UNIVERSITY OF BERGEN

Practicalities of research ethics and data protection

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Agenda

- ethical principles
- informed consent
- data protection
- which studies have to be approved
- what documents to include

Ethical principles

- purpose: protect participants against risks; satisfying the requirements of the Health Research Act:
  - organized and carried out in a responsible manner
  - based on respect for the participants' human rights and dignity (priority over scientific and social interests)
- responsibility: proper project organization, proper data handling / storage, insurance, internal control

Ethical principles

- **proportionality**: balance between beneficial research and participants' welfare and integrity:
  - is research beneficial for (1) participants, (2) group of persons or (3) society / science (knowledge)?
  - risk / inconvenience justified by the exp. benefits?
- **approval** PRIOR to conducting the study: submission to REK; 7 committees; ~1700 appl.

Informed consent

consent must be **voluntary**, **specific**, **informed** and **expressed**:

- **voluntary**: avoid influence that would lead people to accept higher risks; dependent / vulnerable people (payment, researcher-participant-relation)
- **specific**: data acquisition / processing must have specified purposes
- **informed**: information must be relevant + objective (describe purpose, methods, pot. benefits / risks / discomfort); presented in an accessible form, using clear, plain language
- **expressed**: active consent - participant gives a declaration where he / she expresses the consent

Templates under REK → Deadlines and forms → Templates

Informed consent

Competence to give consent:

- legally competent persons and minors from 16: competence to consent to participate in medical research
- minors up to 16 (up to 18 for clinical trials) or adults who lack competence to give consent: parents / next-of-kin have authority to give consent
  however: even if the participant lack competence to give consent, he/she will have the **right to refuse to participate**

Data protection

any information to identify a person (directly / indirectly)

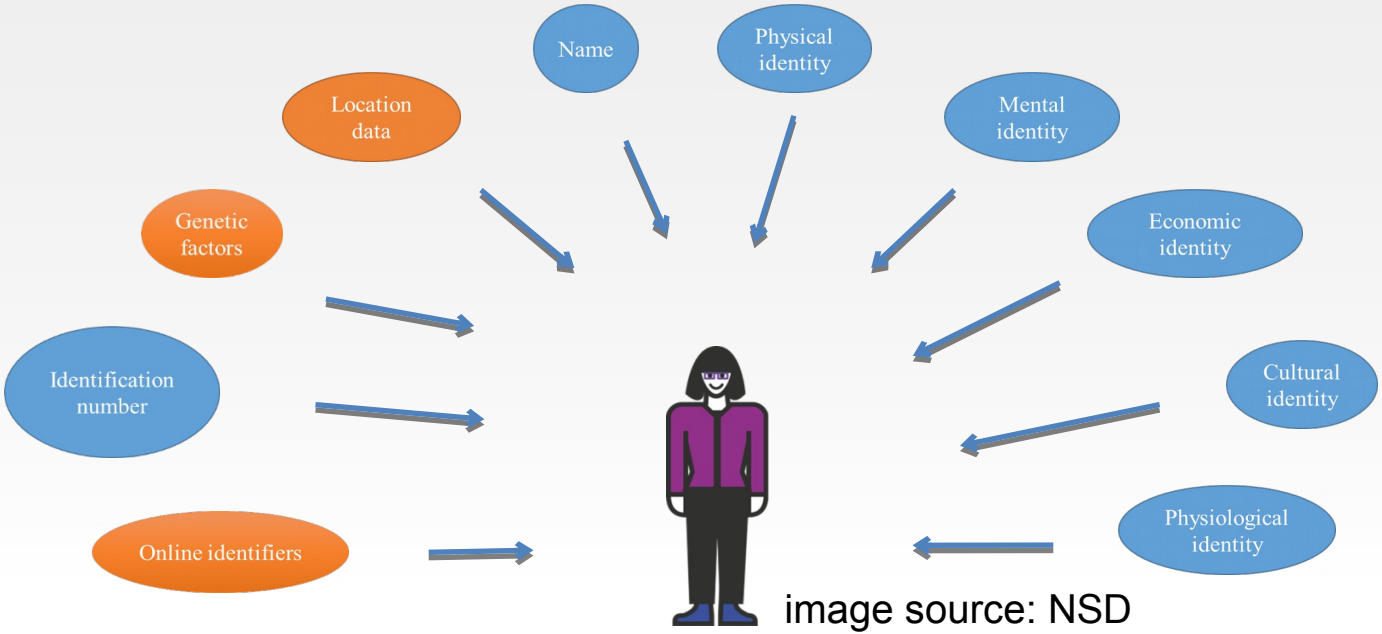
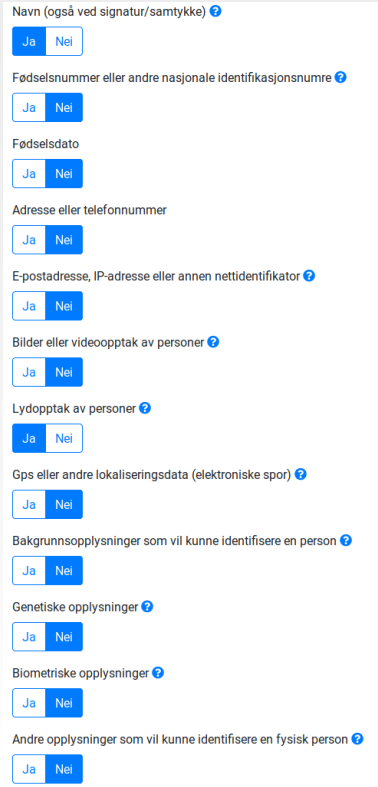


image source: NSD

Data protection

- data must be relevant + necessary to the objective of the project (need to know NOT nice to know; data minimization)
- identification not greater/longer than required
- accurate (incl. right for correction)
- appropriate security: encrypt data – separate key / data – delete key after project conclus.
- institution (UiB, DPO) must ensure the legal basis for processing data



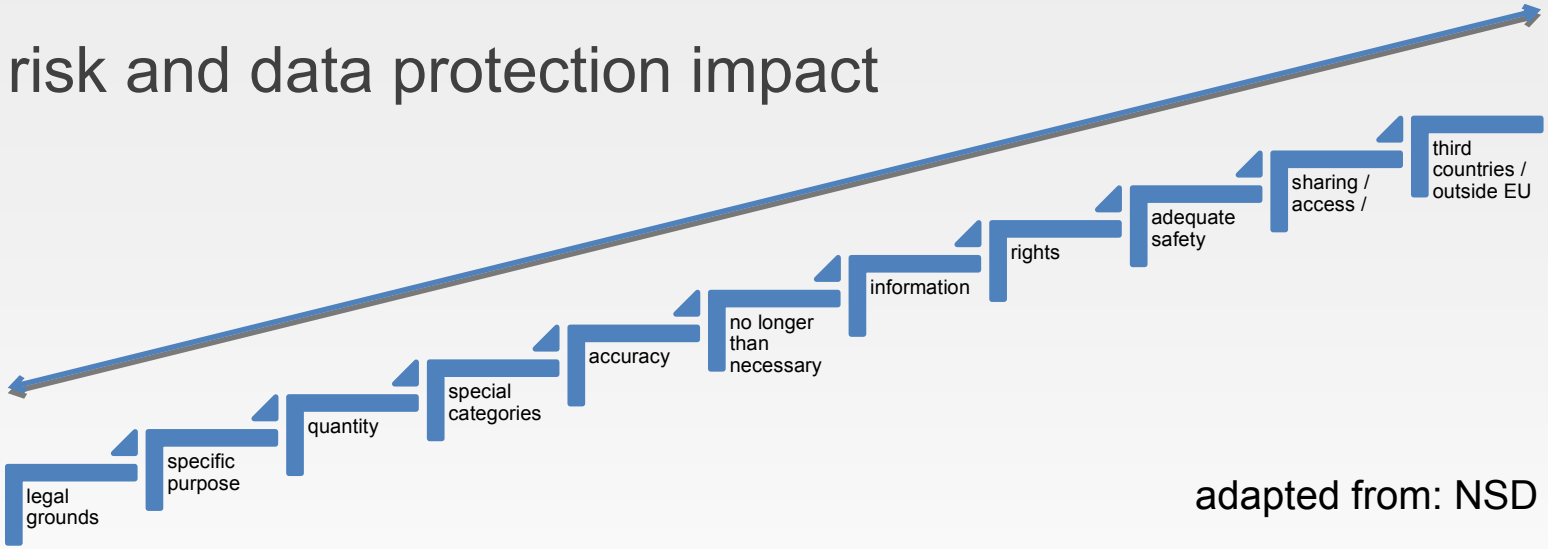
Data protection

especially protected information:

- racial or ethnic origin
- political opinions
- trade-union membership
- religious or philosophical beliefs
- information on sexual orientation and sex life
- health information
- genetic data or biometric data

Data protection

risk and data protection impact



adapted from: NSD

Which studies have to be approved?

REK:

- health research on: (1) human beings; (2) human biological material or (3) personal health data
- don't apply: anonymous information, other (non-health) research using only non-health data, quality control
- if in doubt: application form «Remit assessment»

NSD:

- if any personal information are stored (even signatures on a consent form)

What documents to include?

REK and NSD:

- all used questionnaires or other materials that are used to collect data (e.g., text of instructions and items of online experiments)

REK:

- materials for recruitment (poster, e-mail-draft)
- information sheet / consent form
- study protocol

Literature and further information

- www.etikkom.no/FBIB/
- helseforskning.etikkom.no/reglerogrutiner/loverogregler
- helseforskning.etikkom.no/frister/malforinformasjonsskriv
  https://nsd.no/personvernombud/hjelp/informasjon_samtykke/informere_om.html

Thank you for your interest and your attention!

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