Module 6: Non-technical Aspects of Data Collection

5ARB0: DATA ACQUISITION & ANALYSIS

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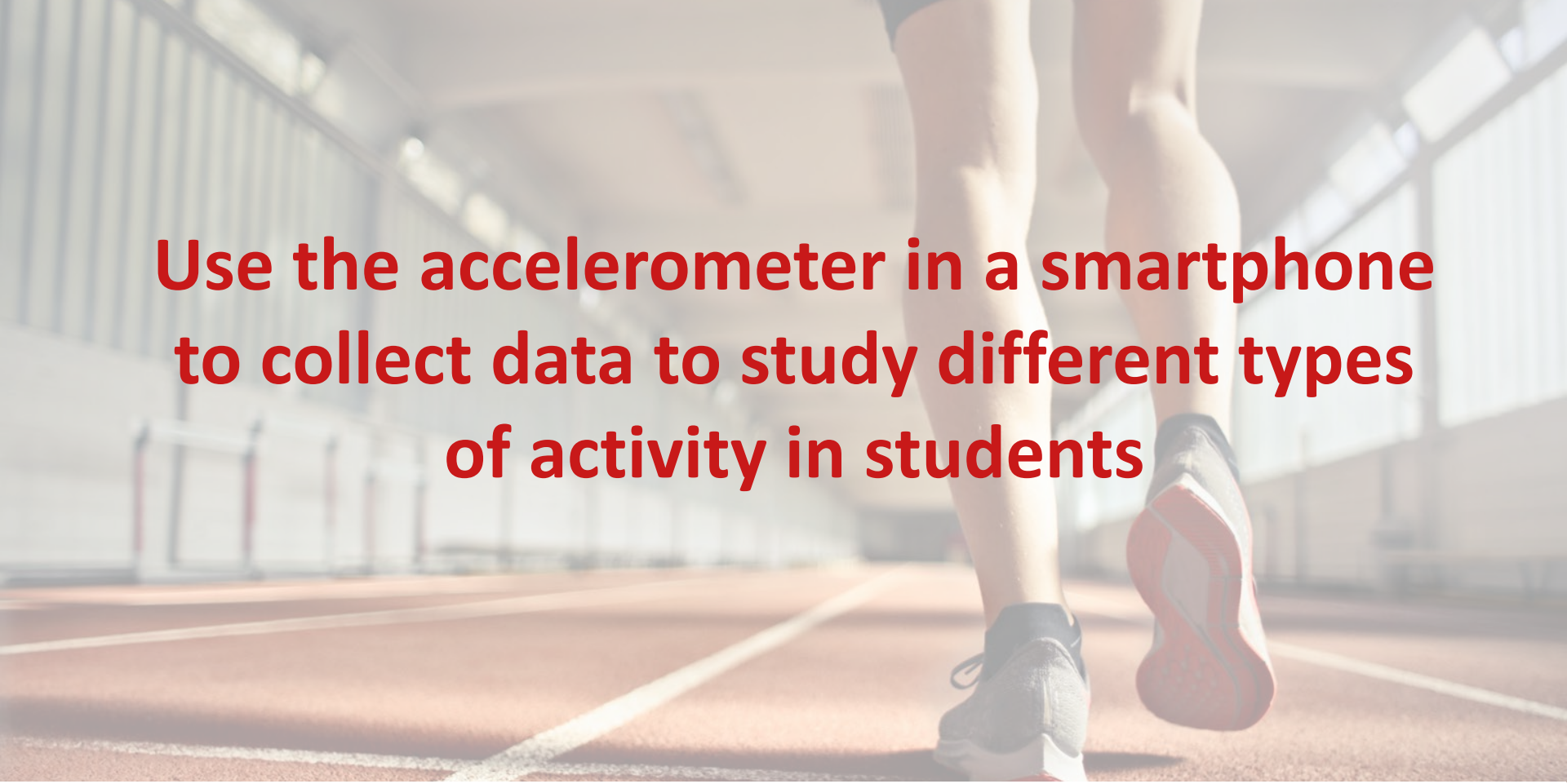
Mastertrack: Artificial Intelligence Engineering Systems



Use the accelerometer in a smartphone to collect data to study different types of activity in students

Use the PPG sensor in a smartwatch to diagnose a sleep disorder

What is the difference?

What is the difference?

- **Healty subjects vs. Patients**
- **Consumer product vs. Medical application**
- **Anonymous data (?) vs. Personal data**

Outline

- **Ethics**
  - Research involving human subjects
  - Medical research involving human subjects
  - Medical device research
- ***Break***
- **Protocols**
- **Privacy (GDPR)**

Example: Stanford prison experiment

Research involving human subjects

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

- **Safety**
- **Wellbeing**
- **Privacy**
- **Research methodology**

What went wrong in Stanford?

- **“Prisoners” safety and wellbeing was harmed**
- **Methodology was poor**
  - Zimbardo acted as prison chief and became part of the experiment
  - Guards got instructions on how to humiliate the prisoners
  - No protocol with clear instructions
- **Experiment was repeated in 2001, no violent behavior towards the prisoners was found**

Examples of research involving human subjects

- **Measuring yourself or others**
- **Using a survey or conducting an interview to obtain data**
- **Conducting expert interviews and using quotations for scientific publication**
- **Testing a prototype/device on users**
- **Using an existing database with personal data**

Ethical review is mandatory

Institutional Ethical Review Board asseses several aspects:

- **What will the research achieve?**
- **Could the research question be answered in a different way?**
- **Is the methodological quality sufficient?**
- **Are risks mittigated sufficiently?**
- **Are the risks acceptable?**

Example: CRISPR-CAS babies (Nov 2018)

World's first gene-edited babies created in China, claims scientist

Unconfirmed scientific breakthrough sparks ethical and moral concerns

A scientist at work at a laboratory in Shenzhen in southern China. Many mainstream scientists have denounced the Chinese report as human experimentation. Photograph: Mark Schiefelbein/AP

The Guardian

Source: theguardian.com

TU/e

Medical research involving human subjects

- **Highly regulated**
  - Declaration of Helsinki
  - Medical research involving human subjects act (WMO)
  - Good Clinical Practice
  - Medical device regulations
- **Patients are vulnerable**
- **Risks can be high(er)**

Declaration of Helsinki (1964)

- Respect for the individual
- Voluntary and informed discissions
- Reasonable likelihood of benefit to the population studied
- Special attention for vulnerable individuals and groups
- Trained investigators, sound research methods
- Protocols approved by ethical committee
- Publication of results

Medical research involving human subjects act (WMO)

Research is subject to the WMO if the following criteria are met:

1. It concerns medical scientific research and
2. Participants are subject to procedures or are required to follow rules of behaviour.

Medical/scientific research is research which is carried out with the aim of finding answers to a question in **the field of illness and health** (etiology, pathogenesis, signs/symptoms, diagnosis, prevention, outcome or treatment of illness), by **systematically collecting and analysing data**. The research is carried out with the intention of **contributing to medical knowledge** which can also be applied to populations outside of the direct research population.

Examples WMO research

Medication:

- Clinical trial to test effectiveness of new COVID vaccination
- Clinical trial to test safety of new HIV medication

Method:

- Clinical trial to test new screening method for early detection of breast cancer
- Finding biomarkers for diagnosis of Parkinson's disease

Product:

- Test validity of new blood pressure device (medical device study)
- Test effectiveness of implantable insulin pump (medical device study)

Examples non-WMO research

- Validation of a new questionnaire to screen for sleep disorders

- Technical validation of new method to use video PPG to measure heart rate

Secondary data analyses of medical data

- **Non-WMO**
- **Medical data is personal data**
- **Ethical and privacy review needed!**

Medical ethical review board (METC)

- **Independent body**
- **Consists of:**
  - Doctors
  - Ethicist
  - Pharmacist
  - Statistician
  - Patient
- **Reviews and Approves:**
  - Trial protocol
  - Suitability of investigators and facilities
  - Methods and materials

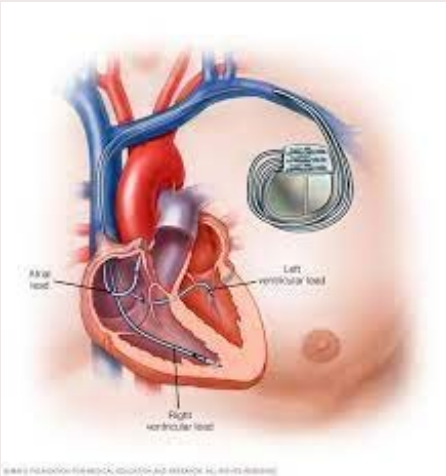
What to prepare for medical ethical review?

- Protocol
- Information for participants
- Informed consent form
- Recruitment tekst (e.g. advertorial)
- Insurance for participants
- Product information

Informed consent procedure

- Participation is voluntary (no pressure in recruitment)
- Information is clear and complete
- Participant can ask questions (to an independent advisor)
- Participant has time to think about decision
- Consent form is signed by both participant and researcher/doctor

Medical device studies



What is a medical device

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Intended use

No medical device	Medical device
Smart watch to measure heart rate during exercise	Detection of cardiac arrhythmias
PC monitor for gaming	PC monitor for radiologist

Investigational Medical Device Dossier (IMDD)

In case of existing device, but new intended use → get information from manufacturer

In case you are the manufacturer → complete dossier yourself

Break

Why a protocol?

- **Ethical assessment**
- **Think before you start**
- **Motivate your choices**
- **Be as specific as possible**

Protocol

- **Introduction/relevance**
- **Aims**
- **Methods**
  - Participants
  - Measurements
  - Procedures
  - Analyses (including statistics)

Participants

Inclusion criteria

What is your population of interest?

Exclusion criteria

Are there people that cannot participate, because of safety or confounding factors?

Measurements

What do you measure?

Which device do you use (medical device?)

Measuring protocol

Technical details (data format, granularity, etc.)

Procedures

Recruitment of participants

Informed consent procedure

Interventions

Data (pre-)processing

Analyses

Detailed description

Statistical analyses

Reproducibility

Personal data

Anonymous vs pseudonymous

Anonymous: not possible to identify somebody from the data (directly or indirectly)

Pseudonymous: direct identifiers (such as name, DoB etc.) are removed and replaced by a code. The code is kept in a separate key file with the identifying information.

Be aware of indirect identifiers, for example rare characteristics.

General Data Protection Regulation (GDPR)

Informed consent

For storage and processing of personal data

For a specific purpose

In addition to consent for participation in research

Consent can be retrieved any time

Prospective vs retrospective data collection

In a prospective study you collect data with a specific goal

In a retrospective study you (re-)use data that has already been collected in another setting (research, clinical care, user data, etc)

- Check if consent is sufficient
- If needed ask re-consent
- Anonymous data is not subject to GDPR
- Other legal basis of processing

Legal basis of processing

Consent

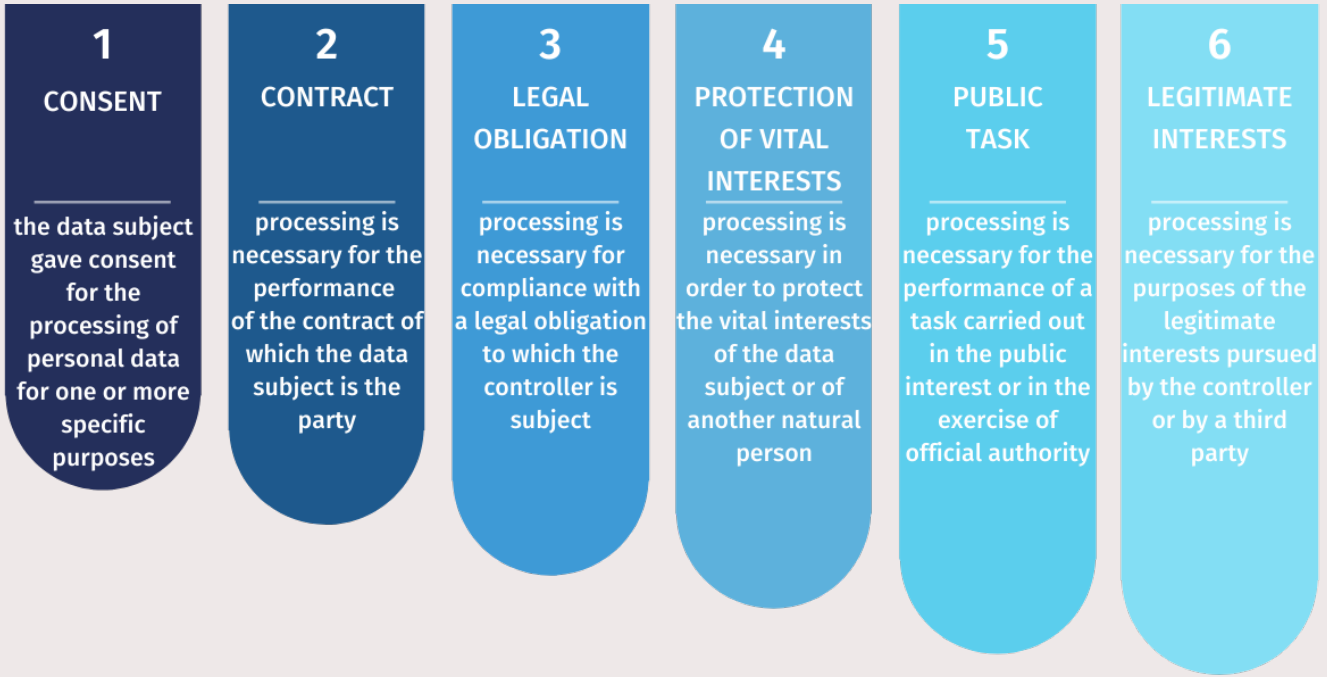
Contract

Legal obligation

Vital interest

Public task

Legitimate interest



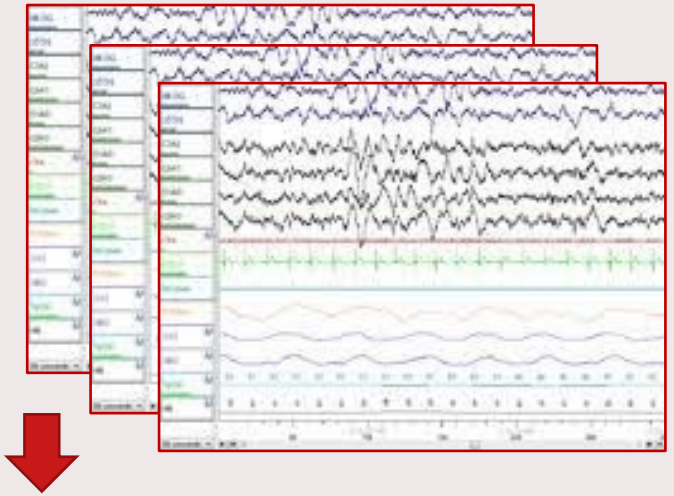
Moving field

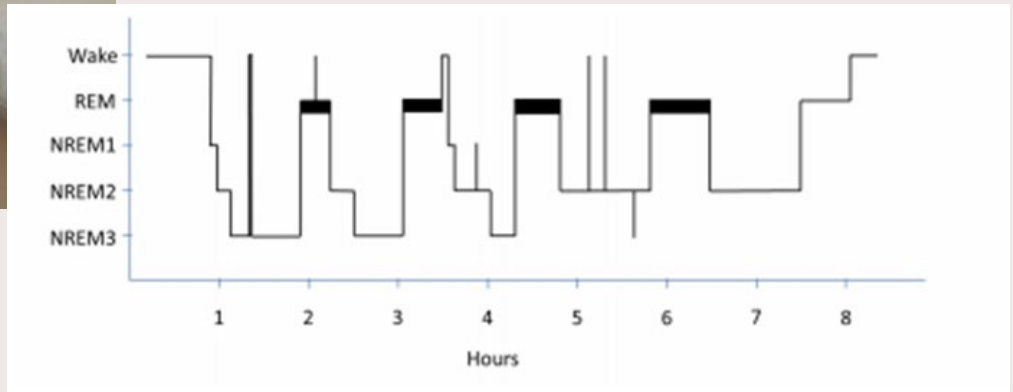
Many new laws (GDPR, MDR, AI act (planned))

Interpretation not always clear

Be aware of responsibilities that come with working with human data

Assignment 2 – sleep monitoring





Assignment 2 – sleep monitoring

Wearable devices that measure sleep

- Consumer products
- Not validated in clinical trial
- Not valid in people with sleep disorders(/disturbed sleep)

Write a protocol for development and validation of a sleep staging algorithm in people with sleep disorders using wearable sensors.

- Detailed instructions on Canvas
- You don't have to execute the study. It should contain enough information for medical ethical assessment.
- Deadline Sunday October 30 20:00h