

**Postgraduate Training & Education
Programme in Biomedical Research
(PEP-BIOMED)**

**Trainings- und Ausbildungsprogramm für
Promotionsstudenten im Bereich
„Biomedizinische Forschung“**

Anhang 6 der Organisationsverfügung 2015-01-
V02 „Grundlagen für wissenschaftliches Arbeiten
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Introduction

The Paul-Ehrlich-Institut (PEI) is both a competent authority responsible for the marketing authorization of biomedicines and an internationally recognized research institute in this field. The combination of regulatory duties and research tasks is unique in Europe and forms the basis of the institute's scientific reputation as well as its state-of-the-art competency regarding the scientific regulatory work. Moreover, it provides the basis for the successful collaboration with regulatory agencies and international health organizations with respect to the harmonization and standardization of marketing authorization procedures.

In this regard, the PEI is responsible for the authorization of clinical trials and the marketing authorization of human and veterinary vaccines as well as biomedicines for the use in humans (vaccines, medicinal products containing antibodies, allergens, blood and blood products, tissues, medicinal products for gene therapy and cell therapeutics). Besides, it is responsible for the recording and assessment of undesirable effects (pharmacovigilance) and the official independent experimental batch testing of biomedicines and in vitro diagnostic devices.

To manage these important responsibilities successfully, thus being able to contribute to the development and marketing authorization of safe and effective biomedicines of highest quality, the institute performs internationally competitive basic and regulatory research (see Research Programme of the PEI).

In this context, PEP-BIOMED provides a sophisticated training programme for PhD candidates working on a dissertation project at the PEI. The programme addresses general research topics, basics of biomedicine regulation and soft skills aspects. PEP-BIOMED takes into account the doctoral degree regulations of the Johann Wolfgang Goethe-Universität (Frankfurt am Main, Germany) and the recommendations of the German Science Council with respect to postgraduate education programmes. For this reason, the regular time frame of an experimental PhD project at the PEI is three years and the programme is designed as a three-year circuit¹. PEP-BIOMED operates at an international level, addresses students world-wide, and communication in English is preferred.

The aim of PEP-BIOMED is to guarantee state-of-the-art supervision and assistance to PhD candidates at the PEI. The proposal is designed for students in natural sciences with a diploma or master's degree as well as licensed veterinarians and medical students working on a three-year experimental dissertation project at the institute².

Objectives

The learning objectives of PEP-BIOMED are based on the research expertise of the institute in the fields of microbiology, virology, immunology, veterinary medicine, allergology, cell & gene therapy and haematology as well as on its internationally recognized regulatory expertise in the field of vaccines & biomedicines. Consequently, the overall aim is to prepare young scientists for a career in life science research and/or in drug development and regulation at universities, research organisations, public authorities or industry.

¹ The regular period of three years for a PhD project at the PEI can be extended only under special circumstances (for example disability-related handicaps or illness).

² PhD students receiving support within an external graduate school/college programme shall not attend PEP-BIOMED. Diploma, master or bachelor students preparing a thesis project at the PEI as well as postdoctoral scientists may voluntarily attend the courses of PEP-BIOMED.

PEP-BIOMED is based on an unbiased, respectful and science-based interaction at the PEI. The programme guarantees high quality research assistance to PhD candidates throughout the entire training period of three years. In this regard, PEP-BIOMED aims at ensuring that PhD candidates acquire a result-oriented, independent scientific working habit as well as all necessary experimental and analytical skills. The programme requires and encourages PhD candidates to develop all competences necessary for a career as an independent scientist.

A further training goal is to equip young scientists with key skills qualifications regarding their work as team players and with respect to the overall career development. In accordance with the Federal Report on Young Scientists (Bundesbericht Wissenschaftlicher Nachwuchs, BuWiN³), the PEI guarantees equal opportunities irrespective of gender or disability.

Executive Summary of the Programme's Key Instruments

Immediately after starting to work on a dissertation project at the PEI, each PhD candidate is summoned to contact the MANAGER of PEP-BIOMED (*Email address: **PEP-BIOMED@pei.de***) seeking for a personal introduction into the programme.

While working on their thesis project, all PhD students at the PEI are supported by both the actual PEI SUPERVISOR of the project and an independent THESIS COMMITTEE. The committee gives advice to both the PhD candidate and the PEI SUPERVISOR supporting the progress of the project and the success of the dissertation.

At the RESEARCH PLENUM, PhD candidates have the opportunity to present their work in the form of scientific seminar presentations. Besides PhD candidates and graduating students, principle investigators and post-doctoral fellows of all research groups as well as other interested scientists of the institute are present.

The three-year LECTURE SERIES given by research and regulatory scientists as well as administration seniors serves accompanying further education in the fields of life science, research management and regulatory tasks.

The COLLOQUIUM offers lectures by experienced external scientists and experts on specific scientific topics. The speakers are usually invited by principle investigators of the PEI according to criteria such as excellence and scientific relevance.

TRAINING COURSES and WORKSHOPS regarding essential scientific techniques and methods or key skills qualification are either offered in-house, or the participation in externally offered respective courses or workshops is supported and acknowledged.

PEI SUPERVISORS organize lab meetings, JOURNAL CLUBS and one-on-one meetings on a regular basis. Lab meetings of the respective group are designed for discussing the projects in a specialized environment. JOURNAL CLUBS serve to provide advanced knowledge of the specific literature, but also aim at training the students in critically reviewing research data and the skills required for successful publication. Regular one-on-one meetings with the PEI SUPERVISOR are imperative for the successful progress of the thesis project.

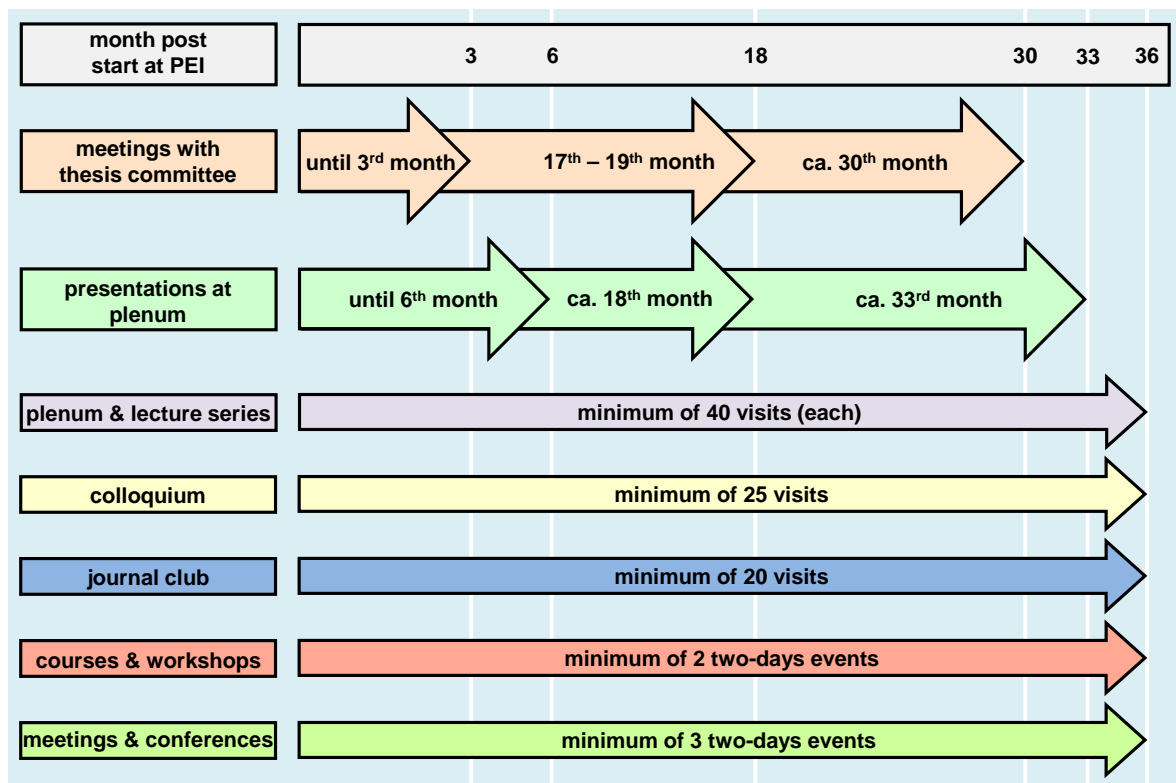
³ <http://www.buwin.de/buwin/2013/>

PEP-BIOMED encourages the further development of social competence and requires from each PhD candidate to assume some SOCIAL ACTIVITIES (organizing courses and colloquia by themselves, co-ordination of leisure activities, taking on voluntary duties, etc.)⁴.

The participation in the different modules of PEP-BIOMED is translated into a CREDIT POINT SYSTEM. From the institute's point of view, successful participation at PEP-BIOMED is a prerequisite for graduation. As a result, PhD candidates shall receive a CERTIFICATE from the MANAGER of PEP-BIOMED addressing the success of participation in PEP-BIOMED in terms of a supplementary qualification (*Email address: PEP-BIOMED@pei.de*).

PEP-BIOMED Timetable

PEP-BIOMED supports and requires independent work and personal responsibility. In this context, PhD candidates are expected to participate actively in the activities offered within PEP-BIOMED and to fulfil all the requirements of the programme within three years and in a timely manner without prior request.



⁴ SOCIAL ACTIVITIES are acknowledged by the MANAGER of PEP-BIOMED. Thus, such activities shall be coordinated in consultation with the MANAGER of PEP-BIOMED beforehand (*Email address: PEP-BIOMED@pei.de*).

THESIS COMMITTEE MEETINGS

MEMBERS

The THESIS COMMITTEE is composed of three to five experienced scientists holding a doctorate for at least 3 years and featuring experience in instructing students on how to conduct scientific work. This includes the PEI SUPERVISOR, the division head and/or the president of the institute (if not identical with the PEI SUPERVISOR). Involvement of senior scientists from other divisions of the PEI is strongly encouraged. Additional members of the THESIS COMMITTEE should, if possible, be the university supervisor and other experienced scientists from the PEI or abroad.

PURPOSE

One main purpose of the THESIS COMMITTEE is to support the design of a promising and hypothesis driven research project with the ultimate aim of successful publication. To this end, the THESIS COMMITTEE gives guidance to the experimental work and supports both the PhD candidate and the PEI SUPERVISOR by unbiased discussion of project planning and progress, research results, and the current state of scientific knowledge in the specific research area. In particular, the THESIS COMMITTEE attempts to assure that the thesis project can be completed within three years and with publishable results.

TIMETABLE OF MEETINGS

PhD candidates inform the MANAGER of PEP-BIOMED (*Email address: PEP-BIOMED@pei.de*) about the composition of the THESIS COMMITTEE not later than six weeks after the start at the PEI. The members of the committee are chosen independently without prior request, and in agreement with the PEI SUPERVISOR. Besides, PhD candidates inform the MANAGER of PEP-BIOMED about planned meetings (or request justifiable deviations from the timetable) in a timely manner without prior request.

During the experimental work at the PEI, PhD candidates meet with their THESIS COMMITTEE at least three times to discuss the initial project proposal, the current scientific results, the further experimental setting, and the publication of accomplishments. These meetings take place at the PEI and are organized by the PhD candidate (fixing an appointment and selection of the location for the meeting) according to the following time table:

- the START-UP MEETING of the PhD candidate with the THESIS COMMITTEE shall take place not later than three months after the start at the PEI
- the FOLLOW-UP MEETING shall take place in the 17th to 19th month
- the THIRD MEETING shall take place not later than sixth month before the completion of the thesis project (generally before the 31th month at the PEI).

Appointments with the THESIS COMMITTEE are arranged independently by the PhD candidate in a timely manner. The PhD candidate informs the MANAGER of PEP-BIOMED on these appointments by sending an Email to the THESIS COMMITTEE members confirming the date (Cc to PEP-BIOMED@pei.de).

Not later than one week before a meeting, the PhD candidate provides the proposal (first meeting) or a results presentation (see below), which needs to be sent to the members of the committee by Email (Cc to PEP-BIOMED@pei.de).

Not later than two weeks after each meeting, the PhD candidate shall provide resolution minutes in a brief outline, which need to be sent to the members of the THESIS COMMITTEE by Email (Cc to PEP-BIOMED@pei.de).

START-UP MEETING

This meeting serves to agree on the design of a promising and hypothesis driven research project. Accordingly, the PhD candidate shall prepare a short hypothesis-driven research proposal. The proposal shall comprise not more than six pages (2500 words) and include:

- project plan describing the current state of research, preliminary work, hypothesis aims, and working programme including scheduled milestones
- information on the collaboration with other groups
- references (bibliography)
- short CV of the PhD candidate.

The proposal shall be presented in the START-UP MEETING for discussion with the THESIS COMMITTEE. The committee can request an appropriate revision of the research proposal. Reasons for this may be fundamental criticism of project design and research outline (e.g. project is not hypothesis-driven, project cannot be handled within three years, or project appears to be high-risk without back-up planning). The adoption of such amendments shall be supervised in future meetings by the committee.

FOLLOW-UP MEETING

For this meeting, the PhD candidate shall prepare a 20-minute results presentation (as well as printed hand-outs) describing the current status of the work and the future experimental planning in the form of a seminar talk. The goal of this meeting is to support the scientific progress of the project and to promote early publication of the results if reasonable. To this end, the THESIS COMMITTEE may again request essential amendments to the presented research outline.

FINAL MEETING

For this meeting, the PhD candidate shall prepare a 20-minute results presentation (as well as printed hand-outs) in the form of a thesis defence lecture together with an outline of the planned final experiments and the agenda for publication. The THESIS COMMITTEE shall investigate if the amendments of the former meetings have successfully been put into action and discuss the research outline for the remaining period. This meeting especially focuses on the support of short term publication and the preparation for thesis defence.

ADDITIONAL MEETINGS

The THESIS COMMITTEE and the PhD candidate may agree upon additional meetings if required.

RESEARCH PLENUM

In the course of their experimental work at the PEI, PhD candidates shall give seminar lectures at least three times before the RESEARCH PLENUM. This forum provides a platform for young scientists to train their English language presentation skills in front of a larger audience. Moreover, it serves as a platform of interdisciplinary exchange and discussion between the scientists of the PEI.

TIMETABLE OF SEMINAR LECTURES

Whenever possible, SEMINAR LECTURES of PhD candidates shall be given in the RESEARCH PLENUM after the respective meeting with the THESIS COMMITTEE. The date for these lectures shall be arranged by the PhD candidates in consultation with the organizer of the RESEARCH PLENUM in a timely manner without prior request. The MANAGER of

PEP-BIOMED shall be informed on scheduled lectures by Email. SEMINAR LECTURES shall be given to the following time table:

- The first lecture is held in the sense of a START-UP SEMINAR and takes place around six months after the start at the PEI. In this lecture the research proposal (see THESIS COMMITTEE MEETINGS) and first results shall be presented.
- The second lecture is held in the sense of a FOLLOW-UP SEMINAR and takes place around 18 months after the start at the PEI. In this lecture the latest status of the work shall be presented taking into account the individual research proposal.
- The third lecture is held in the sense of a FINAL SEMINAR and takes place not later than three month before the completion of the thesis project (generally before the 34th month at the PEI). In this lecture the final status of the work shall be presented while serving as a preparation for the thesis defence.

For each of the SEMINAR LECTURES, PhD candidates prepare a summary of not more than 200 words, which shall be submitted to the organizers of the RESEARCH PLENUM by Email not later than one week before the date for the lecture (Cc to PEP-BIOMED@pei.de). The summary will then be published together with the announcement of the date of the lecture. Lectures shall not exceed a time-limit of twenty minutes followed by approximately ten minutes of discussion.

LECTURE SERIES

The three-year LECTURE SERIES is especially designed to further educate PhD students of the PEI taking into account the unique selling points of the institute. The lectures cover the following subject areas:

- procedures of biomedicine regulation
- general science & research issues
- regulatory research & innovative medicinal product testing
- pathogen-host & biomedicine-organism interactions
- experimental vaccines, therapies & diagnostics.

RETREAT & MEETINGS

The PEI organizes a RETREAT of its scientific staff members on an annual basis. This meeting is designed to (i) promote interdisciplinary exchange between the divisions and research groups, (ii) initiate critical discussion of selected research projects, and (iii) provide further education in research relevant areas. Scientists present their research results or research relevant topics in the form of oral presentations or posters.

Moreover, the LANGENER NACHWUCHSWISSENSCHAFTSPREIS⁵ is awarded at the RETREAT to young scientists of the PEI (PhD candidates or post-doctoral fellows) publishing high-ranking first author publication during the past year.

Besides their participation in the RETREAT, PEI SUPERVISORS actively support PhD candidates in their efforts to attend other national and international research meetings.

⁵ The LANGENER NACHWUCHSWISSENSCHAFTSPREIS is sponsored by the Sparkasse Langen-Seligenstadt and is awarded by the PEI together with the town of Langen.

PUBLICATIONS

Competent scientists in the life sciences are qualified to successfully conduct research activities, which lead to PUBLICATIONS in an internationally accredited journal. In this regard, PEP-BIOMED encourages and supports the PUBLICATION of the PhD candidate's own scientific data. PEI SUPERVISORS are obliged to provide the necessary assistance; a respective motivation of the PhD candidates is expected⁶.

CREDIT POINT SYSTEM

The CREDIT POINT SYSTEM supports the PhD candidates in their efforts to attend the training and further education offerings of PEP-BIOMED. The following table lists the minimum requirements for a certified successful participation in the programme:

Elements	Credit points per	Minimum performance (in three years)	Minimum credit points (in three years)
Meetings with THESIS COMMITTEE	15	3 meetings	45
Presentations at RESEARCH PLENUM	15	3 presentations	45
Attendance at RESEARCH PLENUM	1	40 of approx. 75	40
Attendance at JOURNAL CLUB	1	20 of approx. 40	20
Attendance at LECTURE SERIES	1	40 of approx. 75	40
Attendance at COLLOQUIUM	1	25 of approx. 60	25
COURSES & WORKSHOPS	15 per course	2 courses or workshops	30
RETREAT & other meetings	15	3 meetings	45
SOCIAL ACTIVITIES	5-25	2 annual activities	10
PUBLICATIONS ⁷	100	1	100
Minimum total credit points in three years:			∑ : 400

After successful completion of PEP-BIOMED, the candidates will obtain a CERTIFICATE referencing the acquired additional qualifications. To this end, the certificate (i) states the number of credit points gathered relative to the minimum required for a successful participation in PEP-BIOMED, (ii) provides information on the major courses and meetings attended, and (iii) assesses the overall course performance.

⁶ Papers accepted for PUBLICATION are reported to the MANAGER of PEP-BIOMED (Email address: PEP-BIOMED@pei.de) in order to be acknowledged by CREDIT POINTS.

⁷ PUBLICATIONS in a peer-reviewed journal holding an impact factor.

Candidates shall obtain this CERTIFICATE only after fulfilling all requirements of PEP-BIOMED and submitting a printed hardback of their written thesis to the PEI SUPERVISOR as well as an electronic version (pdf file) to the PEI library⁸.

A successful participation in PEP-BIOMED is a prerequisite for a possible contract continuation of (former) PEI PhD candidates in research or regulation. Moreover, the successful participation of PhD candidates in PEP-BIOMED is also an essential criterion for the further eligibility of the respective PEI SUPERVISORS regarding internal research funding programmes.

GUIDELINES FOR THESIS COMMITTEE MEMBERS

All PhD candidates working on a dissertation project at the PEI are coached by an independent THESIS COMMITTEE composed of three to five experienced scientists holding a doctorate for at least 3 years and having hands-on experience in instructing students on how to conduct and publish scientific work.

The main purpose of the committee is to provide supportive advice to both the PhD candidate and the PEI SUPERVISOR (as part of the THESIS COMMITTEE) with respect to the successful completion of the planned research project as well as the dissertation.

In this regard, the THESIS COMMITTEE has the following tasks:

- The committee meets at least three times with the PhD candidate throughout the course of the three-year dissertation project. The objectives of these meetings are to monitor and support the progress of the dissertation project and to support the PhD candidate in developing independent scientific working habits.
- In the **START-UP MEETING**, the PhD candidate presents the planned dissertation project in the form of a short proposal. The THESIS COMMITTEE shall ensure that the project (i) is hypothesis-driven, (ii) can be completed within three years, and (iii) promises publishable results. Besides, it should pay attention to alternative approaches/side projects with the aim to prevent failure of dissertation due to (unpredictable) problems with the major (high risk) project.
- In the **FOLLOW-UP MEETING**, the PhD candidate presents the results of approximately 18 month of research as well as a research outline for the remaining period of the dissertation project. The THESIS COMMITTEE shall investigate whether the amendments of the START-UP-MEETING have successfully been turned into action and discuss the presented research outline. Besides, the committee shall scrutinize the existing data with respect to a chance of early publication.
- In the **FINAL MEETING**, the PhD candidate presents the conclusions of approximately 30 month of research in the form of a thesis defence lecture. The THESIS COMMITTEE shall investigate whether the amendments of the FOLLOW-UP-MEETING have successfully been turned into action and discuss the research outline for the remaining period. Besides, the committee shall especially enforce the publication of results and prepare the candidate for thesis defence at university.
- During these meetings, the THESIS COMMITTEE can request an appropriate revision of the initial research proposal and essential amendments to the presented research outlines, respectively.

⁸ Under special circumstances, the CERTIFICATE can be granted in retrospect (for example if a scientific PUBLICATION is only accepted after the PhD thesis has been completed).

- The adoption of possible amendments shall be supervised by the committee in future meetings. To this end, the PhD candidate shall provide resolution minutes in a brief outline, which need to be sent to the members of the THESIS COMMITTEE not later than two weeks after each meeting.
- Both, the THESIS COMMITTEE and the PhD candidate can schedule additional meetings, if necessary.

GUIDELINES FOR PEI SUPERVISORS

PEP-BIOMED follows internationally accepted principles regarding the training and further education of PhD candidates. The following guidelines shall establish respective standards for the supervision of PhD candidates at the PEI:

- All new PhD candidates are obligated to receive a personal introduction into PEP-BIOMED. It is the PEI SUPERVISORS's responsibility to ascertain that new PhD candidates introduce themselves to the MANAGER of PEP-BIOMED (*Email address: PEP-BIOMED@pei.de*) in time.
- PEI SUPERVISORS shall fulfil their duties and obligations as part of the PhD candidates' training in a responsible and professional manner. PhD candidates and PEI SUPERVISORS shall communicate respectfully.
- All research group leaders and division/section heads shall support the success of PEP-BIOMED as well as the compliance with the respective regulations by creating the necessary framework conditions.
- PEI SUPERVISORS cooperate with the THESIS COMMITTEE aiming at the promotion of a successful completion of both the research project and the thesis defence.
- At the start of a PhD project, PEI SUPERVISORS shall ascertain that the PhD candidates are in a position to prepare a hypothesis-driven research proposal suitable for achieving publishable results and a PhD degree within three years.
- PEI SUPERVISORS are personally responsible for the PhD candidates' regular participation in Journal Clubs. In addition, they hold regular lab meetings and on-on-one meetings to foster the progress of the PhD projects in their group.
- PEI SUPERVISORS shall actively support the PhD candidate's attendance at (inter)national research meetings and/or external further education programmes as well as their efforts to apply for respective funding.
- PEI SUPERVISORS actively promote the PhD candidates' development regarding an independent scientific work habit by gradually granting them the necessary autonomy for independent research decisions and project management.
- PEI SUPERVISORS shall critically and to the best of their abilities support PhD candidates in the independent publication of their research results via manuscripts and the dissertation.

Appendix C: COMPLETION RECORD

Paul-Ehrlich-Institut



Postgraduate Training & Education Programme in Biomedical Research (PEP-BIOMED)

Completion Record

Name of Participant: _____

Topic of the Project: "" _____

Project Advisor at PEI: _____

Start of Experimental
Dissertation at the PEI: _____

Date of Registration at
the Research Office*: _____

Date of Nomination of
the Thesis Committee
at the Research Office*: _____

Funding: _____

* to be signed by the Research Office!

Members of the Thesis Committee			
Name	Affiliation	Date of Agreement	Signature

Meetings of the Thesis Committee (Minimum of 3)				
Topic	Date of Meeting	Signatures	Date of Protocol	Signature

Attendance at the Research Plenum - 1 st Year			
Date	Topic	Signature of Person in Charge	Credit Points

Attendance at Lecture Series - 1 st Year			
Date	Topic	Signature of Lecturer	Credit Points

Attendance at Journal Club - 1 st Year			
Date	Manuscript [e.g. PMID]	Signature of Person in Charge	Credit Points

Attendance at Colloquium - 1 st Year			
Date	Topic	Signature of Lecturer	Credit Points

Attendance at Courses & Workshops			
Date	Course/Workshop - Host - Hours	Signature of Person in Charge	Credit Points

Attendance at PEI Retreat & Meetings			
Date	Retreat/Meeting - Host	Signature of Person in Charge	Credit Points

Social Activity			
Date	Activity	Signature of Person in Charge	Credit Points

Publications		
Manuscript	Date of Acceptance /Publication	Credit Points