

STANDARDS FOR PhD EDUCATION IN BIOMEDICINE AND HEALTH SCIENCES IN EUROPE

A publication from
ORPHEUS-AMSE-WFME



orpheus

ORganisation of PhD Education in Biomedicine and Health Sciences in the
EUropean System

AMSE
THE ASSOCIATION OF MEDICAL SCHOOLS IN EUROPE


WORLD FEDERATION FOR
MEDICAL EDUCATION

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CONTENTS

BACKGROUND TO THIS DOCUMENT	4
PREFACE	5
INTRODUCTION	6
THE STANDARDS	
1. RESEARCH ENVIRONMENT	8
2. OUTCOMES	9
3. ADMISSION POLICY AND CRITERIA	10
4. PhD TRAINING PROGRAMME	11
5. SUPERVISION	12
6. PhD THESIS	13
7. ASSESSMENT	14
8. STRUCTURE	15
BIBLIOGRAPHY	16

BACKGROUND TO THIS DOCUMENT

This document is the result of extensive discussions at all ORPHEUS annual meetings since 2004. Additional discussions have taken place at annual meetings of Association of Medical Schools in Europe, Association for Medical Education in Europe, Federation of European Biochemical Societies, International Union of Basic and Clinical Pharmacology. Additional input has been received from over 20 workshops and meetings held at universities and specialized organisations. Individual members of ORPHEUS have also contributed importantly. To put all these ideas together the executive committees of ORPHEUS, AMSE and WFME appointed an international Task Force to prepare a standards document. The Task Force first convened November 2010 and had the following members.

- Prof. Jürgen Deckert, Department of Psychiatry, Psychosomatics and Psychotherapy, University of Würzburg, Würzburg, Germany
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PREFACE

Quality assurance is becoming of increasing importance in the internationalisation of research and higher education. The need for and the value of internationally accepted standards as a tool for reforms and quality improvement are generally recognised. This applies also to PhD programmes.¹

The PhD is an international degree, yet the content of PhD programmes and the level of the PhD thesis are less defined. These concerns are amplified in an international context with increasing mobility between countries. Thus there is a need for standards to specify what is meant by a PhD, which is the purpose of the present document.

It is recognised that standards are formulated as a tool that institutions responsible for PhD programmes can use as a basis for their own institutional and programme development. It is therefore suggested that the document could be of use for internal and external academic auditing, benchmarking between institutions, as well as evaluation by external organisations. In particular, it is intended that the document can be of assistance in safeguarding the reputation of the PhD as a research degree and in strengthening career opportunities for PhD graduates.

The document has been prepared by the Organisation for PhD Education in Biomedicine and Health Sciences in the European System (ORPHEUS), the Association of Medical Schools in Europe (AMSE), and the World Federation for Medical Education (WFME). The aim has been to bring together, in a common format, the ORPHEUS position on standards for the PhD degree in biomedicine and the WFME standards for medical education. It is intended that the document could be used as a reference for use in European institutions to enhance the quality of PhD programmes in biomedicine and health sciences. It is recognised that such standards might also be of world-wide utility.

¹ In this document the term *programme* refers to all the activities undertaken by the PhD student, including the research project, courses, teaching assignments, time in other laboratories, writing and submission of the thesis, etc.

INTRODUCTION

The modern concept of the PhD degree, research training under supervision, was developed in the nineteenth century and has since spread to most of the World (ref. 1). In Europe,² PhD training constitutes the main link between the European Higher Education and Research Areas (ref. 2), and high quality PhD programmes are crucial in achieving Europe's research goals.

According to the "Bologna Process" (ref. 3), PhD programmes form the "third cycle" of higher education, following the Bachelor and Master cycles³ as a tool to develop a "knowledge society". However, the core component of the third cycle is the advancement of learning through original research, which makes the third cycle unique and different from the first and second cycles. In particular, PhD programmes are based primarily upon the PhD student doing original, hands-on research. PhD students have therefore in many countries become a mainstay of current scientific research, as well as being the source of future scientists, and a basis for providing persons with the skills needed to build knowledge societies.

² Europe is here currently defined by the World Health Organization as: Albania; Andorra; Armenia; Austria; Azerbaijan; Belarus; Belgium; Bosnia and Herzegovina; Bulgaria; Croatia; Cyprus; Czech Republic; Denmark; Estonia; Finland; France; Georgia; Germany; Greece; Hungary; Iceland; Ireland; Israel; Italy; Kazakhstan; Kyrgyzstan; Latvia; Lithuania; Luxembourg; Malta; Monaco; Montenegro; Netherlands; Norway; Poland; Portugal; Republic of Moldova; Romania; Russian Federation; San Marino; Serbia; Slovakia; Slovenia; Spain; Sweden; Switzerland; Tajikistan; The former Yugoslav Republic of Macedonia; Turkey; Turkmenistan; Ukraine; United Kingdom; Uzbekistan.

³ European Union Ministers meeting in Berlin in September 2003 added an Action Line to the Bologna process entitled "European Higher Education Area and European Research Area – two pillars of the knowledge based society" that underlines the key role of doctoral programmes and research training in this context as a third cycle.

Although extensive consultations by ORPHEUS⁴ have found that the standards proposed in this document have wide support as aims, it must be recognised that the standards are not currently fulfilled in a number of European countries. Thus in some countries there is no tradition for a PhD in clinical medicine or for PhD programmes parallel with medical studies. In some countries the research aspect of the PhD at international level has not been emphasized. In lesser developed parts of Europe, internationalisation is seen as incentive to brain drain, and thus not to be encouraged under present conditions. On the other hand, definition of standards for the PhD is in most cases seen as a means to achieving the desired goal of being able to provide quality PhD education that has international acceptance.

ORGANISATION OF PhD PROGRAMMES

With the increase in number of PhD students⁵ and corresponding investment, the need has arisen for PhD programmes to be structured within defined time limits. Thus, PhD education should now take place within a framework which ensures smooth admission procedures, competent supervision, and qualified assessment. PhD programmes must also now take account of the fact that a large proportion of PhD graduates develop their careers not only within institutions, but also in non-academic positions, and that the programmes should provide them with the skills necessary to do this.

⁴ Organisation for PhD Education in Biomedicine and Health Sciences in the European System, www.orpheus-med.org

⁵ *PhD student* is used in this document synonymously with *doctoral candidate* (a title often used in Europe, in particular by the European Universities Association - Council for Doctoral Education (EUA-CDE) and European Council of Doctoral Candidates and Junior Researchers (EURODOC)), *PhD candidate*, etc.

The organisation for PhD programmes is normally provided by the institution that awards the PhD degrees.⁶ Typically, this would take the form of a graduate school (or equivalent) with its own leader, administration and budget, but other forms of organisation can be equally effective. In all cases the organisation should provide support for students and supervisors to allow the student successfully to complete the PhD programme within the allotted time. In some cases PhD programmes are based on more than one institution.

THE PRESENT DOCUMENT

The present document proposes a set of standards for PhD programmes and the level of a PhD degree in biomedicine and health sciences. Suggestions concerning the administrative organisation of PhD training are given in section 8. The document has been jointly developed by ORPHEUS, AMSE⁷ and WFME.⁸

The proposed standards are based on consensus documents developed by ORPHEUS starting with the first ORPHEUS conference in Zagreb, 2004, and in particular the position paper of the 2009 ORPHEUS conference in Aarhus (refs. 4, 5). The document also builds on the pre-existing trilogy of WFME Global Standards for Quality Improvement in Medical Education (ref. 6), and the 2010 Salzburg II document of the EUA-CDE (ref. 7).

The document has two types of standards:

- **Basic standard.** This describes standards that must be met from the outset.
- **Quality development.** This describes standards that are in accordance with international consensus about good practice. Fulfilment of – or initiatives to fulfil – some or all of such standards should be documented.

In addition there are **Annotations** that are used to clarify, amplify or exemplify expressions in the standards.

⁶ The *PhD degree* described in this document differs from "professional doctorates" awarded in some countries, and which are usually based on advanced educational programmes in extension of a Bachelor+Master programme to give professional competence. The PhD degree should also be distinguished from higher research degrees awarded in some countries for scientific achievements beyond the PhD.

⁷ Association of Medical Schools in Europe, www.amse-med.eu.

⁸ World Federation of Medical Education, www.wfme.org.

1. RESEARCH ENVIRONMENT

Basic standard

- The success of individual PhD programmes must be ensured by being performed in a strong research environment.
- The facilities available to the PhD students must be compatible with the requirements of completing their PhD projects with the standards described in this document.
- Research must be consistent with international ethical standards and approved by appropriate and competent ethics committees.

Quality development:

- Institutions lacking facilities or expertise in particular fields should collaborate with stronger institutions to ensure that the graduate school can offer PhD programmes of the required standard.
- When relevant, and to give access to facilities necessary for the project, PhD programmes should include time in another laboratory, preferably in another country to promote internationalisation.
- The possibility for collaborative degrees⁹ should be explored to promote co-operation between graduate schools.

Annotations:

- Strong *research environment* would apply to the research strength of the supervisor's research group, of the department, and of the graduate school, as well as national and international networking with strong research institutions.
- Measurements of the strength of the research environment would be made using publication record (number of publications, impact factor, etc.), level of external funding, numbers of qualified researchers in the group, department and graduate school, etc.
- The strength of a research environment would be assessed by comparison with other graduate schools.
- *International ethical standards* are e.g. Helsinki Declaration II (clinical), EU Directive 2010/63/EU (animal), and Oviedo Convention (bioethics).
- In this document, *institutions*, are the bodies responsible for awarding the PhD degree, e.g. university, faculty, research institute. Institutions will normally designate the responsibility for conducting PhD programmes to *graduate schools* or similar organisations.

⁹ Collaborative degrees range from joint degrees (by which students receive a single joint PhD degree conferred by two institutions on the basis of a joint PhD study programme), to dual degrees (by which students receive two degrees from collaborating institutions on the background of a joint PhD study programme), to more loose so-called cotutelle agreements (typically with joint supervision).

2. OUTCOMES

Basic standard:

- The PhD programme leading to the PhD degree must provide students with competences that enable them to become a qualified researcher; that is a scientist able to conduct responsible, independent research, according to principles of good research practice.
- Completion of a PhD programme must also be of potential benefit for those who end in careers outside of academic or clinical research, by use of competences achieved during the PhD programme, including solution of complex problems by critical analysis and evaluation, appropriate transfer of new technology and synthesis of new ideas.

Annotations

- Other *competences* relevant for PhD programmes would include¹⁰ that PhD students:
 - have demonstrated a systematic understanding of a field of study and mastery of the skills and methods of research associated with that field;
 - have demonstrated the ability to conceive, design, implement and adapt a substantial process of original research with scholarly integrity at a level that merits international refereed publication;
 - can communicate with their peers, the wider scholarly community and with society in general about their areas of expertise;
 - can be expected to be able to promote, within academic and professional contexts, technological, social or cultural advancement in a knowledge-based society.
- Further competencies include leadership, ability to supervise work of others, project management and ability to teach.
- The PhD qualification corresponds to level 8 in the European Qualifications Framework.

¹⁰ Bologna Process: framework of qualifications of the European Higher Education Area. www.bologna-bergen2005.no/EN/BASIC/050520_Framework_qualifications.pdf.

3. ADMISSION POLICY AND CRITERIA

Basic standard

- To ensure quality of PhD programmes, PhD students must be selected on the basis of a competitive and transparent process.
- Applicants for a PhD programme must have an educational level corresponding to a master's degree, or to a medical¹¹ degree. PhD programmes may be combined with Master's or medical programmes provided that the conditions do not reduce the quality of the individual programmes.
- Before enrolling a PhD student, or at a clearly defined timepoint in the programme, the institution concerned must evaluate and approve the following points:
 - the scientific quality of the research project to be performed by the PhD student,
 - whether the project may reasonably be expected to result in a thesis of the required standard (section 6) within the time frame defined by the programme,
 - the degree to which the project encourages innovation and creativity,
 - the qualifications of the nominated supervisors (see section 5).
- A PhD programme must not be initiated unless the resources for completion of the PhD research project are available.

Quality development

- In choosing PhD students, the potential of the applicant for research should be considered, and not just past academic performance.
- Projects should be assessed either by an external assessment of the written project description or else by presentation of the project to a panel of independent scientists.
- PhD students should have rights and duties commensurate with the value to the institution

of the research work performed by the PhD student.

- Where the student is obliged to obtain extra income, it should be ensured that the student has the necessary time to complete the programme.

Annotations

- According to the Bologna process, a PhD programme follows a 1-2 year *master's programme* and a 3-4 year bachelor programme. Countries with only 4-year master's + bachelor programmes should supplement these with additional qualifications.
- Some countries do not follow the Bologna process, and here other studies or work experience that brings the student to master's level can be used in the admission criteria.
- The possibility for approving the project and supervisors after enrolment allows for a model, where students spend a limited time on project selection and project development, often combined with some course work, before starting the research project. This should not reduce the 3-4 years allocated to the project.
- Criteria for admission might include documentation of proven research competence through, for example, predoctoral research programmes and published papers, achievements in previous studies, and – for medical candidates - clinical experience.
- The wish for *transparency* in the admission process notwithstanding, for many institutions a PhD programme is seen as the continuation of a master's or medical programme. The admission of the institution's own students should not prevent the admission of students from other institutions.
- The *resources* (internal or external) include infrastructure for the project, the running costs, costs of courses, costs for participation in relevant international scientific meetings, and enrolment fees where applicable.
- Sufficient laboratory, informatics and office facilities must be available to the PhD student.
- *Resources* also include the stipend/salary for the PhD student, but the manner in which students are remunerated will vary.

¹¹ The term *medical* in this document includes all health related specialities such as dentistry, pharmacy, veterinary medicine, etc.

4. PhD TRAINING PROGRAMME

Basic standard:

- PhD training programmes must be based on original research, courses and other activities which include analytical and critical thinking.
- PhD programmes must be performed under supervision.
- PhD programmes must ensure that students have substantial training in the rules concerning ethics and responsible conduct in research.
- PhD programmes must be structured with a clear time limit, a length equivalent to 3-4 years full time. Extension of the time frame should be possible, but limited and exceptional. Time frame must be extended in connection with parental leave and sick leave.
- The programme must include formalised courses totalling about 6 months (~30 ECTS points) parallel with the PhD project. A substantial part of the course programme must be concerned with training in transferable skills.
- There must be arrangements to allow PhD students, if relevant, to perform part of their PhD programme at another institution, including those in other countries.
- PhD programmes that are performed in parallel with clinical or other professional training must have the same time for research and course work as any other PhD.
- There must be continuous assessment of the progress of PhD students throughout their PhD programme.

Quality development

- Merit should be given for relevant courses taken elsewhere or other relevant experience.
- For PhDs performed by clinicians, leave-of-absence from clinical duties should be provided for the PhD part of such programmes unless these are coincident.
- Confidential student counselling concerning the PhD programme, supervision, etc., as well as personal matters should be offered by the graduate school.
- Graduate schools should consider having a thesis committee for each PhD student that monitors the progress of the PhD student

through meetings with the PhD student and the supervisors.

- Representatives of the PhD students should interact with the leadership of the graduate school regarding the design, management and evaluation of PhD programmes. Student involvement and student organisations working to enhance PhD programmes at the institution should be encouraged and facilitated.
- There should be an appeal mechanism allowing students to dispute decisions concerning their programmes and assessment of their theses.

Annotations:

- A 3-4 year full time limit has several purposes:
 - it guarantees that there is an upper limit to the amount of scientific work, which can be expected to be included in a PhD thesis, and is an effective way to avoid the requirements for a PhD degree escalating over time;
 - it encourages the PhD student to devote concentrated time to the scientific problem, and to ensure that the programme is based on original research;
 - it allows graduate schools to develop structures for handling a steady stream of PhD students.
- The *formalised courses* would include courses in ethics, health and safety, animal experimentation (if applicable), research methodology and statistics and elective discipline-specific components to support students in their scientific research.
- Courses in *transferable skills* could include training of PhD students in presentation of their research (oral/poster/papers) to academic and non-academic audiences, in university teaching, in linguistic skills, in project management, in grant application, in critical evaluation of scientific literature, in supervision of technicians and research students, and in career development and networking.
- Courses in transferable skills are important both for those who may be expected to continue in research, in either public or private institutions, and for those who continue towards careers in other fields.
- Studies for a medical qualification may be combined with a PhD programme to form a structured MB/PhD or MD/PhD programme. The exact nomenclature will depend on national traditions.

5. SUPERVISION

Basic standard:

- Each PhD student must have a principal supervisor and when relevant at least one co-supervisor to cover all aspects of the programme.
- The number of PhD students per supervisor must be compatible with the supervisor's workload.
- Supervisors must be scientifically qualified and active scholars in the field concerned.
- Supervisors must have regular consultations with their students.
- The institution must ensure that training in supervision is available for all supervisors and potential supervisors.
- The supervisor-student relationship is the key to a successful PhD programme. There must be mutual respect, planned and agreed shared responsibility, and a contribution from both.

Quality development:

- The responsibility of each supervisor should be explicit.
- Supervisors should have broad local and international scientific networks to be able to introduce the PhD student into the scientific community.
- Supervisors should assist with career development.

- Institutions should consider having contracts describing the supervision process to be signed by supervisor, PhD student and head of graduate school.
- The principal supervisor, at least, should have some formal training as a supervisor.
- Supervisors should where possible also act as co-supervisors for PhD students at other graduate schools within the country but also internationally.

Annotations

- For the supervisor to be *scientifically qualified in the field* implies that he or she will normally have a PhD or equivalent degree, and is an *active scholar* with a steady scientific production that contributes to the peer-reviewed literature.
- The term “*regular consultations*” will normally mean several times per month, but frequency will vary during the course of the programme according to the requirements of the individual PhD student.
- The consultations should discuss progress of the PhD project and PhD programme, provide general scientific advice, help on project management, help to identify and initiate follow-up projects, thesis writing, and assistance during publication.
- Web-based supervisor courses could be arranged for all supervisors to ensure that they know the regulations of the PhD programmes as well as their basic duties as supervisors.

6. PhD THESIS

Basic standard:

- The PhD thesis must be the basis for evaluating if the PhD student has acquired the skills to carry out independent, original and scientifically significant research and to critically evaluate work done by others.
- The benchmark for the PhD thesis must be the outcome to be expected from 3-4 years' research at international level. In biomedicine and health sciences this benchmark is the equivalent of at least three *in extenso* papers published in internationally recognized, peer-reviewed journals.
- In addition to the papers presented, the PhD thesis must include a full review of the literature relevant to the themes in the papers, and a full account of the research aims, methodological considerations, results, discussion, conclusions and further perspectives of the PhD project.
- Where the PhD thesis is presented in other formats, such as a single monograph, the assessment committee must ensure that the contribution is at least equivalent to the above benchmark.
- A PhD thesis in clinical medicine must meet the same standards as other PhD theses.

Quality development:

- To encourage international recognition, the thesis should be written, and optimally also defended in English, unless national regulations stipulate otherwise, or where this is not possible or desirable. An abstract of the PhD thesis should be published in English.
- Where the articles or manuscripts are joint publications, co-author statements should document that the PhD student has made a substantial and independent contribution to these. Ownership

of results from PhD studies should be clearly stated. This usually will preclude the same publication being used in more than one thesis.

- PhD theses should be published on the graduate school's home page, preferably *in extenso*. If patent or copyright legislation or other reasons prevent this, at least abstracts of the theses should be publicly accessible.
- There should be a lay summary of the thesis in the local language.

Annotations:

- By *internationally recognized journals* is meant good quality journals in the field concerned that are included in PubMed, Science Citation Index, or similar biomedical and health science literature databases. The quality of the PhD thesis will often be judged by the impact factor of the journals.
- It is generally understood that the PhD student has made a major contribution to each of the individual studies in the thesis and is the first author of at least some of the papers in the thesis.
- By *equivalent of at least three in extenso papers* is meant that some of the papers may be manuscripts having the same level as a published paper.
- Some institutions require that at least one paper is published (sometimes with the additional requirement of impact factors above a certain level).
- Some institutions allow that if papers are published in particularly high-ranking journals, then fewer than three papers can be accepted.
- The recommendation of *English* as best practice relates to this language being the language most widely used in the biomedical and health sciences literature, and thus the language best suited to encouraging internationalisation.

7. ASSESSMENT

Basic standard:

- Acceptance of a PhD thesis must include acceptance of both the written thesis and a subsequent oral defence.
- PhD degrees must be awarded by the institution on the basis of a recommendation from an assessment committee that has evaluated the thesis and the oral defence with respect to the standards described in section 6.
- The assessment committee must consist of established and active scientists who are without connection to the milieu where the PhD was performed, and without any conflict of interest. At least two should be from another institution.
- To avoid conflict of interest, the supervisor must not be a member of the assessment committee.
- In the case of a negative assessment of the written PhD thesis, the PhD student must normally be given the opportunity to rewrite the thesis. Where there is a negative assessment of the oral defence, the student must normally be allowed an additional defence. In exceptional cases, the assessment committee can reject a thesis without offer to reconsider.

Quality development:

- The oral defence should be open to the public.
- To promote internationalisation, the institution should where possible ensure that the assessment committee includes at least one member from another country.
- Apart from the thesis, the institution should ensure that sufficient transferable skills have been acquired during the PhD programme.

Annotations:

- The form of *assessment committee* varies between institutions. It is here used to describe the independent persons who advise concerning the acceptability of the PhD thesis and oral defence.
- The assessment committee is not to be confused with a committee that may be set up by the institution as part of the award process.
- To allow PhD students to find employment as soon as possible after submitting the thesis, it is important that the time between submission and defence is as short as possible consistent with critical assessment.
- Institutions should explore the use of information technologies to allow some members of the assessment committee to participate in the thesis evaluation and defence at a distance, in order to achieve an independent, competent, but also a more affordable international examination

8. STRUCTURE

The manner in which PhD programmes are organised will depend on the structure of the institution which offers these programmes, and will also depend on national regulations and relevant stakeholders. Relevant stakeholders would include graduate school heads, graduate school administrations, students, faculties, universities, institutions, governments and appropriate international organisations.

This section points to features considered important regarding the organisation responsible for PhD education. The organisation is here referred to as a graduate school, but it is recognised that other forms of organisation are also used.

Basic standard:

- The graduate school must have sufficient resources for proper conduct of PhD programmes. This includes the resources appropriate to support the admission of PhD students, implementation of the PhD programmes of the PhD students enrolled, assessment of PhD theses, and awarding of PhD degrees.

Quality development:

- There should be procedures for regular review and updating of the structure, function and quality of PhD programmes. This will normally include both supervisor and student feedback.
- The graduate school should have a homepage, in the national language and in English, including transparent information about policies concerning
 - the responsibilities of the head of graduate school and the administration,
 - quality assurance and regular review to achieve quality improvement,
 - admission policy including a clear statement on the process of selection of students,
 - the structure, duration and content of the PhD programme,
 - the methods used for assessments of PhD students,
 - the formal framework for following the progress of the individual student,
 - supervisor appointment policy outlining the type, responsibilities and qualifications of supervisors,
 - effective use of information and communication technology.

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