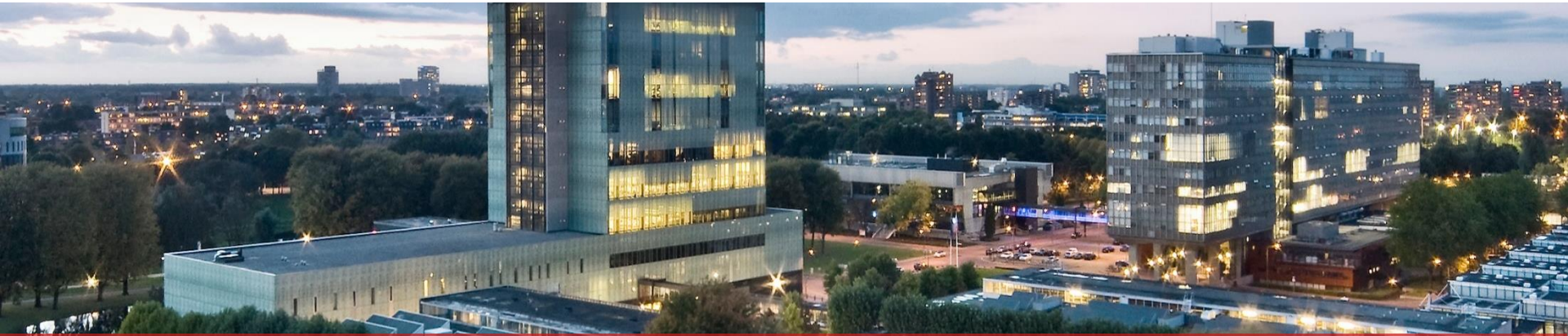

Ethical Review Board introduction October 2021

Jolanda Habraken – Secretary Ethical Review Board

Anne Aarts – Data Steward

Annaluisa Franco – ERB ID coordinator

Today’s plan:

- Introduction to Ethics and ERB
- Ethics and Data management: practical tips
- Questions

Research with human participants

Even with best intentions, scientific research may pose risk or harm to human participants

- Safety
- Wellbeing
- Privacy
- Research methodology

Research with human participants

Examples

- Safety: Using a newly developed prototype in a pre-school building. The device caught fire → fire in the classroom
- Wellbeing: Using a survey with questions about a traumatic episode in a person's life. Answering these questions caused psychological distress and anxiety
- Privacy: Medical data from thousands of people retrieved from corona tests were leaked and sold recently in the Netherlands
- Research methodology: Research with insufficient methodological quality leads to invalid results. This is considered unethical because the time and effort participants put in the study will not lead to valid outcomes

TU/e

Mandatory ethical review of research projects

- To prevent incidents like this. Participants in scientific research need to be protected
- Responsibility of the researcher/student
- Obligation from the Netherlands Code of Conduct for Research Integrity:

  Responsibility: "….. a researcher does not operate in isolation and hence **taking into consideration** – within reasonable limits – **the legitimate interests of human and animal test subjects**, as well as those of commissioning parties, funding bodies and the environment. **Responsibility also means conducting research that is scientifically and/or societally relevant**."

→ Mandatory ethical review for all research with human participants and/or with personal data – ERB

→ Weighing of benefits and risks/harm

TU/e

Examples of research with human participants

- Measuring yourself or others
- Using a survey or conducting an interview to obtain data – also when participants are asked to report about their organization or other aggregated level
- Conducting expert interviews and using quotations for scientific publication
- Testing a prototype/device on users
- Using an existing database with personal data
- Research using human material such as skin, blood or bones

- Medical device development and medical scientific research are highly regulated!

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What is allowed? Minimal risk for participant

- Healthy adults (no medical research)
- Voluntary (no peer pressure)
- Explicit consent
- Anonymous
- Not burdensome
- No harm or discomfort
- No compensation
- Covert observation only in public space

- No sensitive topics that are very personal or intimate (e.g. sexual preferences, religion, alcohol and drug use, diseases)
- Not invasive (no puncture)
- CE certified device for intended use or non-CE-certified device or CE-certified devices for unintended use with < 18 V
- See Safety and Risk analysis document

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More than minimal risk for participant

- More than minimal risk for participant → submit to ERB → processing time 2-6 weeks

- Medical or medical device research → submit to METC → processing time 2 weeks – several months


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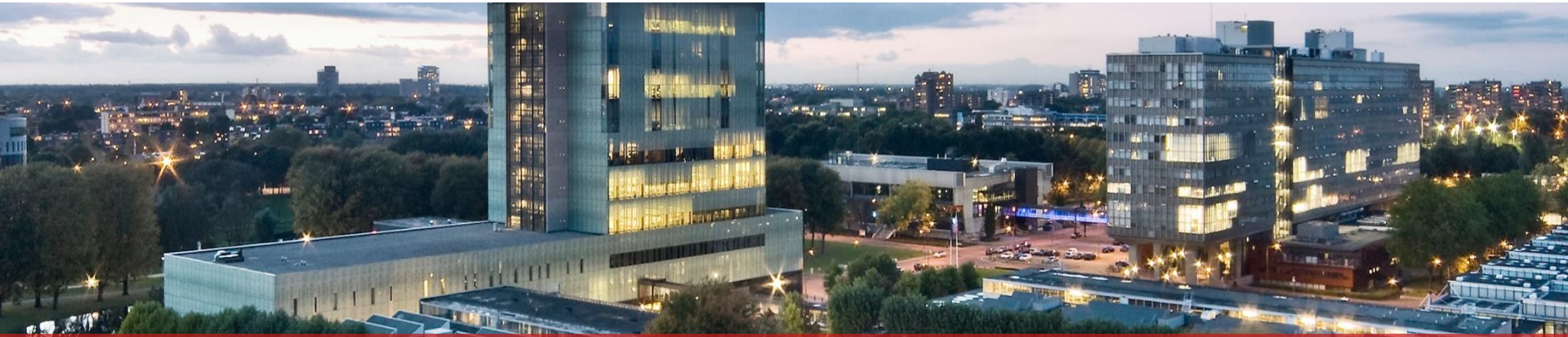


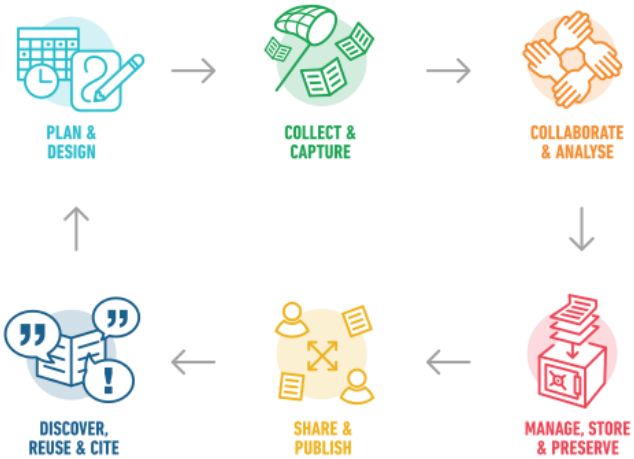
Ethical Review & Data Management
October 2021

Anne Aarts – Data steward

What is research data management?

- Research data management (RDM) = concerns the way you collect, analyze, store, share, archive and publish research data, in order to satisfy the needs of current and future data users

- Caring for your data with the purpose to:
  1. protect their mere existence
  2. share them with others
     - A. for reasons of reproducibility checks
     - B. for reasons of reuse



Why is research data management important?

- Scientific integrity and Code of Conduct
- GDPR/AVG
- Funder requirements
- It reduces risk of data loss
- It can help you get recognized for your work
- It puts public-funded research in the public sphere
- It promotes scientific integrity and quality of data (combat scientific fraud)
- By making your data findable and usable for other researchers this enables collaboration through data sharing
- By making research results more accessible, it contributes to better and more efficient science overall!

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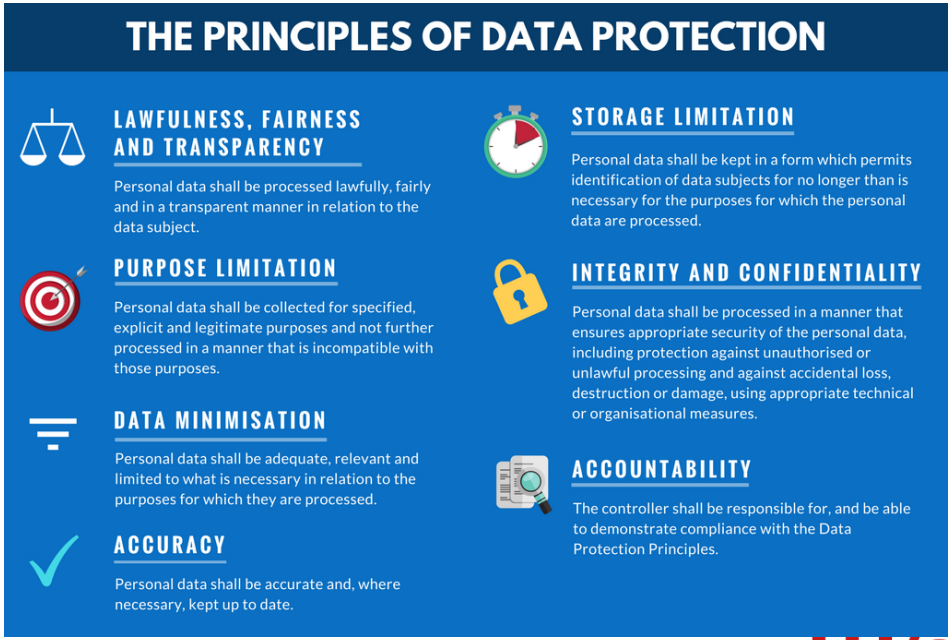
What is the GDPR (in Dutch the AVG)?

- Regulation that lays down rules to protect natural persons with regard to processing of personal data



How can you do RDM in practice?

- Example research project at ID: You have developed a prototype and will collect user experiences via interviews. You will make audio recording those interviews and published the results in scientific journal.

- Things you must do:
  - Ask for consent for participation and for the processing of personal data
  - Organize your data in a clear folder structure and give files descriptive names
  - Make your data human- and machine readable by explaining the content of the data
  - Share and storage data in a safe and secure manner: use solutions offered by the TU/e
  - Archive the data so it can be re-used by yourself and/or others

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Take home messages

- When designing and performing a research project, always take the participants and their perspective into account

- Try to minimize the risks (ethical, medical ethical, research data management or privacy) as much as possible and be compliant with rules and regulations (e.g., GDPR, scientific integrity, code of conduct)

- Always discuss your research project with your supervisor. If needed you can also contact experts (data steward, policy officer medical/device research) for support

Contact information

- Ethics
  - Advice or help on ethical questions: ethics@tue.nl
  - More information on Ethics: https://intranet.tue.nl/ethics

- RDM and privacy
  - Advice or help on RDM-related questions: rdmsupport@tue.nl
  - More information on RDM: https://www.tue.nl/en/our-university/library/rdm

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