Research Ethics and Legal Compliance:
Informed Consent and Data Licensing

Sebastian Netscher

CESSDA Training at the Data Archive for the Social Sciences
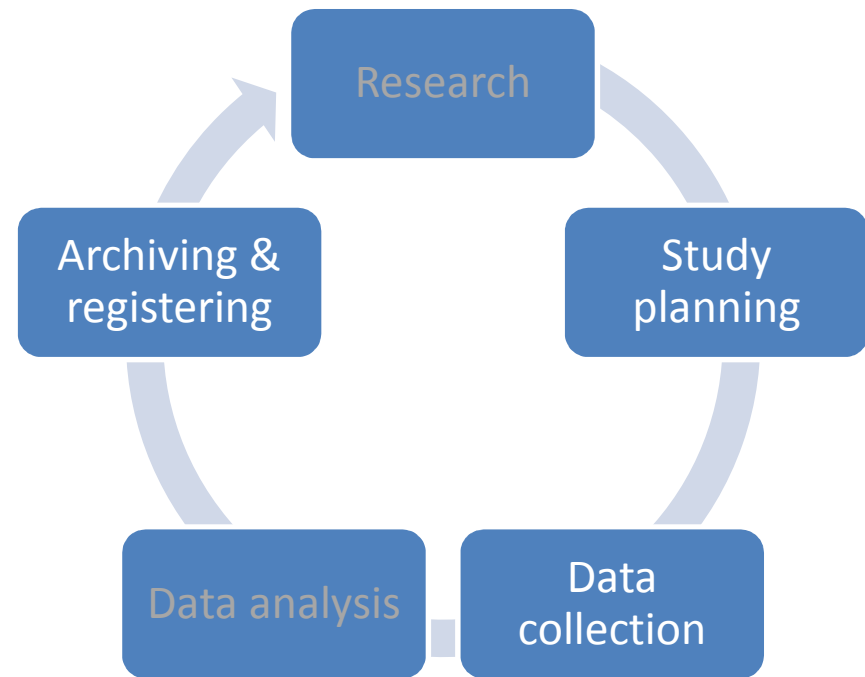
GESIS - Leibniz Institute for the Social Sciences

@CESSDA_Data

Informed Consent

Informed Consent

- Obtaining agreement from your participants to participate in your study

- Weak consent will lead to poorer data because participants may try to protect themselves

  ⇒ causes item (sensitive data) or even unit non-response

Image: CC-0

EU-Directive 1995/46/EC

- Participants in research have the right to
  - withdraw from participation
  - access their data
  - get information about
    the use of their data

- Personal data need special protection
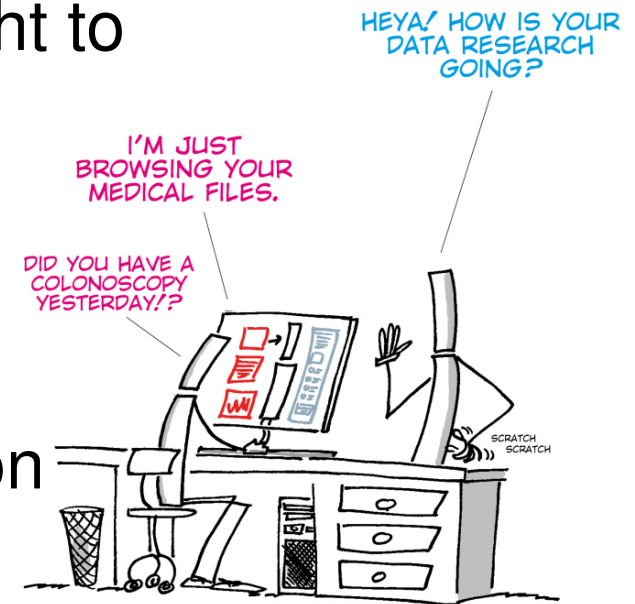 - have to be stored in the EU
  - have to be anonymized

HEYA! HOW IS YOUR DATA RESEARCH GOING?

I'M JUST BROWSING YOUR MEDICAL FILES.

DID YOU HAVE A COLONOSCOPY YESTERDAY!?

SCRATCH SCRATCH

cc-by http://hochstenbach.wordpress.com
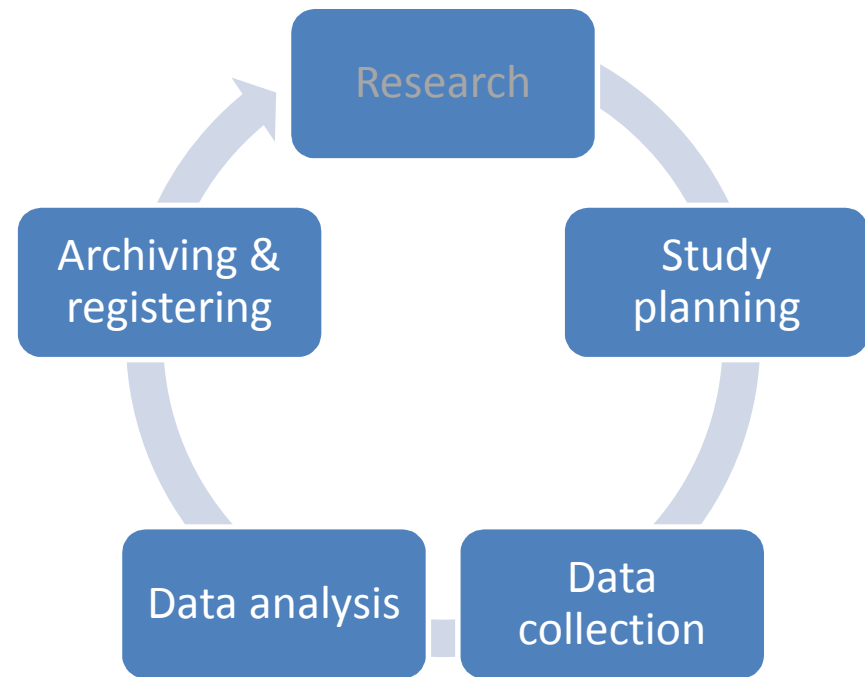
Image by P. Hochstenbach (CC-by)

Elements of Consent Forms

- Informed consent includes information on:
    - project and the researcher(s)
    - participation in the study
    - use of information within and beyond the project
    - protection of personal data
    - right to withdraw

- Can be given written form (favourable) or verbally
    ⇒ always obtain informed consent

Image: CC-0

Anonymization

Anonymization

- Strategy to protect the identity of participants
  - legal requirements, e.g. EU-Directive 1995/46/EC
  - ethical reasons (protection from harm)

- Identifying participants
  - direct identifiers, e.g. names, addresses, pictures etc.
  - indirect identifiers, i.e. combination of different information in the data

- Anonymization is an early task (study planning)
  - types of data to collect
  - data protection laws

Anonymization Strategies

- Direct identifiers
    - keep sensitive data on separate files
    - use meaningful pseudonyms and replacements
    - remove variables with sensitive data
    - voice alteration or image blurring

- Indirect identifiers
    - restrict upper and lower ranges of variables
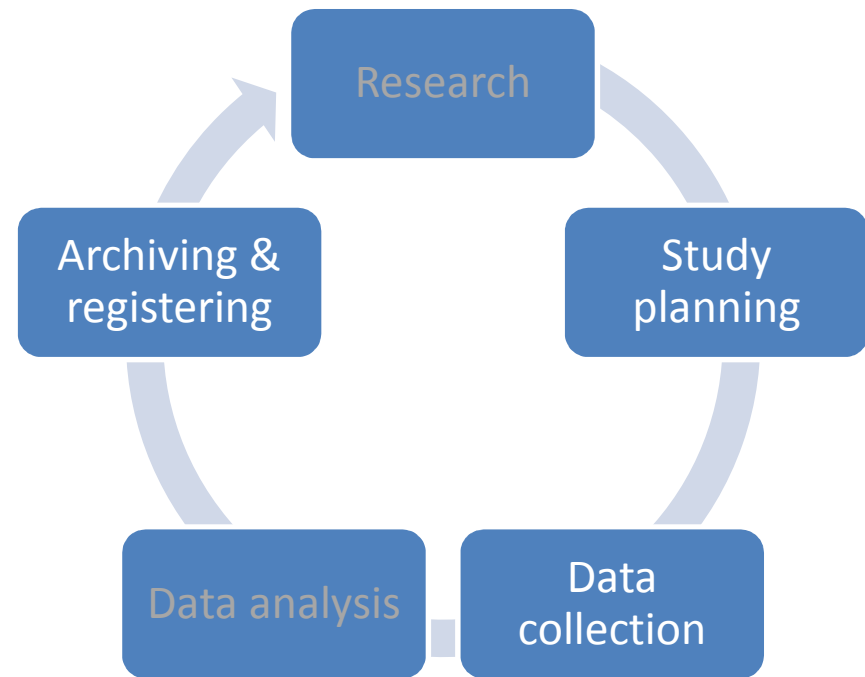   - low-level aggregation of data

Anonymization: Keep in Mind

- Document anonymization and changes undertaken

- Avoid
  - inconsistency
  - over-anonymization

- If anonymization is impossible
  - obtain informed consent for using and sharing non-anonymous data
  - control access and regulate reuse
  - place confidential data under embargo

DATA HANDLING

Image by A. Herrema & H. Bouwteam (CC-by)

Data Licensing

Intellectual Property Rights

- Intellectual Property Rights (IPR)
  - cover scientific work
  - do neither extend to an idea nor subsist in facts but to an organized collection of data

- IPRs are not universal
  - vary from country to country
  - are territorial
    - ⇒ it matters where they are applied not where they originate

Reusing Data

- Copyright
  - assigns the owner of IPR protects against unauthorized copies or derivatives of work

- The right of usage
  - defines conditions of reused
    ⇒ reusing data,
       clarify conditions, first

Image by A. Herrema & H. Bouwteam (CC-by)

Licensing Data

- Give permission to someone else to reuse data

- To license data
  - clarify who owns the data, first
  - check for template license of your institute of funder

- Licenses can be
  - irrevocable and
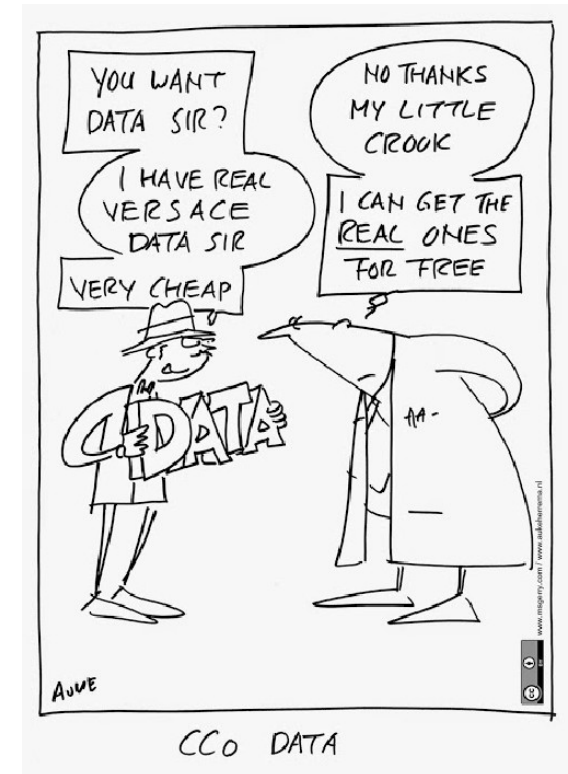 - not suitable for third party licensing or for confidential, sensitive objects etc.

Image by A. Herrema & H. Bouwteam (CC-by)

What Licenses Look Like

- Licenses define conditions of reuse
- Extract of UKDA end user license
  http://ukdataservice.ac.uk/get-data/how-to-access/conditions
  - not to use the data for commercial purposes …
  - …no transfer of any interest in intellectual property
  - …without warranty or liability of any kind
  - …abide by any further conditions notified to you
  - …ensure that the means of access … are kept secure
  - …use the correct methods of citation … in publications
  + access conditions for weakly anonymized data

Further Readings

- ANDS Guides (2012): Ethics, Consent & data Sharing. Available at: http://www.ands.org.au/guides/ethics-working-level.pdf.
- Ball, Alex (2014): How to License Research Data. Available at: http://www.dcc.ac.uk/resources/how-guides/license-research-data.
- Creative Commons. Available at https://creativecommons.org/.
- Directive 95/46/EC of the European Parliament and of the Council, 24 October 1995. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:NOT.
- Lagoze, C., Block, W.C., Williams, J., Abowd, J. and Vilhuber, L. (2013): Data Management of Confidential Data. doi:10.2218/ijdc.v8i1.259 . Available at: http://www.ijdc.net/index.php/ijdc/article/view/8.1.265.
- McGeever, Mags (2007): IPR in Databases. Available at http://www.dcc.ac.uk/resources/briefing-papers/legal-watch-papers/ipr-databases#top.
- Open Data Commons. Available at http://opendatacommons.org/.
- UK Data Service: Consent for data sharing: http://ukdataservice.ac.uk/manage-data/legal-ethical/consent-data-sharing/consent-forms [Examples on various consent forms].

DMP Section 4: Ethics and …

💬 work in 2-4 groups,

🕐 time: about 30 minutes

☑ choose one of the following topics

DMP Sections 4: Ethics and …

a) informed consent (*Section 4.1*)
   ⇒ outline the process of obtaining informed consent …
      … how you gained consent (for data sharing and preservation)
      … how you handle sensitive data and
         how protect participants' identity

b) Intellectual Property Rights (*Section 4.2*)
   ⇒ reusing data of others, under which conditions
   ⇒ processing data, consider …
      … who is the owner
      … will the data be licensed
      … the conditions of reuse

FOSTER

cessda

DMP Sections 4.1: Informed Consent

- seek informed consent in written form

- outline
  - aim of your project as well as name of primary researcher(s) and institute(s)
  - importance and implication of participation
  - use of data within the project as well as beyond the project (archiving and sharing)
  - protection of sensitive information, e.g. via anonymization
  - right to withdraw, access the data etc.
  - ⇒ get the consent form signed and hand over a copy

DMP Sections 4.2: Intellectual Property Rights

- re-using data from others, consider …
  - … who is the copyright holder and who needs to be cited
  - … what are the conditions of reuse
  - ⇒ better seek for permission than for forgiveness
- licensing data for the reuse of others, consider …
  - … how sensitive your data are
  - … if and how you have to control access
  - … if your data need additional protection, e.g. being accessible only via a Secure Data Center
  - ⇒ archive your data to control access and use