



REK

DE REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Health Research Act & ethical considerations

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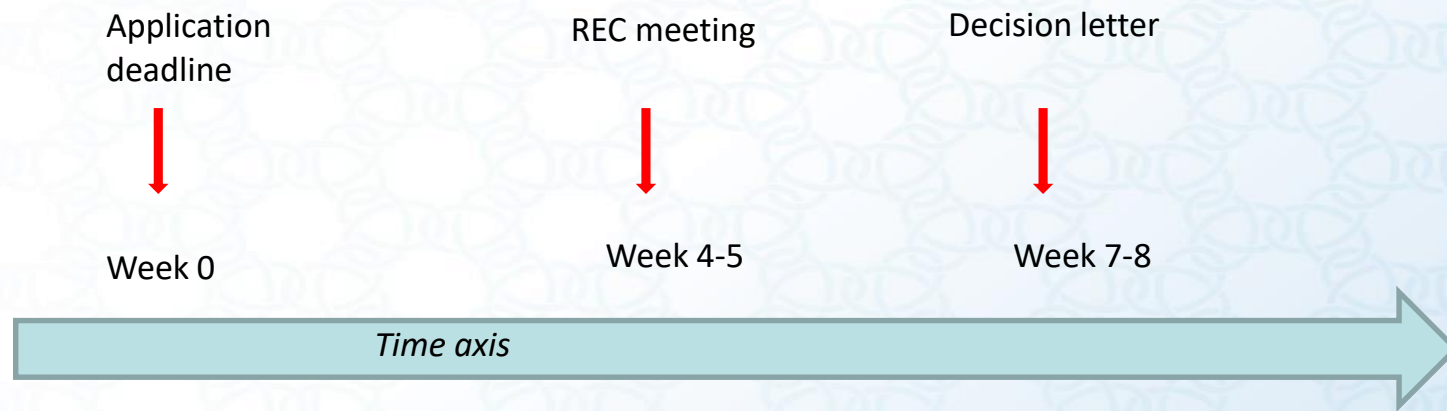
BASIC PRINCIPLES OF RESEARCH ETHICS ..

- Respect the participants / safeguard their autonomy
- The principle of proportionality
- Minimize risk and maximize benefit
- Participants can withdraw their consent at any time
- Be cautious with research on vulnerable groups

.. AS A FOUNDATION FOR THE LEGAL REQUIREMENTS

- REC approval (!) in advance
- Medical research must be organized and conducted safely/soundly [forsvarlig]
- Consent as the main rule
 - voluntary and informed consent (avoid dependency relations)
 - be truthful and objective/neutral when presenting the project
- Waiver of consent possible if
 - minimal risk to participants AND
 - significant societal benefit(s) AND
 - consent is «difficult» to obtain
- Organization of the project
 - responsible institution(s)
 - relevant competence
- Stand by/support (when relevant)
- Quality of science (above a minimum standard)
- Insurance for the participants

*BUT: still often a requirement
for information!*



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