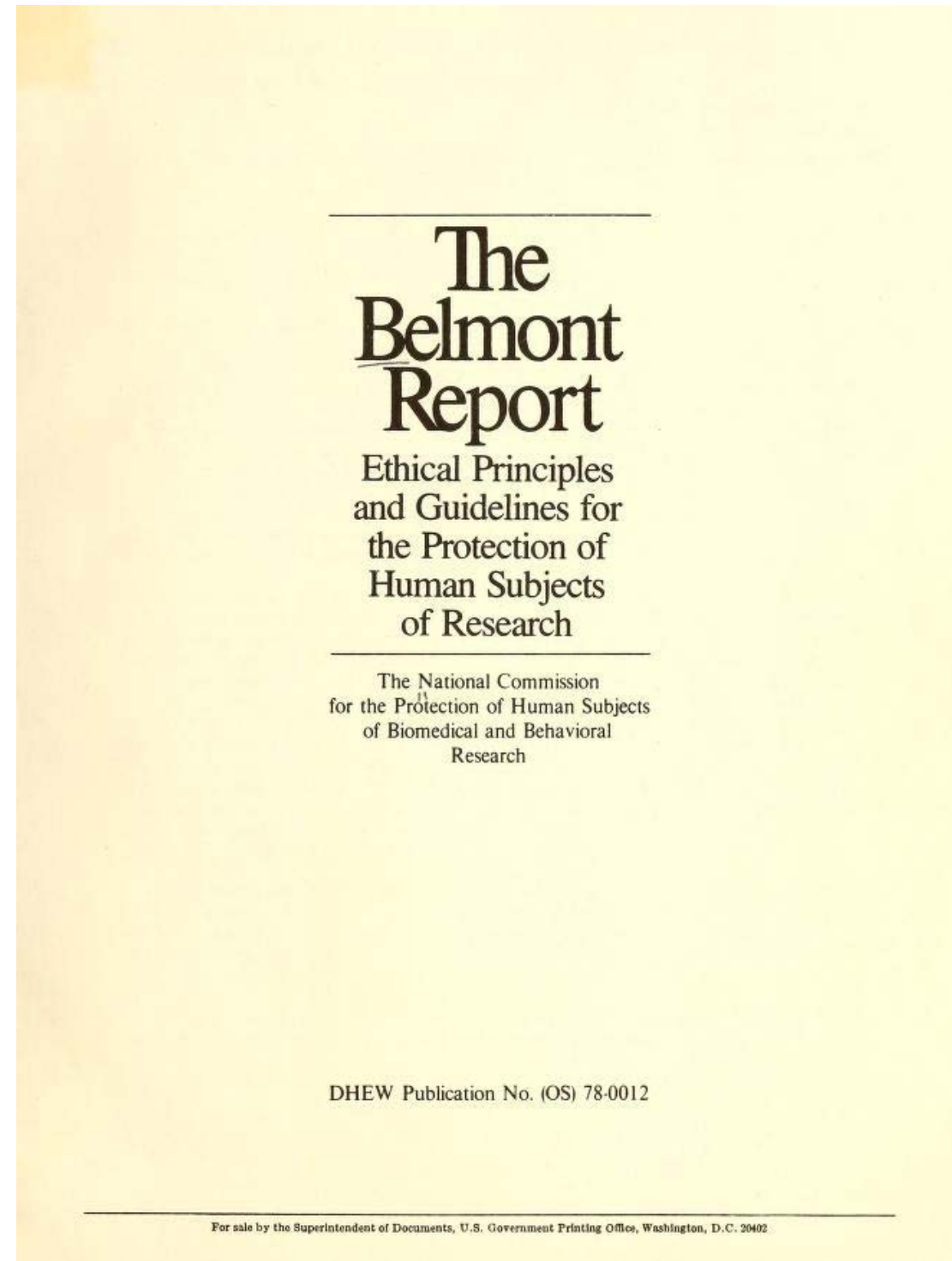




Why is the notion of vulnerability relevant to research ethics?

"An identifiably increased likelihood of incurring additional or greater wrong" (Hurst, 2008, p. 191)

Consent-based definitions
Harm-based definitions



Ethical Principles (Research with vulnerable groups)

US Belmont Report (1979)



HURST, S. A. (2008). VULNERABILITY IN RESEARCH AND HEALTH CARE; DESCRIBING THE ELEPHANT IN THE ROOM? BIOETHICS, 22, 191-202.

Table 1. Examples of vulnerability in international guidelines for research ethics

Source	Cited examples of vulnerability in human subjects research
Belmont report	• Racial minorities • The economically disadvantaged • The very sick • The institutionalized
45 CFR 46	• Children • Prisonners • Pregnant women and foetuses
Declaration of Helsinki	• Incompetent persons • Persons susceptible to coercion • Persons who will not derive direct benefits from participation • Persons for whom research is mixed with clinical care
CIOMS	• Those with limited capacity or freedom to consent or to decline to consent . . . [including] children, and persons who because of mental or behavioural disorders are incapable of giving informed consent, • Junior or subordinate members of a hierarchical group . . . [such as] medical and nursing students, subordinate hospital and laboratory personnel, employees of pharmaceutical companies, and members of the armed forces or police, • Elderly persons, • Residents of nursing homes, • People receiving welfare benefits or social assistance and other poor people, • The unemployed, • Patients in emergency rooms, • Some ethnic and racial minority groups, • Homeless persons, • Nomads, • Refugees or displaced persons • Prisoners • Patients with incurable disease • Individuals who are politically powerless • Members of communities unfamiliar with modern medical concepts
ICH tripartite guidelines	• Members of a group with a hierarchical structure such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees in the pharmaceutical industry, members of the armed forces, and persons kept in detention • Patients with incurable diseases • Persons in nursing homes • Unemployed or impoverished persons • Patients in emergency situations, • Ethnic minority groups, • Homeless persons • Nomads, • Refugees, • Minors, • Those incapable of giving consent



Bracken-Roche, Bell, Macdonald, & Racine, 2017
Hurst, 2008

Is vulnerability an 'inherent' quality of VG?
The problem with prescriptive group lists.

Vulnerability is caused by both individual and
situational factors.

UK

UK Research Governance Framework for
Health and Social Care (2005)

UK Policy Framework for Health and Social
Care Research (2020)

NHS - Health Research Authority

Economic and Social Research Council
(ESCR)

Higher Education - REC

Discipline specific - e.g., BPS, BACP



Children

Prisoners

Vulnerable adults – e.g., persons with
mental health issues

Patients in emergency settings

Ethnic minority groups



RESEARCH FRAMEWORK



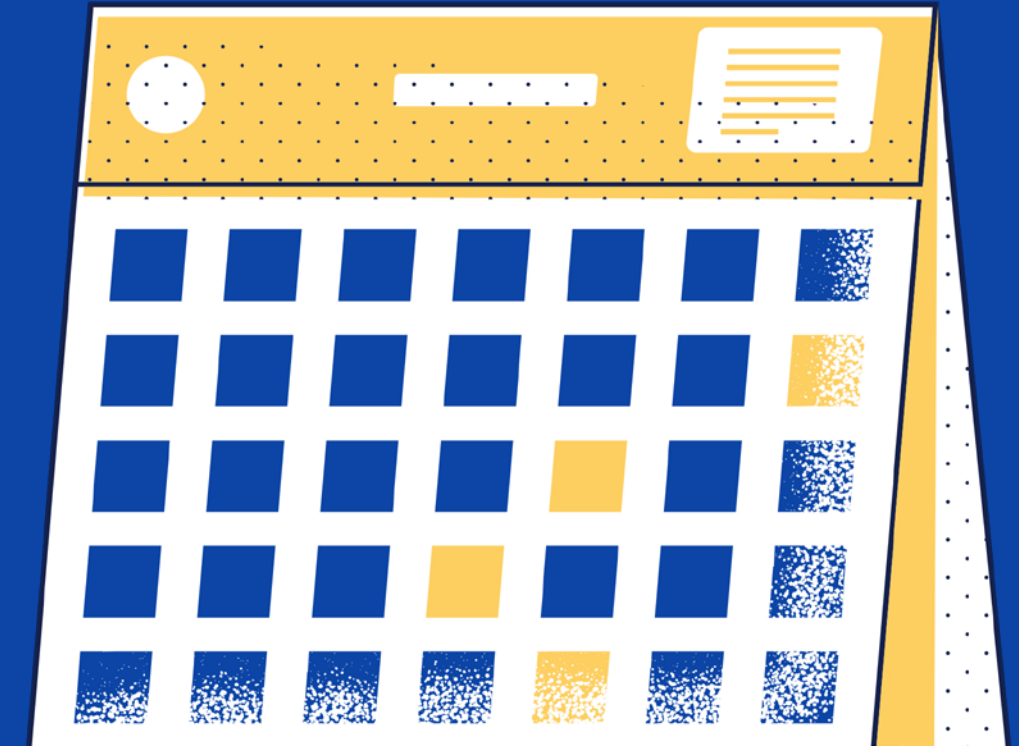
Research Proposal

Recruitment Process

Managing Risk



TODAY'S SESSION



Mental Health Capacity Act
(2015)

UK Policy Framework for
Health and Social Care
Research (2020)

Consent and Participant
Information Guidance (NHS
Health Research Authority)

BPS Code of Human Research
Ethics (2014)

"The existence of lengthy, detailed and prescriptive professional or institutional regulations raises the risk of researchers following the letter, but not the spirit, of the regulations and may in consequence lead to research being carried out that is ethically flawed. Overly detailed regulations may also make it more difficult for RECs to engage with the nuances of the ethics of individual cases."
(BPS, 2014, p.7)