# Research ethics

# QM-Lecture 4

Joke Haafkens

# OOPS!!!

- Dear Dr. Haafkens,
- Thank you for your recent submission to BMC Public Health. Before we can proceed with peer review we will need you to make some changes to your manuscript. We would be very grateful if you could make these changes promptly, as we cannot start the peer review process until we have received a version containing the changes.
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- 2.) **Ethics**
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- Research involving human subjects, human material, or human data, must have been performed in accordance with the Declaration of Helsinki (http://www.wma.net/en/30publications/10policies/b3/index.html) and must have been approved by an appropriate ethics committee. Experimental research on vertebrates or any regulated invertebrates must comply with institutional, national, or international guidelines, and where available should have been approved by an appropriate ethics committee. ***A statement detailing what ethical approval has been obtained, including the name of the ethics committee and the reference number where appropriate, must appear in all manuscripts. If a study has been granted an exemption from requiring ethics approval or does not require approval, this should also be detailed in the manuscript (including the name of the ethics committee that granted the exemption). For all research involving human subjects, informed consent to participate in the study should be obtained from participants (or their parent or guardian in the case of children under 16) and a statement to this effect should appear in the manuscript. Please refer to our Editorial Policies for full details of the ethical requirements for the journal: http://www.biomedcentral.com/about/editorialpolicies#Ethics.***
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- The study used a social scientific method to explore the perspectives of researchers on what is needed to conduct research on health inequalities in their country.

- The Dutch Medical Research Involving Human Subjects Act (WMO) states that a study must undergo a medical ethics review if it is medical/scientific research and participating individuals are subjected to procedures or are required to follow rules of behavior. Clinical trials

- Social scientific research does not fall within the scope of this law, unless subjects are asked to questions to bring about a temporary change in the subject's lifestyle or the nature of
- Therefore, this study was exempt from review by the medical ethics research committee

# Attention to ethics is crucial

- Also is qualitative or non-clinical research where no formal ethical review is required

# Two types of ethics

- Professional ethics (how you deal with colleagues, supervisors, intellectual property data fabrication, plagiarism, publication)

- Research ethics: relation between researcher and the people they study

# Fundamental principles of research ethics

- **Respect for persons**: the autonomy and the dignity of study participants must be protected at all times. No force. They can always withdraw if they want
- **Beneficence**: Minimize psychological and social risks and maximize potential benefits for *all participants*
- **Justice:** Distribute risks and benefits equally. Inform all and not just a few participants about your study
- **Respect for communities:** Do not put a community or a group of people at risk by asking them to participate in your study. (E.g., drug users)

# Informed consent required at all times

*Inform participant about*

- The purpose of your study
- What is expected from them in terms of input and time, travel time
- Potential risks and benefits from participation
- That they can withdraw their contribution at any time

# Informed consent required at all times

*Inform participant about*

- Their confidentiality will be protected and how
- The name and contact information of the PI and the investigator where participants can acquire info about the study
- Contact information about local ethics committee, if appropriate

# Written consent!!!

- Get written consent
- For people who cant read/write, read the consent form and ask them to sign the form in the way they can or record oral consent.
- Consult your local ethics board for examples of ethics forms that are used in your country

# Make an ethics plan and SOPs for all studies

- Reflect on ethical issues in your own study
- Design ethics work plan, personnel, make forms
- Apply ethics for all study participants
- Include enough time for this

- Prevent oops experiences