



DEPARTMENT OF GLOBAL PUBLIC HEALTH

K9F5743 Fundamentals of Quality Assurance in Medical Science and Public Health Research, 1.5 credits (hec)

Grunderna i kvalitetssäkring inom medicinsk vetenskap och folkhälsforskning, 1,5 högskolepoäng

Third-cycle level / Forskarnivå

Approval

This syllabus is approved by the The Committee for Doctoral Education on 2023-12-12, and is valid from Spring semester 2024.

Responsible department

Department of Global Public Health, Faculty of Medicine

Prerequisite courses, or equivalent

No prerequisite courses, or equivalent, demanded for this course.

Purpose & Intended learning outcomes

Purpose

The goal of this course is to provide an introduction to quality assurance practices in public health intervention studies as well as observational studies within medical sciences and public health research. This course will provide you with the basic knowledge and skills necessary to carry out human subjects research studies in compliance with relevant regulations and standards of the fields. The purpose is also to help you apply key skills that you will need throughout your career, such as research planning and documentation. This course is targeted for human subjects researchers working with personal data derived from epidemiological cohorts, healthcare records, administrative registers, or qualitative studies, as well as those carrying out public health intervention or implementation studies.

Intended learning outcomes

Upon successful completion of the course, the student will be able to:

Reason regarding how key pieces of legislation and international treaties impact studies that rely on personal data.

Describe and discuss recommendations and restrictions that influence researchers' decisions to share data, including balancing ethical and legal concerns against the principals of open science.

Explain the concept of Good Clinical Practice (GCP) and contrast the structured requirements of GCP with recommendations for best practices within observational and public health intervention studies.

Distinguish the roles and responsibilities of the research team members (including doctoral students and their supervisors) in relation to the processing and handling of personal data and the planning and documentation of studies, and discuss how these are regulated in different research settings.

Reflect on the steps required for study planning and protocol development, secure data collection and management, and appropriate research documentation of human research studies, at the level of the doctoral student researcher.

Appraise and critique the quality assurance practices of studies employing personal data, including the student's own planned or ongoing studies.

Critically reflect on the role of quality assurance practices in promoting the application of sound scientific and ethical principals in medical research.

Course content

Students will develop an understanding of quality assurance practices across different human subjects research settings, with a practical focus of bringing these principals to bear on the student's own ongoing research. Through self-directed learning and a series of lectures, students will become familiar with the principals of quality assurance. Guided discussions will focus on the challenges encountered in the practical application of quality assurance principals, how to align the quality assurance practices with the specific needs of the study, and the roles that different members of the larger research team play in the larger process. Students will become familiar with legislation and regulations that guide ethical and scientifically sound medical research. Students will learn practical approaches and about tools available to help them plan and document their own research and securely collect and manage data.

Forms of teaching and learning

This course uses a blended learning approach, relying on online activities (including recorded lectures, quizzes, and discussion boards), self-directed learning, and live group discussions (online or in person) focusing on concrete applications of quality assurance principals in different kinds of studies.

Language of instruction

The course is given in English.

Grading scale

Pass (G) /Fail (U)

Compulsory components & forms of assessment

Compulsory components

The final summative examination is compulsory.

Forms of assessment

To pass the course, the student must show that the learning outcomes have been achieved. Assessments methods include both formative assessments and an individual examination (or summative assessment). All forms of assessments are used with the goal of contributing to the development of the student's knowledge and skills. Formative assessments include quizzes and in class activities such as discussions, short presentations, and group assignments. The purpose of these is to allow students to receive feedback throughout the course in order to track their learning and identify areas where they need further development.

An individual written examination is used as the summative examination. Students who do not obtain a passing grade will be offered two additional chances to resubmit their exam. Students who do not obtain a passing grade upon re-examination will be given top priority for admission the next time the course is offered.

Course literature

Links to articles and recommended reading materials will be provided on the course's homepage.