

# ACGME Program Requirements for Graduate Medical Education in Molecular Genetic Pathology

## Common Program Requirements are in BOLD

Effective: July 1, 2007

### I. Introduction

#### I.A. Definition of the Subspecialty

Molecular Genetic Pathology (MGP) is the subspecialty of Medical Genetics and Pathology in which the principles, theory, and technologies of molecular biology and molecular genetics are used to make or confirm clinical diagnoses of Mendelian genetic disorders, disorders of human development, infectious diseases and malignancies, to assess the natural history of those disorders, and to provide the primary physician with information by which to improve the ability to provide optimal care for individuals affected with these disorders. Molecular Genetic Pathology includes a body of knowledge and techniques necessary to study diseases associated with alterations in genes, provides information about gene structure, function, and alteration, and applies laboratory techniques for the diagnosis, treatment, and prognosis of individuals with these disorders.

#### I.B. Duration and Scope of Education

Educational programs in molecular genetic pathology must be 1 year in length and provide a structured educational experience for qualified physicians seeking to acquire additional competence in all current aspects of the discipline including basic science, diagnostic laboratory procedures, laboratory management, and consultation. Programs must be designed to teach trainees to integrate molecular genetic pathology into medical consultations with clinicians in the diagnosis and care of patients.

### II. Institutions

#### II.A. Sponsoring Institution

**One sponsoring institution must assume ultimate responsibility for the program, as described in the Institutional Requirements, and this responsibility extends to fellow assignments at all participating institutions.**

II.A.1. Postgraduate fellowships in molecular genetic pathology will be accredited in institutions that also sponsor residencies accredited by the Accreditation Council for Graduate Medical Education (ACGME) in medical genetics and pathology. Requests for exceptions to this policy will be reviewed on a case-by-case basis.

II.A.2. The molecular genetic pathology program must be jointly sponsored by the academic units responsible for Pathology and Clinical Medical Genetics. Further, the sponsoring institution must ensure that activity is

supported by other disciplines, including internal medicine, pediatrics, and obstetrics-gynecology.

## **II.B. Participating Institutions**

**II.B.1. Assignment to an institution must be based on a clear educational rationale, integral to the program curriculum, with clearly-stated activities and objectives. When multiple participating institutions are used, there should be assurance of the continuity of the educational experience.**

**II.B.2. Assignment to a participating institution requires a letter of agreement with the sponsoring institution. Such a letter of agreement should:**

**II.B.2.a) identify the faculty who will assume both educational and supervisory responsibilities for fellows;**

**II.B.2.b) specify their responsibilities for teaching, supervision, and formal evaluation of fellows, as specified later in this document;**

**II.B.2.c) specify the duration and content of the educational experience; and**

**II.B.2.d) state the policies and procedures that will govern fellow education during the assignment.**

## **III. Program Personnel and Resources**

### **III.A. Program Director**

**III.A.1. There must be a single program director responsible for the program. The person designated with this authority is accountable for the operation of the program. In the event of a change of either program director or department chair, the program director should promptly notify the executive director of the RRC through the Web Accreditation Data System of the ACGME.**

**III.A.2. The Program Director, together with the faculty, is responsible for the general administration of the program, and for the establishment and maintenance of a stable educational environment. Adequate lengths of appointment for both the program director and faculty are essential to maintaining such an appropriate continuity of leadership.**

**III.A.3. Qualifications of the program director are as follows:**

**III.A.3.a) The program director must possess the requisite specialty expertise, as well as documented educational and**

administrative abilities.

**III.A.3.b) The program director must be certified in by the American Board of Medical Genetics (in clinical Medical Genetics) or the American Board of Pathology, or possess qualifications judged to be acceptable by the RRC and certification in Molecular Genetics Pathology or possess qualifications judged to be acceptable by the Residency Review Committees.**

**III.A.3.c) The program director must be appointed in good standing and based at the primary teaching site.**

**III.A.4. Responsibilities of the program director are as follows:**

**III.A.4.a) The program director must oversee and organize the activities of the educational program in all institutions that participate in the program. This includes selecting and supervising the faculty and other program personnel at each participating institution, appointing a local site director, and monitoring appropriate fellow supervision at all participating institutions.**

**III.A.4.b) The program director is responsible for preparing an accurate statistical and narrative description of the program as requested by the RRC, as well as updating annually both program and fellow records through the ACGME's Accreditation Data System.**

**III.A.4.c) The program director must ensure the implementation of fair policies, grievance procedures, and due process, as established by the sponsoring institution and in compliance with the Institutional Requirements.**

**III.A.4.d) The program director must seek the prior approval of the RRC for any changes in the program that may significantly alter the educational experience of the fellows. Such changes, for example, include:**

**III.A.4.d).(1) the addition or deletion of a participating institution;**

**III.A.4.d).(2) a change in the format of the educational program;**

**III.A.4.d).(3) a change in the approved fellow complement for those specialties that approve fellow complement.**

**On review of a proposal for any such major change in a program, the RRC may determine that a site visit is necessary.**

**III.B. Faculty**

**III.B.1. At each participating institution, there must be a sufficient number of faculty with documented qualifications to instruct and supervise adequately all fellows in the program.**

**III.B.2. The faculty, furthermore, must devote sufficient time to the educational program to fulfill their supervisory and teaching responsibilities. They must demonstrate a strong interest in the education of fellows, and must support the goals and objectives of the educational program of which they are a member.**

**III.B.3. Qualifications of the physician faculty are as follows:**

**III.B.3.a) The physician faculty must possess the requisite specialty expertise and competence in clinical care and teaching abilities, as well as documented educational and administrative abilities and experience in their field.**

**III.B.3.b) The physician faculty must be certified by the American Board of Medical Genetics or the American Board of Pathology, or possess qualifications judged to be acceptable by the RRC.**

**III.B.3.c) The physician faculty must be appointed in good standing to the staff of an institution participating in the program.**

**III.B.4. The responsibility for establishing and maintaining an environment of inquiry and scholarship rests with the faculty, and an active research component must be included in each program. *Scholarship* is defined as the following:**

**III.B.4.a) the scholarship of *discovery*, as evidenced by peer-reviewed funding or by publication of original research in a peer-reviewed journal;**

**III.B.4.b) the scholarship of *dissemination*, as evidenced by review articles or chapters in textbooks;**

**III.B.4.c) the scholarship of *application*, as evidenced by the publication or presentation of, for example, case reports or clinical series at local, regional, or national professional and scientific society meetings.**

**Complementary to the above scholarship is the regular participation of the teaching staff in clinical discussions, rounds, journal clubs, and research conferences in a manner that promotes a spirit of inquiry and scholarship (e.g., the offering of guidance and technical support for fellows involved in research such as research design and statistical analysis); and the provision of support for fellows' participation, as appropriate, in scholarly activities.**

**III.B.5. Qualifications of the nonphysician faculty are as follows:**

**III.B.5.a) Nonphysician faculty must be appropriately qualified in their field.**

**III.B.5.b) Nonphysician faculty must possess appropriate institutional appointments.**

**III.C. Other Program Personnel**

**Additional necessary professional, technical, and clerical personnel must be provided to support the program.**

**III.D. Resources**

**The program must ensure that adequate resources (e.g., sufficient laboratory space and equipment, computer and statistical consultation services) are available.**

**III.D.1.** A sufficient volume and variety of current specimens from adult and pediatric patients must be available to provide MGP fellows a broad exposure to consultation regarding medical genetic testing for congenital and acquired diseases--without diluting the educational experience of fellows in affiliated Pathology and Medical Genetics residencies.

**III.D.2.** The institutions and laboratories participating in the program must be appropriately accredited and/or licensed.

**III.D.3.** Fellows must have ready access to a major medical library. Library services should include electronic retrieval of information from national medical databases.

**III.D.4.** Fellows must have ready on-site access to appropriate texts and journals in each institution participating in the program.

**IV. Fellow Appointments**

**IV.A. Eligibility Criteria**

**IV.A.1. The program director must comply with the criteria for fellow eligibility as specified in the Institutional Requirements.**

**IV.A.2.** MGP fellows should have completed training in an ACGME accredited residency in either Medical Genetics or Pathology, or be a physician certified by the American Board of Medical Genetics.

**IV.B. Number of Fellows**

**The RRC will approve the number of fellows based upon established**

written criteria that include the adequacy of resources for fellow education (e.g., the quality and volume of patients and related clinical material available for education), faculty-fellow ratio, institutional funding, and the quality of faculty teaching.

#### **IV.C. Fellow Transfers**

To determine the appropriate level of education for fellows who are transferring from another residency program, the program director must receive written verification of previous educational experiences and a statement regarding the performance evaluation of the transferring fellow prior to their acceptance into the program. A program director is required to provide verification of residency education for fellows who may leave the program prior to completion of their education.

#### **IV.D. Appointment of Fellows and Other Students**

The appointment of fellows and other specialty fellows or students must not dilute or detract from the educational opportunities available to regularly appointed fellows.

### **V. Program Curriculum**

#### **V.A. Program Design**

##### **V.A.1. Format**

The program design and sequencing of educational experiences will be approved by the RRC as part of the review process.

##### **V.A.2. Goals and Objectives**

The program must possess a written statement that outlines its educational goals with respect to the knowledge, skills, and other attributes of fellows for each major assignment and for each level of the program. This statement must be distributed to fellows and faculty, and must be reviewed with fellows prior to their assignments.

#### **V.B. Specialty Curriculum**

**V.B.1.** The program must possess a well-organized and effective curriculum, both didactic and clinical. The curriculum must also provide fellows with direct experience in progressive responsibility for patient management.

**V.B.2.** Programs should be structured so that fellows are involved in MGP throughout the year. The program must include both didactic instruction and practical experience with the molecular biology and the biochemistry of nucleic acids and proteins including structure, function, replication

mechanisms, in vitro synthesis, and the roles of DNA and various RNA classes and proteins in cellular biology. Programs should instruct fellows in an understanding of the mechanism of regulation of gene expression in prokaryotes and eukaryotes, and the biochemical mechanisms of mutations. The program should instruct fellows in the detailed knowledge of disease processes at the molecular level and the methods used for their detection. These diseases include but are not limited to: solid tumors, leukemia-lymphomas, infectious diseases, inherited Mendelian diseases, non-Mendelian and acquired genetic diseases (e.g., mitochondrial disorders, triplet repeats, expansion disorders, cytogenetic aberrations, and imprinting disorders). In addition, fellows should be instructed in tissue typing/identity testing and the principles of linkage analysis. The program should instruct fellows in their role as consultants and in the application of molecular techniques and interpretation of results with regard to diagnosis, prognosis, treatment and recurrence risk in patient care decision making.

- V.B.3. Fellows must maintain a logbook of MGP cases in which they were involved in sufficient detail to ascertain their involvement in establishing the primary diagnosis and the transmittal of this information. A case is defined as the complete laboratory evaluation of an individual or an individual specimen (e.g., tumor specimens). If a family study is involved, the entire family is considered as a single case. Completion of the case will involve appropriate communication of the results (e.g., written report, verbal communication to referring physician and/or counseling of the individual or family). The logbook should contain sufficient information to demonstrate experience with the breadth of techniques and variety of diseases necessary to direct an MGP diagnostic laboratory service.
- V.B.4. The program must provide a sufficient volume and variety of MGP specimens and other educational material for the fellow to acquire the qualifications of a consultant in MGP. Fellows must be instructed to create and must keep a logbook of each accession in which they are involved.
- V.B.5. Fellows must gain experience as consultants in clinical decision making in collaboration with professionals from related disciplines and in the cost-effective use of molecular genetic pathology testing.
- V.B.6. The program must provide Fellows with the experience required to set up and to operate a MGP laboratory and to supervise and train laboratory personnel in other advanced techniques as they are developed.
- V.B.7. MGP fellows who are pathologists should participate and must gain an understanding of the principles involved in the diagnosis, management, and treatment of patients with genetic disorders as well as in the counseling of the patient and the family. This experience must include participation in clinical conferences and exposure to patient care. MGP fellows who are medical geneticists must have exposure to autopsy and surgical pathology. This experience should emphasize contemporary diagnostic techniques and require involvement in autopsies, surgical

pathology, the review of slide sets of diseases relevant to Molecular Genetic Pathology, and other relevant pathology activities.

- V.B.8. There must be regularly scheduled inter-departmental MGP conferences as well as intra-departmental conferences, lectures, seminars, journal clubs and other structured educational activities. Both teaching staff and fellows must attend and actively participate in these sessions on a regular basis.
- V.B.9. Instruction should include the use of study sets and files of both usual and unusual cases, as well as other educational materials.

#### **V.C. Fellows Scholarly Activities**

**Each program must provide an opportunity for fellows to participate in research or other scholarly activities, and fellows must participate actively in such scholarly activities.**

#### **V.D. ACGME Competencies**

**The residency program must require its fellows to obtain competence in the six areas listed below to the level expected of a new practitioner. Programs must define the specific knowledge, skills, behaviors, and attitudes required, and provide educational experiences as needed in order for their fellows to demonstrate the following:**

- V.D.1. ***Patient care* that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health;**
- V.D.2. ***Medical Knowledge* about established and evolving biomedical, clinical, and cognate sciences, as well as the application of this knowledge to patient care;**
- V.D.3. ***Practice-based learning and improvement* that involves the investigation and evaluation of care for their patients, the appraisal and assimilation of scientific evidence, and improvements in patient care;**
- V.D.4. ***Interpersonal and communication skills* that result in the effective exchange of information and collaboration with patients, their families, and other health professionals;**
- V.D.5. ***Professionalism*, as manifested through a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to patients of diverse backgrounds;**
- V.D.6. ***Systems-based practice*, as manifested by actions that demonstrate an awareness of and responsiveness to the larger context and system of health care, as well as the ability to call effectively on other resources in the system to provide optimal health care.**

## **VI. Fellow Duty Hours and the Working Environment**

**Providing fellows with a sound didactic and clinical education must be carefully planned and balanced with concerns for patient safety and fellow well-being. Each program must ensure that the learning objectives of the program are not compromised by excessive reliance on fellows to fulfill service obligations. Didactic and clinical education must have priority in the allotment of fellows' time and energy. Duty hour assignments must recognize that faculty and fellows collectively have responsibility for the safety and welfare of patients.**

### **VI.A. Supervision of Fellows**

**VI.A.1. All patient care must be supervised by qualified faculty. The program director must ensure, direct, and document adequate supervision of fellows at all times. Fellows must be provided with rapid, reliable systems for communicating with supervising faculty.**

**VI.A.2. Faculty schedules must be structured to provide fellows with continuous supervision and consultation.**

**VI.A.3. Faculty and fellows must be educated to recognize the signs of fatigue, and adopt and apply policies to prevent and counteract its potential negative effects.**

### **VI.B. Duty Hours**

**VI.B.1. Duty hours are defined as all clinical and academic activities related to the residency program; i.e., patient care (both inpatient and outpatient), administrative duties relative to patient care, the provision for transfer of patient care, time spent in-house during call activities, and scheduled activities such as conferences. Duty hours do *not* include reading and preparation time spent away from the duty site.**

**VI.B.2. Duty hours must be limited to 80 hours per week, averaged over a four-week period, inclusive of all in-house call activities.**

**VI.B.3. Fellows must be provided with 1 day in 7 free from all educational and clinical responsibilities, averaged over a 4-week period, inclusive of call. *One day* is defined as 1 continuous 24-hour period free from all clinical, educational, and administrative duties.**

**VI.B.4. Adequate time for rest and personal activities must be provided. This should consist of a 10-hour time period provided between all daily duty periods and after in-house call.**

### **VI.C. On-call Activities**

**The objective of on-call activities is to provide fellows with continuity of**

patient care experiences throughout a 24-hour period. *In-house call* is defined as those duty hours beyond the normal work day, when fellows are required to be immediately available in the assigned institution.

- VI.C.1. In-house call must occur no more frequently than every third night, averaged over a 4-week period.
- VI.C.2. Continuous on-site duty, including in-house call, must not exceed 24 consecutive hours. Fellows may remain on duty for up to 6 additional hours to participate in didactic activities, transfer care of patients, conduct outpatient clinics, and maintain continuity of medical and surgical care.
- VI.C.3. No new patients may be accepted after 24 hours of continuous duty.
- VI.C.4. *At-home call (or pager call)* is defined as a call taken from outside the assigned institution.
  - VI.C.4.a) The frequency of at-home call is not subject to the every-third-night limitation. At-home call, however, must not be so frequent as to preclude rest and reasonable personal time for each fellow. Fellows taking at-home call must be provided with 1 day in 7 completely free from all educational and clinical responsibilities, averaged over a 4-week period.
  - VI.C.4.b) When fellows are called into the hospital from home, the hours fellows spend in-house are counted toward the 80-hour limit.
  - VI.C.4.c) The program director and the faculty must monitor the demands of at-home call in their programs, and make scheduling adjustments as necessary to mitigate excessive service demands and/or fatigue.
- VI.D. **Moonlighting**
  - VI.D.1. Because residency education is a full-time endeavor, the program director must ensure that moonlighting does not interfere with the ability of the fellow to achieve the goals and objectives of the educational program.
  - VI.D.2. The program director must comply with the sponsoring institution's written policies and procedures regarding moonlighting, in compliance with the ACGME Institutional Requirements.
  - VI.D.3. Any hours a fellow works for compensation at the sponsoring institution or any of the sponsor's primary clinical sites must be considered part of the 80-hour weekly limit on duty hours. This refers to the practice of *internal moonlighting*.

**VI.E. Oversight**

**VI.E.1. Each program must have written policies and procedures consistent with the Institutional and Program Requirements for fellow duty hours and the working environment. These policies must be distributed to the fellows and the faculty. Duty hours must be monitored with a frequency sufficient to ensure an appropriate balance between education and service.**

**VI.E.2. Back-up support systems must be provided when patient care responsibilities are unusually difficult or prolonged, or if unexpected circumstances create fellow fatigue sufficient to jeopardize patient care.**

**VI.F. Duty Hours Exceptions**

**An RRC may grant exceptions for up to 10% of the 80-hour limit to individual programs based on a sound educational rationale. Prior permission of the institution's GMEC, however, is required.**

**VII. Evaluation**

**VII.A. Fellow**

**VII.A.1. Formative Evaluation**

**The faculty must evaluate in a timely manner the fellows whom they supervise. In addition, the residency program must demonstrate that it has an effective mechanism for assessing fellow performance throughout the program, and for utilizing the results to improve fellow performance.**

**VII.A.1.a) Assessment should include the use of methods that produce an accurate assessment of fellows' competence in patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice.**

**VII.A.1.b) Assessment should include the regular and timely performance feedback to fellows that includes at least semiannual written evaluations. Such evaluations are to be communicated to each fellow in a timely manner, and maintained in a record that is accessible to each fellow.**

**VII.A.1.c) Assessment should include the use of assessment results, including evaluation by faculty, patients, peers, self, and other professional staff, to achieve progressive improvements in fellows' competence and performance.**

**VII.A.2. Final Evaluation**

The program director must provide a final evaluation for each fellow who completes the program. This evaluation must include a review of the fellow's performance during the final period of education, and should verify that the fellow has demonstrated sufficient professional ability to practice competently and independently. The final evaluation must be part of the fellow's permanent record maintained by the institution.

**VII.B. Faculty**

The performance of the faculty must be evaluated by the program no less frequently than at the midpoint of the accreditation cycle, and again prior to the next site visit. The evaluations should include a review of their teaching abilities, commitment to the educational program, clinical knowledge, and scholarly activities. This evaluation must include annual written confidential evaluations by fellows.

**VII.C. Program**

The educational effectiveness of a program must be evaluated at least annually in a systematic manner.

**VII.C.1.** Representative program personnel (i.e., at least the program director, representative faculty, and one fellow) must be organized to review program goals and objectives, and the effectiveness with which they are achieved. This group must conduct a formal documented meeting at least annually for this purpose. In the evaluation process, the group must take into consideration written comments from the faculty, the most recent report of the GMEC of the sponsoring institution, and the fellows' confidential written evaluations. If deficiencies are found, the group should prepare an explicit plan of action, which should be approved by the faculty and documented in the minutes of the meeting.

**VII.C.2.** The program should use fellow performance and outcome assessment in its evaluation of the educational effectiveness of the residency program. Performance of program graduates on the certification examination should be used as one measure of evaluating program effectiveness.

**VII.C.3.** The program should maintain a process for using assessment results together with other program evaluation results to improve the residency program.

## **VIII. Experimentation and Innovation**

**Since responsible innovation and experimentation are essential to improving professional education, experimental projects along sound educational principles are encouraged. Requests for experimentation or innovative projects that may deviate from the program requirements must be approved in advance by the RRC, and must include the educational rationale and method of evaluation. The sponsoring institution and program are jointly responsible for the quality of education offered to fellows for the duration of such a project.**

## **IX. Certification**

**Fellows who plan to seek certification in Molecular Genetic Pathology should communicate with the office of their respective office regarding the full requirements for certification.**

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