

THE GENETICS PROGRAM OF OHIO  
**STANDARDS AND CRITERIA:**  
*for*  
*Ohio Regional Comprehensive*  
*Genetics Centers*





OVERVIEW OF REGIONAL COMPREHENSIVE GENETICS CENTERS STANDARDS & CRITERIA DOCUMENT

Background.....2  
Purpose of the Regional Comprehensive Genetics Centers Program.....2  
Operational Description of a Regional Comprehensive Genetics Center.....3  
Authority for the Regional Comprehensive Genetics Centers Program.....3  
Components of Regional Comprehensive Genetics Centers.....3  
Contact Information.....3

SERVICE COMPONENTS OF REGIONAL COMPREHENSIVE GENETICS CENTERS

Clinical Services Standards & Criteria  
    General Genetics Clinics.....4  
    Prenatal Genetics Clinics.....4  
    Specialty Clinics.....4-5  
Education, Collaboration and Referral Services Standards & Criteria  
    Patient/Family Education.....5-6  
    Patient/Family Referral Information.....6  
    Community Education.....6  
    Professional Education.....6-7  
Outreach Services Standards & Criteria  
    Associate Genetics Centers.....7  
    Satellite Genetics Centers.....7  
    Outreach Genetics Clinics.....7-8  
Research and Evaluation Activities Standards & Criteria  
    Center Level Activities.....8  
    Data Collection and Reporting Requirements.....8

ADMINISTRATIVE COMPONENTS OF REGIONAL COMPREHENSIVE GENETICS CENTERS

Facility Arrangements/Policies Standards & Criteria.....9-10  
Staffing Composition/Administration Standards & Criteria.....10-11  
Guiding Operational Principles of Regional Comprehensive Genetics Centers.....11-12

REFERENCES.....13

Background of the Program

In 1974, the Genetics Program of Ohio was established. This program promoted the concept of a regionalized approach for offering genetics services in the state, and the first state plan for providing these services was developed. Later, in order to assure core genetic services (genetic evaluation, treatment, counseling and education) were provided to Ohioans, the director of health was authorized to develop programs to provide these core services throughout the state. Regional Comprehensive Genetics Centers (RCGC) have been funded by the Ohio Department of Health (ODH) since that time to assure that these core genetic services are available to all Ohioans with or at risk for genetic disorders.

The RCGC Standards and Criteria have been developed to assist the director of health in designating Ohio's RCGCs. Priority for grant funding support shall be given to centers that meet or exceed the ODH RCGC Standards and Criteria.

The intent and purpose of the Standards and Criteria are twofold:

- 1) to assist ODH in carrying out its mission of protecting and improving the health of all Ohioans, in this case, through the support of genetics clinical and educational services; and
- 2) to serve as the foundation for quality assurance of Ohio's RCGCs.

The document outlines service and administrative components required of centers that are requesting consideration by ODH to become a RCGC or Associate Genetics Center. The RCGC Standards and Criteria serves as the basis for monitoring and evaluating each state-funded genetics center.

Purpose of the Regional Comprehensive Genetics Program of Ohio

The purpose of the Genetics Program of Ohio is to ensure and enhance the quality and availability of comprehensive care and services for children and adults in Ohio with or at risk for genetic disorders and congenital anomalies. In addition to clinical care, the program promotes genetics-related education to increase awareness in Ohioans about genetic disorders and birth defects.

Operational Description of a Regional Comprehensive Genetics Center

A RCGC will operate as an identifiable, functional unit within an approved care facility.\* It will be organized for and be capable of providing coordinated, multi disciplinary comprehensive care and services to persons with or at risk for genetic-related disorders. It shall provide the comprehensive health care services necessary for the accurate diagnosis and continuing expert evaluation, treatment and management of people who have inherited disorders, chromosomal disorders, teratogenic disorders and other complex birth defect conditions. Its primary goals are to reduce the burden of these conditions for residents affected with genetic conditions and their families and to promote an increased general awareness of these conditions through educational programs for all

\* An accredited state or other medical school, a hospital or a clinic accredited by the Joint Commission on Accreditation of Health Care Organizations.

residents of the State of Ohio. Comprehensive care ensures continuity of care from the genetics specialists to the primary care providers, home and community.

Authority for the Regional Comprehensive Genetics Centers of Ohio

The director of the ODH under the authority of section 3701.502 of the Ohio Revised Code is authorized to encourage and assist in the development of programs of education, detection and treatment of genetic diseases and provide for habilitation, rehabilitation and counseling of persons possessing a genetic trait of, or afflicted with, genetic disease.

Components of Regional Comprehensive Genetics Centers

Each RCGC funded by the State of Ohio *must* meet or exceed the required ("shall") Standards and Criteria and *may* meet many of the optional ("should") Standards and Criteria outlined under the following:

**4 major Service Components of:**

1. Clinical Services
2. Educational and Collaborative Services
3. Outreach Activities
4. Research and Evaluation Activities

**3 major Administrative Components of:**

1. Facility Arrangements
2. Staffing Composition
3. RCGC Guiding Operational Principles

Contact Information

Anyone requesting additional information on the contents of this document or services provided through the Genetics Program of Ohio should direct inquiries to:

Ohio Department of Health  
Bureau for Children with Medical Handicaps  
Genetics Program  
246 N. High St.  
Columbus, OH 43215

Phone: (614) 728-4677  
Fax: (614) 728-3616

SERVICE COMPONENTS OF RCGC PROJECTS

Clinical Services Standards & Criteria

I. "General clinical services" of a Regional Comprehensive Genetics Center *shall* include:

- A. Family focused evaluation, testing, treatment, genetic counseling and management of patients with or at risk for genetic-related disorders by a multi-disciplinary team with experience and expertise in the management of these disorders.
- B. Inpatient as well as outpatient care.
- C. Access to laboratory services including cytogenetic, biochemical and molecular genetic services.

II. Three fundamental "clinic types" of services *shall* include:

- A. GENERAL GENETICS CLINICS providing services to individuals with:
  - 1. Known or suspected genetic disorders
  - 2. Congenital anomalies/birth defects
  - 3. Metabolic diseases
  - 4. Mental retardation, developmental or behavioral disorders
  - 5. Consanguinity or ethnicity associated with increased risk for specific disorders
  - 6. Genetic predisposition to disease, e.g., cancer
  - 7. Family history of the above
- B. PRENATAL CLINICS focusing on those at risk for an unfavorable pregnancy outcome or who have had abnormal prenatal screening results. Examples include but are not limited to:
  - 1. Risks associated with advanced maternal age
  - 2. Couples with a previous child affected with a genetic disorder or birth defect(s)
  - 3. Couples with a family history of a genetic disorder or birth defect
  - 4. Couples with multiple pregnancy losses
  - 5. Risks associated with maternal illnesses, medications, exposures or infections
  - 6. Pregnancies with abnormal screening test results
  - 7. Pregnancies identified as abnormal by fetal ultrasonography
- C. SPECIALTY CLINICS that provide genetic counseling services as part of a multidisciplinary approach to the care of patients who have been diagnosed with complex genetic-related disorders medically involving several body systems.

1. Bureau for Children with Medical Handicaps Specialty Teams

- Metabolic Service Teams (MST)

All RCGCs shall have a designated Metabolic Service Team (MST) affiliated with the ODH Bureau for Children with Medical Handicaps (BCMh) program. The RCGC MST specialty teams shall provide evaluation, diagnosis and treatment services, and ongoing medical/nutritional management for individuals with or at risk for a metabolic disorder screened for in Ohio's Newborn Screening Program in accordance with Ohio Revised Code Administrative Rules 3701-55 (02-09). At a minimum, each MST must include two core staff members: 1) a physician who is board certified in medical genetics and who is an approved provider for the program for medically handicapped children and 2) a registered, licensed dietitian with experience &/or training in working with patients with Inborn Errors of Metabolism. The MST may also include additional staff such as pediatric neurologists, pediatric endocrinologists, genetic counselors, nurses, social workers, etc.

- Other BCMH Specialty Teams

RCGCs *shall* provide genetic counseling services to all BCMH genetic disease-related specialty clinic teams in their facility such as, but not limited to:

- BCMH-approved Myelomeningocele specialty teams
- BCMH-approved Craniofacial specialty teams
- BCMH-approved Cystic Fibrosis specialty teams
- BCMH-approved Hemophilia specialty teams

2. Other Non-BCMh Specialty Clinics/Teams

RCGCs *should* provide genetic counseling services to other genetic disease related specialty teams such as, but not limited to:

- Down Syndrome
- Fetal Alcohol Syndrome
- Marfan Syndrome
- Muscular Dystrophy
- Neurofibromatosis
- Prader Willi
- Sickle Cell, etc.

Education, Collaboration & Referral Services Standards & Criteria

III. Education, Collaboration and Referral Services of a Regional Comprehensive Genetics Center *shall* include:

A. Patient/family education consisting of:

- 1. Up-to-date patient/family education related to all aspects of the patient's condition including its complications and management.

● ● ●

**RCGC STANDARDS AND CRITERIA**  
Service Components of RCGC Projects Continued

2. Information about genetic conditions offered to patients/families in a manner best suited to their needs and culture in:
    - Their primary language
    - An appropriate educational level
  3. An established and regular internal mechanism (e.g. center conferences/meetings) to discuss patient/family needs and problems, establish coordinated care plans, ensure continuity of care and evaluate patient progress and effectiveness of care.
  4. Collaboration with local, state and national organizations to enhance patient/family education about specific conditions and to increase availability of peer support resources of other individuals with the same condition(s).
- B. Collaboration with and Patient/Family Referral information to public health programs as needed such as:
1. Bureau for Children with Medical Handicaps (BCMh) — RCGCs shall assure all children under 21 years of age with special health care needs receive referral information about the BCMh Diagnostic, Treatment and Service Coordination programs.
  2. Help Me Grow (HMG) — RCGCs shall assure all children 0-3 years of age with eligible conditions receive referral information about Ohio HMG Early Intervention Services program.
- C. Community education consisting of:
1. Culturally sensitive outreach education about genetic-related disorders and prevention strategies to community agencies, schools and the general public including content such as:
    - How to identify individuals who might benefit from genetic services
    - The need for and value of genetic services
    - Where and how to get these services
  2. Availability of culturally sensitive, age-appropriate programs and written materials designed for various target audiences including those with various language and literacy levels.
- D. Professional education and training consisting of:
1. Training and continuing education targeting health care and other

● ● ●

**RCGC STANDARDS AND CRITERIA**  
Service Components of RCGC Projects Continued

- professional groups and service providers about genetic-related disorders and services especially related to:
- How to identify individuals who might benefit from genetic services
  - The need for and value of genetic services
  - Where and how to get patients/families referred for these services
2. Integrating genetics into medical training and continuing education curriculums of other professional groups.

Outreach Services Standards & Criteria

IV. Outreach activities of a Regional Comprehensive Genetics Center should include:

- A. Associate Genetics Centers and Satellite Genetics Centers:
1. An Associate Genetics Center is funded directly through ODH, operates under its own administration, in a non-RCGC health care facility, through formal agreement or contract with an RCGC to which referrals can be made for the full range of genetic services as needed.
  2. A Satellite Genetics Center operates in a non-RCGC health care facility; under contract to an RCGC — through which its funding flows and to which referrals can be made for the full range of genetic services as needed.

Associate and Satellite Genetics Centers should:

1. Increase accessibility and availability of some of the genetic services of an RCGC to an underserved target population(s) through regularly scheduled clinics and educational outreach services that are coordinated by genetics staff based at the site.
  2. Be staffed by Board Eligible/Board Certified (BE/BC) genetic counselors or other board certified/board eligible/state licensed genetic health care professionals under the supervision of a clinical geneticist.
- B. Outreach Genetics Clinics that:
1. Increase the accessibility and availability of genetic services to an under served target population(s) through periodically scheduled clinics and educational outreach services.
  2. Are operated by an RCGC and convened in various community-based facilities located outside of the RCGC's home county.
  3. Are coordinated locally, (usually by an employee of the host community-

● ● ●

## RCGC STANDARDS AND CRITERIA

### Service Components of RCGC Projects Continued

based facility,) and staffed by a visiting medical geneticist and/or other visiting credentialed genetic health care professional as defined under Administrative Components — Section II.

4. Are convened on a periodic basis and offer a limited range of genetic-related clinical and educational services under the auspices of an RCGC to which referrals can be made for the full range of genetic services as needed.

#### Research And Evaluation Standards & Criteria

V. Research and evaluation activities of an RCGC *shall* include:

##### Center-level Activities

- A. Implementation of appropriate methods to monitor and evaluate the quality of its patient care and services.
- B. A process for identifying and resolving individual patient, as well as RCGC services or program complaints/problems.
- C. Compliance with all state and federal data collection, program evaluation and other reporting requirements.

##### ODH Data Collection and Reporting Requirements

- D. Setting up, collecting and electronically reporting RCGC individual clinical case data and education event data to ODH in compliance with RCGC database categories/data fields and definitions.
- E. Monitoring and reporting of RCGC performance measures as defined by ODH to measure regional/statewide program results and impact.
- F. Participating in a project self-evaluation and site visit monitoring process as requested by the ODH.
- G. Participating in research and evaluation activities recommended by the director of health and ODH advisory councils (such as Newborn Screening and OCCSN).

Additional research and evaluation activities of a RCGC *should* include:

- H. Participation in formal research in the field of clinical, cytogenetic, biochemical and/or molecular genetics.

#### ADMINISTRATIVE COMPONENTS OF RCGC PROJECTS

I. Facility arrangements and policies for an RCGC *shall* include:

● ● ●

## RCGC STANDARDS AND CRITERIA

### Administrative Components of RCGC Projects

- A. Identification with an ODH-defined, multi-county Genetics Region in the State of Ohio.
- B. Location in an identifiable unit located in an accredited state or other medical school, a hospital or a clinic accredited by the Joint Commission on Accreditation of Health Care Organizations.
- C. Proper licensure/certification, if such a license/certificate is required for operation, by the ODH or any other licensing/certifying agency.
- D. Compliance with agency assurances and other documentation as required by ODH.
- E. Access to medical support services necessary for the diagnosis of genetic or congenital disorders, e.g., imaging and consultants.
- F. An identifiable clinic area with rooms for examination, counseling, management, evaluation and staff conferencing which are appropriately equipped for delivery of services and privacy for patients and/or family.
- G. Adequate space designated for administrative tasks, record keeping, data management and storage of supplies and educational material.
- H. Designated telephone number(s) through which all services can be accessed and for contacting the RCGC staff during regular working hours.
- I. Designated web page describing RCGC services and a link to the ODH website <http://www.odh.ohio.gov/odhPrograms/cmh/genserv/genserv1.aspx>
- J. Accessibility by those with physical handicaps.
- K. Permission for the review of facility records by ODH staff.
- L. Written protocols identifying laboratories that will accept specimens for necessary tests, payment methods, unique services and typical turnaround time used for diagnostic evaluations are kept, and a tracking system is maintained for all specimens.
- M. A referral system for treatment and management of genetic disorders. This *shall* include access to licensed clinical laboratory facilities for handling of clinical specimens; medical support services available for diagnosis of genetic or congenital disorders; and full consultative services appropriate to genetic services provided, including some or all of the

N. Availability of written policy on service fees, billing procedures and available financial assistance, as well as schedules of clinics and office hours.

**RCGC STANDARDS AND CRITERIA**  
**Administrative Components of RCGC Projects Continued**

following: perinatologists; obstetricians; pediatricians; neurologists; ophthalmologists; psychologists; psychiatrists; and dietitians.

- N. Compliance of laboratories associated with the RCGC with accepted guidelines of laboratory and clinical services issued by organizations such as the American College of Medical Genetics (ACMG) and the College of American Pathologists (CAP).
- O. Availability of written policy on service fees, billing procedures and available financial assistance, as well as schedules of clinics and office hours.

II. Staffing composition/administration of an RCGC *shall* include:

- A. A Medical/Project Director who is a clinical geneticist and who is board certified by the American Board of Medical Genetics (ABMG).
- B. A Core Team comprised of a:
  1. Board certified clinical geneticist — (M.D. or D.O.)
  2. BCMH-approved geneticist/physician provider
  3. BE/BC genetic counselor — (M.S.)
  4. RCGC database coordinator — (an individual with experience using standard Query Language ((SQL)) in the Microsoft Access environment + ability to do data management, data extraction and data cleaning)

Also available to the Core Team *should* be:

- C. An Extended Team comprised of the following:
  1. Biochemical geneticist
  2. Medical geneticist (Ph.D.)
  3. Cytogeneticist
  4. Molecular geneticist
  5. Radiologist with experience in genetic disorders and syndromes
  6. Perinatologist
  7. Ultrasonographer with expertise in
    - a. Prenatal including fetal echocardiology
    - b. Postnatal
  8. Others (nurses, social workers, educators, dieticians)
- D. All staff *shall* be licensed/certified by the State of Ohio and be board eligible/certified in their specialty area.

Staff meetings and training *shall* include:

- E. RCGC Administrative staff meetings that are convened at least quarterly.

**RCGC STANDARDS AND CRITERIA**  
**Administrative Components of RCGC Projects Continued**

- F. Continuous updating of knowledge and skills of staff through in-service education programs and attendance at conferences, seminars and workshops.

Statewide meetings

- G. RCGC project directors or their designees, *shall* attend all ODH RCGC Directors' Meetings.
- H. RCGC staff shall attend other genetics related work groups and other statewide meetings sponsored by ODH.

III. Guiding Operational Principles: Policy, procedure and practices of a Regional Comprehensive Genetic Center *shall* be developed based on the following Guiding Operational Principles:

Access to services

- A. Services are available, accessible and family centered.
- B. Referral policies facilitate entry of the population to be served.
- C. Patients receive referrals to qualified specialists when such services are indicated.
- D. Consumers have access to appropriate services, treatment, resource information and direction provided by support groups to meet their changing needs throughout their lifespans.
- E. Services are provided regardless of the patient's/family's disability, medical condition or ability to pay.

Communication

- F. A forum is in place for dealing with ethical/legal issues that arise in clinical care situations especially as related to patient confidentiality, discrimination and informed consent.
- G. Genetic information is communicated in the consumer's primary language and in a manner that allows families to make meaningful decisions.
- H. Foreign language translators and interpreters for the hearing impaired are available as needed.
- I. Educational materials are provided in a variety of culturally competent formats and educational levels.

Confidentiality & Sensitivity to Patient Needs

- J. There is an understanding that genetic information is inherently personal and sensitive medical information and the highest standards of confidentiality of patient information are known and practiced by all staff and in accordance with the Health Insurance Portability and Accountability Act (HIPPA) guidelines.
- K. Persons requiring genetic services and their families shall have the freedom to utilize the RCGC of their choice and actively participate in decision-making regarding their own health care.
- L. Meaningful input by those using the services (consumer input) is routinely obtained for the purposes of planning and evaluation of RCGC services.

1. *Guidelines for Clinical Genetic Services for the Public's Health.* Council of Regional Networks for Genetic Services (CORN), Edited by Sallie B. Freeman, Ph.D., Cynthia F. Hinten, M.S., M.P.H., Louis J. Elsas, II, M.D., April 1997.
2. *Consumer Indicators of Quality Genetic Services*, published by the Alliance of Genetic Support Groups, 4301 Connecticut Ave., N.W., Washington, D.C., 1999.
3. *Ohio Hemophilia Treatment Center Standards & Criteria.* Ohio Department of Health, Columbus, Ohio, rev. 1999.
4. *The Regional Comprehensive Genetic Services Program of Ohio; 1998 Genetics State Plan and Report To The Community.* Ohio Department of Health, 1998.
5. *Integrating Genetic Services into Public Health—Guidelines for State and Territorial Programs from the National Newborn Screening and Genetics Resources Center (NNSGRC);* Edited by Celia I. Kaye, Renata Laxova, Judith E. Livingston, Michelle A. Lloyd-Puryear, Marie Mann, Edward R.B. McCabe, Bradford L. Therrell. *Community Genetics* 2001;4: 175-196.
6. *Ohio Genetics Task Force, Report and Recommendations to the Ohio Department of Health,* Ohio Department of Health, 2003.
7. *Genetics Education and Training of Health Care Professionals, Public Health Providers, and Consumers; Draft Report of the Secretary's Advisory Committee on Genetics, Health, and Society.* Department of Health and Human Services, USA. 2010.
8. *Healthy people 2020 U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotions; ODPHP Publication No. B0132;* [http://www.healthypeople.gov/2020/TopicsObjectives2020/pdfs/HP2020\\_brochure.pdf](http://www.healthypeople.gov/2020/TopicsObjectives2020/pdfs/HP2020_brochure.pdf), November 2010.

**BUREAU FOR CHILDREN WITH MEDICAL HANDICAPS**

246 N. High St.  
Columbus, OH 43215  
(614) 728-4677



**Ohio Department of Health**

*To protect and improve the health of all Ohioans*

*An Equal Opportunity Employer/Provider*