DEPARTMENT OF GLOBAL PUBLIC HEALTH

K9F5740, Quality Assurance in Research From a Global Perspective, 3 credits (hec)

Kvalitetssäkring av forskning ur ett globalt perspektiv, 3 högskolepoäng

Third-cycle level / Forskarnivå

Approval

This syllabus was approved by the The Committee for Doctoral Education on 2023-12-27, and was last revised on 2025-02-07. The revised course syllabus is valid from spring semester 2025.

Responsible department

Department of Global Public Health, Faculty of Medicine

Prerequisite courses, or equivalent

Knowledge about general data protection regulation (GDPR) and about documentation and handling of research data, corresponding to the compulsory introduction to doctoral education at KI.

Purpose & Intended learning outcomes

Purpose

This course provides the students with the knowledge needed to secure quality public health research from planning the study, protocol development, carrying out data collection, data management, to final decision on making the data publicly available. Further, the course touches on project management, intercultural aspects of respectful and responsible international research partnerships with links to decolonizing global health and the sustainability 2030 agenda.

The focus is on understanding the international, national and local legislation, ethical guidelines and international treaties when involved in clinical and public health research. The course is most useful for people who work in different settings and want to learn about the specifics in global research collaborations and how to ensure highest ethical and safety standard. The course focuses on primary data collection of human data including different data collection formats

spanning from population-based surveys, facility-based data collection, interviews, qualitative approaches etc. Practical aspects of designing questionnaires, formulate relevant questions, and transferring them to appropriate formats will be included.

The participants will understand how to protect patient's safety, and how to create trustful data without neglecting the processes within teams to create fruitful research collaborations.

Intended learning outcomes

Knowledge and understanding
• Understand and describe the meaning of the Helsinki Declaration and other key ethical milestone documents, Good Clinical Practice standards and GDPR
• Understand and contrast legal documents of collaboration and data sharing agreement, Memorandum of Understandings including Swedish, European and international legislations including most recent guidance such as European Code of Conduct- ALLEA
• Appreciate and justify procedures to collect and document data collection throughout all stages to ensure safety and quality including safe data storage and data transfer

Skills and abilities
• Appreciate the different responsibilities of the investigator, study team members and sponsor throughout the data collection
• Develop protocols and comprehensive data management plans, risk benefit assessments, project risk assessments
• Develop data collection tools throughout all stages of drafting appropriate questions
• Appreciate and summarize management aspects to ensure that all data collection standards include highest ethical, safety and collaboration standards
• Create data quality assurance plans to safeguard quality data collection including handling of consent, data safety, and research documentation

Judgement and approach
• Able to judge project proposals and research documentation from aspects of data quality, safety, ethics and inclusion
• Define and assess challenges, risks and ethical concerns

Course content

The course provides insights into research ethics, and how applications to different authorities are done. It also touches public health trials but not any specifics of clinical drug or medical product trials. We will also cover the content of the WHO Handbook for good clinical research practice (Handbook for Good Clinic Practice (GCP): guidance for implementation).

Forms of teaching and learning

The course is based on e-(self)learning and flipped classroom methodologies including reading materials, short, recorded lectures, assignment combined with group work and group discussion. Students will present experiences, and cases and their solutions will be presented and discussed under teachers' supervision. Q&A will be provided.

Language of instruction

The course is given in English

Grading scale

Pass (G) /Fail (U)

Compulsory components & forms of assessment

Compulsory components

Each student must present own work as well as participate in a group work. Each student must show activity on the course's home page with at least five questions, presentation and/or comments on others' postings. Absence or lack of online activity can after the examiner's assessment be compensated by an individually written essay.

Forms of assessment

Examination: 2000-word data collection and management plan which will also be presented and discussed during the course.

Course literature

Peter G. Smith, Richard H. Morrow, David A. Ross. Field Trials of Health Interventions: A Toolbox Copyright Year: 2015, ISBN 13: 9780198732860 Field Trials of Health Interventions: A Toolbox - Open Textbook Library (umn.edu) and selected journal papers