

# Consent: health and biomedicine

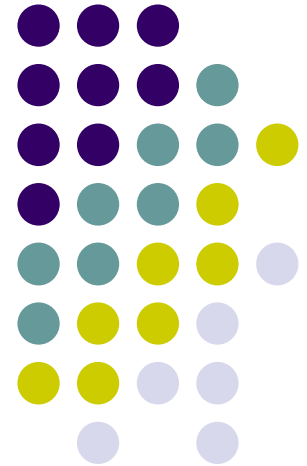
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Conflict of interest: None declared



# Evolution of consent



- The Nuremberg Doctors' Trial 1946
- Tuskegee Study of Untreated Syphilis 1932-1972
- Public Health Service Sexually Transmitted Diseases (STD) Inoculation Study in Guatemala 1946-8
- Declaration of Helsinki 1964 (last update 2013)
- First RECs in UK late 1960s/early 1970s
- Central Office for Research Ethics Committees 2000
- Health Research Authority 2011
- Human Tissue Act 2004 following Alder Hey Affair
- GDPR 2018

# Consent and publication



- Absolute requirement
- **Guide for authors**
- ‘Authors should include a statement in the manuscript that informed consent was obtained for experimentation with human subjects.’
- ‘Appropriate consents, permissions and releases must be obtained where an author wishes to include case details or other personal information or images of patients and any other individuals’

# Declaration of Helsinki: version 7

## ( paragraph 26 )



- In medical research involving human subjects capable of giving **informed consent**, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study.
- The potential subject must be informed of the right to **refuse to participate in the study or to withdraw consent** to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.
- After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential **subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.**
- **All medical research subjects should be given the option of being informed about the general outcome and results of the study.**
- <http://www.wma.net/en/30publications/10policies/b3/>

# GDPR and consent



- The person has consented to the use of their data
- Consent is obtained in a way that is understandable and accessible to the subject, and that there is an opportunity for the person to withdraw from the study at any time: (Article 7).
- ‘The right to be forgotten’. This means to be able to request, in certain conditions, the complete erasure of their data.
- But not necessarily if data lawfully obtained and is still necessary for the purpose for which it was obtained (Article 17).

# Who gives consent



- The patient/ participant
- A legal representative
- Consider mental and physical capacity
- Legal age of consent/ children (varies worldwide)
- Provision for emergency research e.g. adrenaline cardiac arrest trial

# Obtaining and recording consent



- Written
- Verbal
- Electronic
- Culturally sensitive
- Storing records of consent
  
- Evolving from studies with a limited time span and data access, into a long term perspective with future use of data by others and open access publication
- Misconduct investigations may be many decades later

# Withdrawal of consent



- Up to what point and how
- Use of previously collected data and tissue
- Ability to collect follow-up healthcare data (safety)
- **Clinical trials** CTR Article 28(3) states that withdrawal of informed consent shall not affect any activities already carried out and the use of data obtained on the basis of the informed consent before that withdrawal
- [https://ec.europa.eu/health/sites/health/files/files/documents/qa\\_clinicaltrials\\_gdpr\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/documents/qa_clinicaltrials_gdpr_en.pdf)



# Case Reports and Consent



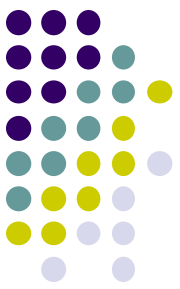
- Potentially identifiable material
- Once published, dissemination including images cannot be prevented even if the article is retracted or removed

# Consent documentation



- Recruitment material/ advertisements
- Interview/ screening schedules
- Participant information sheets
- Consent forms
- Information/ assent material for children/age appropriate
- Information for all study groups

# Documentation: part of a check list



- Voluntary
- Withdrawal
- Inducements and coercion
- Taking, storage and destruction of tissue samples/ recordings
- Data/ samples: storage/ duration/ sharing and with whom
- Privacy: publication/ quotations/ images
- Independent source of information
- Factors specific to the project: disclosure/ audit of records by regulatory authorities and sponsors

# Further information



- Health Research Authority <http://www.hra-decisiontools.org.uk/consent/docs/Consent%20and%20PIS%20Guidance.pdf>
- Medical Research Council <https://mrc.ukri.org/research/policies-and-guidance-for-researchers/guidance-on-patient-consent/>
- Writing case reports, consent for publication and General Data Protection Regulation (GDPR) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7190758/>
- PARAMEDIC2 trial <https://warwick.ac.uk/fac/sci/med/research/ctu/trials/critical/paramedic2>