

Bioethics: Autonomy and Health (Fall 2012)

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CHALLENGES OF INFORMED CONSENT

By way of introduction...



◎ Repo! The Genetic Opera

- ◎ Are there limits to what someone can freely and voluntarily consent?
 - Should some options not be offered?
- ◎ Given the asymmetric power relation between physicians or researchers on the one hand and patients or subjects on the other, how can free, voluntary, and informed consent be obtained?

Requirements and Aims of Informed Consent

- ⊙ Crucial aspect of respecting autonomy of patients and research subjects
 - But respecting autonomy involves more than offering informed consent form!
- ⊙ “requires much more than avoiding deception and coercion. It requires an attempt to instill relevant understanding and to avoid many forms of manipulation” (Beauchamp & Childress 118)

Tuskegee Syphilis Study



Meanings of 'Informed Consent'

- ⊙ Autonomous authorization
 - More than mere assent
 - Does not have to be perfect to have moral force
- ⊙ Legally and institutionally valid consent
 - Based on social rules, avoiding legal liability
- ⊙ Can autonomously authorize without being able to give valid consent and *vice versa*



CERTAINLY OUT OF THE HOUSE,
OUT OF THE NEIGHBORHOOD,

Willowbrook Hepatitis Study

Limits of Informed Consent (?)

- ⊙ Cannot always tailor to informational and autonomy needs of particular patient/subject
- ⊙ Limitations in information processing, understanding, reflective and true beliefs
- ⊙ Therapeutic privilege
 - Controversial, can be narrowly or broadly interpreted
- ⊙ Research study designs
 - General vs. specific consent
 - Single- and double-blind studies

Forms of Influence & Obligations

⊙ Coercion

- “one person intentionally uses a credible and severe threat of harm or force to control another” (B&C 133)
- Credible threat + subject responds as if threatened

⊙ Persuasion

- Remonstratión, appeal to reason

⊙ Manipulation

- “swaying people to do what the manipulator wants by means other than coercion or persuasion (134)

⊙ Problems of inducement in medical research, attempts to convince patients to agree with physician in medical care, paternalistic policy measures



Nuremberg Code

Nazi Experiments & Nuremberg

Discussion Questions

- Imagine that there was a proposed study that could potentially lead to the eradication of a (non-lethal but prevalent) sexually transmitted disease. The research design calls for a large infected group that can be tested and re-tested at regular intervals, and they cannot find volunteers in their local community.
 - If the most efficient and reliable results could be obtained by infecting adults through deception, would it be justified? What if they consented to the research but not to the possibility of deception?
 - What if the adults were a poor, uneducated population in a developing country? What if they gave a general consent?
 - What if the subjects were cognitively disabled children?

Guatemala STD Research

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	Unique Line Number	PCSBI #	Source	PCSBI HSPI Archives	Experiment Number	Date	Subject Age	Subject Sex	Subject Num	Additional Population Description	Sulf a Urin	Gonorrhea +/-	Gonorrhea Test	Gonorrhea Sugars	Syphilis +/-
2	7106	CSW-0001	Notebook 1: Daily Laboratory Recor	CTLR_0000003	nd	2/11/1947	18	F	nd	nd	nd	nd	culture	nd	nd
3	7107	CSW-0001	Notebook 1: Daily Laboratory Recor	CTLR_0000003	nd	2/13/1947	18	F	nd	nd	nd	nd	culture	nd	nd
4	7108	CSW-0001	Notebook 1: Daily Laboratory Recor	CTLR_0000004	nd	2/15/1947	18	F	nd	nd	nd	nd	nd	nd	nd
5	7176	CSW-0001	Gonarrhea Experiment #1	CTLR_0001742	nd	6/1946, 8/1946, 11	18	F	nd	nd	nd	nd	nd	nd	nd
6	7621	CSW-0002	Notebook 1: Daily Laboratory Recor	CTLR_0000133	nd	7/30/1947	nd	F	3	nd	nd	nd	gram neq diplococci	nd	nd
7	7622	CSW-0002	Notebook 1: Daily Laboratory Recor	CTLR_0000191	nd	9/25/1947	nd	F	3	nd	nd	nd	-(before), -(after)	nd	nd
8	7623	CSW-0002	Notebook 1: Daily Laboratory Recor	CTLR_0000192	nd	9/26/1947	nd	F	3	nd	nd	nd	-(before), -(after)	nd	nd
9	7624	CSW-0002	Notebook 1: Daily Laboratory Recor	CTLR_0000195	nd	9/27/1947	nd	F	3	nd	nd	nd	-	nd	nd
10	7625	CSW-0002	Notebook 1: Daily Laboratory Recor	CTLR_0000201	nd	10/2/1947	nd	F	3	nd	nd	nd	nd	nd	nd
11	7626	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000236	nd	11/18/1947	nd	F	3	nd	nd	nd	-(after)	nd	nd
12	7627	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000237	nd	11/19/1947	nd	F	3	nd	nd	nd	-(before), -(after)	nd	nd
13	7628	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000258	nd	12/9/1947	nd	F	3	nd	nd	nd	nd	nd	nd
14	7629	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000260	nd	12/9/1947	nd	F	3	nd	nd	nd	nd	nd	nd
15	7630	CSW-0002	Gonarrhea Experiments - Military	CTLR_0001942	nd	1/20/1948	nd	F	3	nd	nd	nd	nd	nd	nd
16	7631	CSW-0002	Gonarrhea Experiments - Military	CTLR_0001952	nd	1/21/1948	nd	F	3	nd	nd	nd	nd	nd	nd
17	7633	CSW-0002	Gonarrhea Experiments - Military	CTLR_0001924	nd	1/28/1948	nd	F	3	nd	nd	nd	nd	nd	nd
18	7632	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000308	nd	1/28/1948	nd	F	3	nd	nd	nd	nd	nd	nd
19	7634	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000374	1	6/28/1948	nd	F	3	nd	nd	nd	nd	nd	nd
20	8063	CSW-0002	Gonarrhea Experiments - Military	CTLR_0001912	nd	6/29/1948	nd	F	nd	nd	nd	nd	nd	nd	nd
21	7635	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000374	1	6/29/1948	nd	F	5	nd	nd	nd	nd	nd	nd
22	7636	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000388	nd	7/3/1948	nd	F	5	nd	nd	nd	nd	nd	nd
23	7637	CSW-0002	Gonarrhea Experiments - Military	CTLR_0001970	nd	9/25/1947 and 9/26	nd	F	5	nd	nd	nd	nd	nd	nd
24	7638	CSW-0002	Notebook 4: Guatemala Journal Sta	CTLR_0000552	22	9/25+26/1947	nd	F	5	nd	nd	nd	nd	nd	nd
25	7639	CSW-0002	Gonarrhea Experiment 9-26	CTLR_0001859	nd	Sept. 26	nd	F	5	nd	nd	nd	nd	nd	nd
26	8275	CSW-0003	Notebook 1: Daily Laboratory Recor	CTLR_0000103	nd	7/1/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
27	8276	CSW-0003	Notebook 1: Daily Laboratory Recor	CTLR_0000159	nd	8/21/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
28	8277	CSW-0003	Notebook 1: Daily Laboratory Recor	CTLR_0000181	nd	9/18/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
29	8278	CSW-0003	Notebook 1: Daily Laboratory Recor	CTLR_0000195	nd	9/27/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
30	8279	CSW-0003	Notebook 2: Daily Laboratory Recor	CTLR_0000219	nd	10/16/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
31	8280	CSW-0003	Notebook 2: Daily Laboratory Recor	CTLR_0000222	nd	10/27/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
32	12857	CSW-0004	Notebook 1: Daily Laboratory Recor	CTLR_0000120	nd	7/17/1947	nd	nd	nd	nd	nd	nd	nd	nd	nd
33	13329	CSW-0004	Notebook 1: Daily Laboratory Recor	CTLR_0000157	nd	8/19/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
34	13328	CSW-0004	[CSW-4, CSW-10, CSW-7]	CTLR_0001544	nd	8/21	nd	F	nd	nd	nd	nd	nd	nd	nd
35	13327	CSW-0004	[CSW-4, CSW-10, CSW-7]	CTLR_0001547	nd	8/23/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
36	13334	CSW-0005	Notebook 1: Daily Laboratory Recor	CTLR_0000032	nd	4/9/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
37	13335	CSW-0005	Notebook 1: Daily Laboratory Recor	CTLR_0000138	nd	8/4/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
38	13336	CSW-0005	Notebook 4: Guatemala Journal Sta	CTLR_0000537	16	8/4/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
39	13337	CSW-0005	Notebook 1: Daily Laboratory Recor	CTLR_0000140	nd	8/6/1947	nd	F	nd	nd	nd	nd	nd	nd	nd
40	13338	CSW-0005	Notebook 1: Daily Laboratory Recor	CTLR_0000143	nd	8/8/1947	nd	F	nd	nd	nd	nd	nd	nd	nd



“ETHICALLY IMPOSSIBLE”
STD Research in Guatemala
from 1946 to 1948

Presidential Commission
for the Study of Bioethical Issues

September 2011

Presidential Commission Report

Daily Show on the U.S. apology...



Questions? Comments?

