FEB 2023

Training and Certification

TO PROMOTE AND SAFEGUARD GOOD PRACTICES AT THE INSTITUTE OF PSYCHOLOGY

RESEARCH COMMITTEE, PSYCHOLOGY RESEARCH ETHICS COMMITTEE, EXECUTIVE BOARD

CORRESPONDENCE: v.ly@fsw.leidenuniv.nl AND t.m.g.berge@fsw.leidenuniv.nl

Contents

Training and certification – Background and relevance

Code of conduct and quality assurance

Researchers and other team members flourish in a culture that is characterized by independence and integrity. All employees, including senior staff, PhD candidates, temporary personnel as well as students at the Institute of Psychology and others who are conducting research within the institute or using its facilities, are expected to conduct research according to the highest ethical and professional scientific standards.

The Institute of Psychology endorses the Netherlands Code of Conduct for Research Integrity. This code covers scientific and scholarly research in the broadest sense and applies to all employees at the institute. To provide a working environment that promotes and safeguards good practices that are in line with these codes of conduct, the institute and its management has appointed committees such as the Research Committee and the Psychology Research Ethics Committee (CEP). These committees, respectively, play a role in for instance the evaluation of Training and Supervision plans of PhD candidates and applications for ethical approval of research conducted within the institute that does not fall under the Medical Research Involving Human Subjects Act (WMO). Support groups at the institute and faculty level contribute to good practice through, for instance, providing help and advice concerning (safety of) lab protocols and ethical, data management and privacy aspects of research. The activities undertaken by these committees and support groups are just one way to protect the interests of those involved in research and to assure the quality of the research.

Why training and certification?

The quality of the research as well as the safety of people involved in research largely depend on the expertise and skills of the investigators and other members of a research team. For instance, knowledge about correct lab protocols and adequate skills to perform the tasks (e.g., physiological measurements, applying protocols in pain or stress research…) are critical to ensure the safety of those involved in the research, including participants and students who perform the research. The right set of knowledge, skills, and competence in data collection and processing of team members are for example important to assure the overall quality of the research data and the validity of the research results. Thus, team members have to be qualified through education, research-specific training, and experience to be able to carry out their respective task(s) in line with legislation, national and local guidelines and protocols. Importantly, legislation, guidelines and protocols continuously change, such that good practice should be accompanied by an investment in regular updating of knowledge, skills, and expertise.

A lifelong learning mentality is by definition not limited to early career team members, but is at least as important for those holding a senior position. Apart from being a role model for the early career team members, those in a more senior position often carry the end responsibility for projects and play a supervisory role. Next to meeting the requirements of their own position, supervisors and the Principle Investigators are also responsible for ensuring that their PhD candidates and students are sufficiently trained to carry out their duties compliant with the relevant legislation, guidelines and protocols. Depending on the type of methods employed in the investigation, PhD candidates and students may need to be trained in research-specific guidelines and protocols (e.g., guidelines for hygienic testing in FSW labs) before they can commence with their activities.

Broader context

The relevance of training and certification should be seen in light of an academic context in which research quality (over quantity) and engaging in lifelong learning is valued and appreciated. The entire management team plays an important role in promoting a culture where lifelong learning is supported as well as recognized and rewarded. In line with this, employees should be facilitated and guided by offering information about and resources for training. In addition, clear and up to date protocols, procedures, and guidelines need to be made available and accessible to all members of the institute.

Although clear standards offer an important basis for good practice, it needs to be acknowledged that not every ethical dilemma or responsible action will be addressed by existing standards. A key aspect of responsible research practice is the application of good judgment and personal integrity. Ultimately, all employees play a role in contributing to an open, safe, and inclusive culture in which standards for good practices can be discussed and where everyone feels responsible and accountable.

This document

There are different formats of training available for researchers and other team members to ensure participant's safety and to assure the quality of research. Some training is obligatory, while others are recommended depending on the nature of the research, the role of the research team member and the tasks carried out. In this document, an overview is provided of the different training that is either obligatory or recommended for employees at this institute.

Specifically, this document provides practical information about the obligatory and recommended training and certification for:

- Research involving human participants – clinical investigations and research methods using rigorous manipulations and medical devices;
- Research-specific skills – (f)MRI research;
- Generic research skills – data management;
- Supervision of PhD candidates;
- Training for PhD candidates

Note that the training and certification options are not limited to what is listed in this document. Rather, this document should be treated as a living document. All members of the Institute of Psychology are invited to provide input for improving and extending this overview and make suggestions for the development/facilitation of relevant training and courses.

Research involving human participants

Research involving human participants that is subject to WMO (Medical Research Involving Human Subjects Act)

Research involving human participants that is subject to WMO has to meet other standards compared to research that does not fall under WMO. Research that is subject to WMO needs approval from an accredited Medical Research Ethics Committee (MREC) or the CCMO. The Medische-Ethische Toetsingscommissie Leiden Den Haag Delft (METC-LDD) is the local MREC where investigators from the institute could submit their applications. For this type of research, the METC-LDD often requires involved investigators to be BROK-certified. In the below, practical information is provided about how researchers from the institute can receive this training and certification.

This course can be considered most advanced and intensive among the courses offered concerning Good Clinical Practice (GCP) and WMO and is only mandatory when a MREC requires it (see below). For team members of WMO research that are not the investigators themselves (e.g., assistants and those who carry out single routine activities) and/or do not require BROK®-certification according to the METC-LDD, lighter versions of training is strongly recommended. Below, practical information about the different courses ranging from introductory to more advanced is detailed.

Research involving human participants that is NOT subject to WMO

For research that is NOT subject to WMO, accredited GCP and WMO training is not obligatory, but in some cases strongly recommended at the institute. Principle Investigators and researchers that are responsible for and/or involved with the design, conduct, and/or completion of research approved by the CEP are recommended to follow the Expert WMO-GCP course for clinical trials in the Netherlands. This is particularly relevant if these researchers employ research methods using rigorous manipulations (e.g., stress research) and medical devices (e.g., for physiological measurements).

Along the same line, other team members (e.g. research assistants, student assistants) that are primarily involved in conducting such research are recommended to follow the Introductory WMO-GCP course to conduct clinical trials in the Netherlands.

Introductory WMO-GCP course to conduct clinical trials in the Netherlands

This online training covers basic GCP principles and an introduction to the Dutch laws applicable to the conduct of clinical trials in the Netherlands. After completion of 2 online training modules covering an introduction and the conduct of a clinical trial, a certificate will be granted.

For whom? Students or other members of the research team who are primarily involved in *conducting* the research that is subject to the WMO (with/at a UMC). This training is particularly useful for team members who are new to WMO research and are involved in a project-specific task and/or a single project. For research that is not subject to WMO, but does involve rigorous manipulations (e.g., stress research) and medical devices (e.g., for physiological measurements), this course is also strongly recommended for these team members.

Sign up. Enrolment for the course can be done on this website.

Investment. This course takes about 2 hours and consists of 2 online modules. The costs are ~65 euro excl BTW. Costs for this course have to be covered by project-specific funding or basic funding from the department.

Information and contact. Visit this website for more information about the online WMO-GCP training.

Expert WMO-GCP course for clinical trials in the Netherlands

This online training covers everything related to the ICH Good Clinical Practice (GCP) and Dutch legislation (WMO) applicable to clinical trials in the Netherlands. After completion of all 7 online training modules covering aspects from design to close-out of a clinical trial, an accredited WMO/GCP certificate will be granted. The certificate is valid for three years and can/must be renewed.

For whom? This training is strongly recommended for investigators and other personnel who are involved in research that is subject to the WMO with/at a UMC and who are not required to become BROK-certified. Other research personnel may include coordinator, project manager, data manager, or research assistants involved in data collection; people who carry out a single routine activity, treatment, or standard care in the context of a study; and people who conduct fundamental research in the lab. (Principle) Investigators and researchers that are responsible for and/or involved with the design, conduct, and/or completion of research NOT subject to WMO are also recommended to follow this course, in particular if they use research methods involving rigorous manipulations (e.g., stress research) and medical devices (e.g., for physiological measurements).

Sign up. Enrolment for the course can be done on this website. Enrolment for re-certification can be done here.

Investment. This course takes about 8 hours and consists of 7 online modules. The costs are ~175 euro excl BTW. The certificate is valid for three years and can/must be renewed. Costs for this course have to be covered by project-specific funding or basic funding from the department.

Information and contact. Visit this website for more information about the online WMO-GCP training.

Basic course on regulations and organization for clinical investigators (BROK)

In the BROK training, the researcher will receive training about the laws and regulations, organization and implementation of human research. A researcher becomes registered as BROK-certified if all aspects have been successfully completed including e-learning course modules, an on-site centre-specific session, and the exam. The certificate is valid for three years and can/must be renewed.

For whom? Overall, this course is mandatory for investigators who are responsible for and/or involved with the design, conduct, and/or completion of clinical research. At the approval of the METC application, the METC may require the involved investigator to be BROK-certified. In general, researchers who are involved in research that is subject to WMO and who perform the investigation with or at a UMC have to follow the BROK.

Sign up. FSW Researchers can sign up for the BROK course and choose FSW as affiliation. The chairperson of the BROK committee will then decide the location for the on-site centre-specific

session. This location is LUMC for FSW researchers unless the research will be conducted at another UMC.

Investment. This course takes about 15 hours and consists of multiple modules including an e-learning format, an on-site centre-specific session, and an exam. The costs are ~565 euro excl BTW. The certificate is valid for three years and can/must be renewed. The procedure for renewal is less intensive and involves a lower fee (~75 euro). Costs for this course have to be covered by project-specific funding or basic funding from the department.

Information and contact. Visit this website for more information about the BROK course and re-certification. For questions about the BROK training at the LUMC, please contact Yavanna van Oostveen or Mirjam Perquin via: grp@lumc.nl

Generic research skills – Research Data Management

A data management training is mandatory for all PhD candidates (see below). This training is organised and tailor-made to the Behavioural Sciences by the data stewards.

For all other staff, data management training is also highly recommended in order to support compliance with the national and local guidelines pertaining research data management. Data management related courses offered by the university are accessible for all staff; these workshops are delivered by the Centre for Digital Scholarship, such as a workshop 'How to write a DMP'.

A data management training tailored to the Behavioural Sciences for staff members other than PhD candidates is currently being developed by the data stewards and will become available in the coming year.

How to write a Data Management Plan (DMP)

For whom? Leiden University employees, researchers. For PhD candidates there is a tailor-made course available (see here).

Sign up. Employees of Leiden University can register free of charge by sending an e-mail to datamanagement@library.leidenuniv.nl with the preferred date for attendance (see here for options), research institute and any specific questions. Questions about availability can also be emailed to the same address; additional courses may be organised with sufficient interest.

Investment. One session of 2,5 hours with presentations and handouts. Participants will bring their own device to write a first version of a data management plan. Afterwards, participants will receive additional information to help them finalize their own data management plan.

Information and contact. More information about the course can be found here. Questions, remarks and course registration can be done via datamanagement@library.leidenuniv.nl

Research-specific certification

(f)MRI research: LIBC safety training and MRI scan license.

For whom? Everyone who wants to enter the MRI scanner room at the LIBC has to take part in the LIBC safety training first. After taking part in the safety training, the researcher can assist a license holder of another project as a scan buddy. The researcher will then be trained to become a license holder.

Sign up. The main researcher is allowed to sign up for the training before obtaining ethical approval.

Information and contact. For more information about this training, please contact the LIBC support team: supportlibc@lumc.nl

Supervision – training for PhD supervisors

HRM Learning & Development Course: Supervising PhD candidates

The quality of the research done by PhD candidates depends in part on the guidance from the supervisor. This is one of the reasons why it is mandatory for all staff at UHD/associate professor level or higher and/or Principle Investigators and (Co)supervisors that supervise PhD candidates for the first time to successfully complete the HRM Learning & Development Course: Supervising PhD candidates.

For whom? Mandatory for 1. all staff at UHD/associate professor level or higher at the institute and/or 2. Principle Investigators and (Co)supervisors at the institute that supervise PhD candidates for the first time and who have at least 3 months experience with supervising PhD candidates.

Sign up. Leiden University staff members can register for courses via SAP Self Service by clicking on the 'Register (Staff)' button.

Investment. About 12 hours: 4 sessions varying from 2 to 4 hours

Information. In this course, the practical aspects of supervision are addressed and it focuses on the role of the supervisor as a coach. Moreover the following topics are also addressed:

- Developing a supervision plan
- Developing scenarios for frequently occurring difficult situations
- Training conversation skills for giving feedback
- Recognising risks and warning signs

The training course consists of a combination of theory and practice. Newly acquired skills will be honed using role play. More information about this course can be found here.

Contact. You can reach HRM Learning and Development by telephone on weekdays between 09:00 and 12:00 hours. Phone**:** +31 71 527 3195 Email: HRMOpleidingen@BB.leidenuniv.nl

Graduate school – training for PhD candidates

All PhD candidates with an employee status or contract PhD candidates have to follow a programme over the full period of appointment, that comprises of at least:

- 140 hours of academic activities (training in the candidate's specialism, conference attendance etc.), and
- 140 hours of activities focusing on transferable skills. Transferable skills are skills that promote personal development and that can be applied to a wide range of (future employment) settings. For all PhD candidates at the institute, the following PhD courses are **mandatory**: PhD Introductory Meeting, Scientific Conduct Course, and Research Data Management Training

Depending on the type of methods employed in the investigation, PhD candidates and students may need to be trained in research-specific guidelines and protocols (e.g., guidelines for hygienic testing in FSW labs) before they can commence with their activities. Supervisors and the Principle Investigators are also responsible for ensuring that their PhD candidates and students are sufficiently trained to carry out their duties compliant with the relevant legislation, guidelines and protocols. In case of doubts and questions about which guidelines and protocols are relevant, PhD candidates and their supervisors should contact their lab coordinator, the CEP, or SOLO for advice.

PhD Introductory Meeting

For whom? Mandatory for all new PhD candidates at the institute.

Sign up. Course registration can be done here.

Investment. Participation in the introductory meeting carries a study load/workload of 5 hours. Attendance is tracked online and automatically processed in LUCRIS (Converis).

There is an online (3,5 hours) and an offline (4,5 hours) version of this course. The real-life version is strongly advised. The Academy building, the theatre performance and the opportunity to meet fellow PhD students all make this meeting worth the trip to Leiden!

Information. During this day candidates become familiar with doing a PhD at Leiden University: what is expected of a PhD candidate, which facilities and services PhD candidates can use and which training courses are mandatory. PhD candidates will also meet a member of the Executive Board.

Contact. HRM Learning and Development can be reached by telephone on weekdays between 09:00 and 12:00 hours. Phone**:** +31 71 527 3195 Email: HRMOpleidingen@BB.leidenuniv.nl

Research Scientific Conduct for PhDs (Social and Behavioural Sciences)

For whom? PhD candidates and postdocs from the institute in the first year of their doctoral research.

Sign up. Course registration can be done using the registration buttons on the right side of this page. Please note the difference between **Staff** (employee of Leiden University) and **Extern/LUMC** (e.g. extern, self-funded researchers or employee at LUMC).

The course is free of charge for all PhD candidates and postdocs of the institute.

Investment. The workshop takes 3 hours. Before the meeting PhD candidates are asked to read the Code of Conduct for Research Integrity, our online module Scientific Conduct and to prepare homework about these documents (homework sheet will be emailed to the participant prior to the meeting).

Information. PhD candidates learn to what extent science already has - or perhaps needs to develop - a system to prevent scientific misconduct and what role they can play as an individual scientist. And topics like: What is scientific misconduct? How do you handle misconduct situations? Does your supervisor ask you to bend the rules in name of science? To what extent are scientists biased? What are the 'grey areas'? are all being discussed.

Contact. HRM Learning and Development can be reached by telephone on weekdays between 09:00 and 12:00 hours. Phone**:** +31 71 527 3195 Email: HRMOpleidingen@BB.leidenuniv.nl

Data management training course

The course touches upon all aspects of data management, with examples drawn from the practice of social science research. The Data Stewards and a senior researcher will clarify the policy of the Institute of Psychology and add personal notes and advice. After the first session, participants will write their own data management plan, and then present it to the group during the second session. This will provide an opportunity for participants to exchange their experiences of writing their plan and receive feedback on their plan from the Data Librarians.

For whom? All new PhD candidates in the institute are required to follow the training and submit a data management plan within 6 months after the start of their PhD project.

Sign up. The course is provided twice a year. Enrolment for the course can be done via emailing the Data Stewards. Additionally, the Data Stewards will approach the PhD candidates by sending an invitation via the departmental chair.

Investment. This course takes about 14 hours and consists of 2 group sessions, assignments and online material that can be studied individually.

Information and contact. Visit this website for more information about the data management training.

Additional training

Apart from the mandatory courses mentioned above there are much more training courses aimed for personal and/or professional development. All the HRM Learning and Development courses can be found here.

The university offers a variety of platforms to support professional development, e.g., Career Platform for young researchers and the Leiden University Career Zone.