

ACCP Guidelines for Clinical Research Fellowship Training Programs

Definition

A research fellowship is a directed, highly individualized, postgraduate training program designed to prepare the participant to function as an independent investigator.

Introduction

The purpose of fellowship training programs is to develop competency and expertise in the scientific research process, including hypothesis generation and development, study design, protocol development, grantsmanship, study coordination, data collection, analysis, and interpretation, technical skills development, presentation of results, and manuscript preparation and publication. A fellowship candidate is expected to possess appropriate practice skills relevant to the knowledge area of the fellowship. Such skills may be obtained through prior practice experience or completion of a residency program.

Under the close direction, instruction and supervision of a qualified investigator-preceptor, the fellow receives a highly individualized learning experience, utilizing the fellow's research interests and knowledge needs as a focus for his/her education and training. Fellowships are typically offered through schools/colleges of pharmacy, academic health centers, the pharmaceutical industry, and/or specialized care institutions. A fellowship graduate should be capable of conducting independent and collaborative research and functioning as principal investigator.

Training Program Requirements

1. A minimum of 3,000 hours of the fellowship training time should be devoted to research-related activities over a minimum period of two years.
2. Administrative institutional support for the preceptor's research program and the fellowship training program.
3. Availability of advanced educational opportunities (e.g., graduate level coursework) in research-related topics. Such coursework may include, but is not limited to, courses in research design and methods, biostatistics, ethical issues, pharmacokinetics, pharmacodynamics, pharmacoeconomics, and others as appropriate to the specific fellow and program.
4. Availability of appropriate facilities (e.g., laboratory and/or clinical) to conduct research.
5. Availability of qualified personnel to teach clinical, laboratory, and/or computer technology-based research skills.
6. Ready access to scientific literature and computer facilities.

Preceptor Qualifications

1. A clinical scientist with an established and on-going record of independent research accomplishments and expertise in the area of specialization related to the fellowship, which may be exemplified by:
 - a. fellowship training, a graduate degree, and/or equivalent experience;
 - b. principal or primary investigator on research grants and/or projects; and
 - c. published research papers in peer-reviewed scientific literature on which the preceptor is the primary or senior author.
2. Active collaborative research relationships with other scientists.

Fellowship Applicant Criteria

1. Masters or doctoral degree in a health science discipline required
2. Residency or equivalent clinical experience preferred.
3. Demonstrated interest in or an aptitude for a career in research.

Fellowship Experiences

Ideally, a research fellow should initiate and complete at least one original research project. However, it is recognized that this may not be possible in every case. Whether through the completion of one project from start to finish or through participation in multiple projects, the fellow should obtain extensive experience in:

1. Development of at least one scientific hypothesis
2. Development of experimental methods to test the developed hypothesis.
3. Preparation of a protocol and submission of the protocol to the appropriate institutional review committee.
4. Grantsmanship, including identification of appropriate funding sources for specific projects and the preparation and submission of a grant for extramural funding consideration.
5. Study design and coordination and data collection.
6. Statistical analysis of data.
7. Data analysis and interpretation
8. Development of clinical, laboratory, and/or computer-based research skills as appropriate to the specific training program
9. Abstract preparation and submission
10. Presentation of research at peer-reviewed scientific meetings
11. Manuscript preparation and submission for publication in peer-reviewed journals.
12. Participation in journal clubs, research workshops, and/or seminar series.
13. Instruction in biomedical science ethics.