Fox Chase Cancer Center Cancer
Risk Assessment Program (RAP)

Manual Title(s) **Cancer Program**	Page 1 of 6
Manual Section: **2.3**	Manual Subject **Genetic Evaluation and Management Cancer Risk Assessment, Genetic Counseling and Testing**
Effective Date: 00-00-2013	Revision Date:

POLICY:

The Fox Chase Cancer Center, in order to serve patients, individuals and families at risk for carrying genetic mutations for *various types of cancer* [1] has developed clinical standards for risk assessment and counseling and provision of genetic test results for all patients undergoing risk assessment. In addition a *research protocol* [2] for obtaining family, personal and medical history data, (tissue and blood samples for targeted high risk patients) is available and considered a voluntary component of participation. These clinical standards have been established to adhere to the highest level of quality in these programs and are in compliance with 2012 American College of Surgeon Standards 2.3 for cancer risk assessment and in accordance with the National Comprehensive Cancer Network Guidelines.

Definitions:

1. *Various types of cancer*: all cancers associated with cancer syndromes.
2. *Research Protocol*: Protocol is for the Risk Assessment Program Registry (IRB# 09-831) that collects health history and family history of cancer. Donation of blood and permission to access stored tissue from previous procedures, with potential for future donation of blood, should supply become depleted, will be requested from participating patients.

REFERRAL:

Referrals are accepted from treating physicians, advanced practice clinicians (NPs and PAs), nurse navigators, other in-house or community health care providers and self-referral by calling 1-877-627-9684.

Patients who are seeking genetic risk assessment closer to home will be given a list of counselors in their area as identified from the National Society of Genetic Counselors – Find a Counselor link on nsgc.org

PROCEDURES:

I **Program Staffing and Education Requirements**
   a. Physician

1. Board certified physician with experience in cancer genetics. Documented education in cancer genetics per 2012 American College of Surgeons accreditation standards and ASCO Policy Statement (2009). ASCO online course is recommended.(http://university.asco.org/cancer-genetics-review
2. Ongoing yearly documentation of 1 CME course in genetics/genomics. (See Resources)

b. Cancer risk counselor (genetic counselor or nurse)
   1. Genetic Counselor: An American Board of Genetics Counseling (ABGC) board certified (CGC) board eligible or in some states a licensed genetic counselor, per 2012 American College of Surgeons accreditation standards.
   2. Nurse: Genetics Clinical Nurse (GCN, BSN required) or an Advanced Practice Nurse in Genetics (APNG), credentialed through the Genetics Nursing Credentialing Commission (GNCC) as per 2012 American College of Surgeons accreditation standards.
      - Certification requires 5 years of experience working in cancer genetics/risk assessment with 50% of practice in cancer genetics and submission of 50 case reports from clinical cancer risk assessment.
      - Minimum of 50 contact hours of education in cancer genetics for APNG and 45 contact hours for the GCN (Genetics Nurse Credentialing Commission retrieved 08/01/2012 from: http://www.geneticnurse.org/
   3. Continuing Education credits for genetic counselor or nurse
      a. Genetic counselor - 25 Category 1 CE credits over 10 years, i.e. 2.5 per year (National Society for Genetic Counselors)
      b. ; for genetics nurse - 50 contact hours over a five year period, i.e. 10 CE per year maintaining 50% of practice in cancer genetics. (Genetic Nursing Credentialing Commission, Inc.)

II Staffing Responsibilities

a. Physician
   - Responsible to oversee the medical management and risk reduction plan.
   - Participation in genetic testing disclosure
     - Ideally, be present at disclosure to discuss medical management, risk reduction recommendations and clinical follow up plan per the NCCN guidelines **OR**
     - See the patient in a separate clinical visit for medical management and risk reduction plan following post disclosure **WITH**
     - Signed documentation of medical management risk reduction plan.

b. Cancer Risk Counselor(GC or GCN)
    - Review Family History/Pedigree prior to education and counseling visit to determine
        i. Pattern of inheritance
        ii. Differential list of cancer syndromes
        iii. What testing would be ordered
    - Abstract personal and medical history from the Health History Questionnaire or at in-person visit
    - Patient is informed of risk and benefits of genetic testing and informed consent for testing is obtained.
    - Patient is informed of optional participation in Risk Assessment Research and voluntary informed consent is obtained. consent
    - Provide cancer risk education and counseling as described in section III below
    - Development of medical management and risk reduction plan in collaboration with physician
    - Documentation of initial counseling, disclosure visit and medical management plan
    - Completion of post-counseling checklists

c. Advanced Practice Nurse in Genetics
    - Same responsibilities as Cancer Risk Counselor above
    - Provide genetic testing disclosure along with medical management and risk reduction plan as defined by Advanced Practice Nurse's Scope of Practice.
        - Signed documentation of medical management and risk reduction plan.

III **Cancer Risk Assessment and Counseling Components (**outlined in National Cancer Institute Genetic Physician Desk Query Document, cancer.gov)

a. Risk Assessment Process
    - Obtain personal, medical and family history information (three generation family history)
    - Determining cancer risk
        - Analysis of family history
            - Mendellian pattern of inheritance
            - Pattern of cancer (sporadic, familial or hereditary)
            - Prioritized suspected cancer syndromes
        - Methods of quantifying cancer risk
    - Assessment of patient understanding of risk, cancer syndrome
    - Options for genetic testing
        - Test to be offered (if more than one syndrome, inform which test to be done first)
        - Informed consent
        - Costs/insurance coverage

- Implications of test results
  - Medical, psychological impact of genetic information/testing
  - Disclosure counseling visit scheduled (what will happen at visit)
  - Privacy and confidentiality

b. Disclosure of genetic test results
- Interpretation of test results
- Discussion of further testing that may clarify risks (e.g. Large rearrangement testing and testing for other genes based on patient's cancer differential syndrome list)
- Assessment of emotional and behavioral response to test results
- Recommendations for coping and family communication
- Medical management, risk reduction and screening recommendations
- Plan for testing other family members
- Patients having a Variant of Uncertain Significance (VUS) will be contacted by the genetic counselor/genetic nurse when the VUS is reclassified

IV Documentation Accountabilities – for chart
- Intake form should be completed prior to first appointment in order to generate patient ID number for study
- Other documentation forms Include:
  - Consent forms
  - Health History Questionnaire (document of personal and medical history)
  - Family history
  - Post counseling checklists for education, pre-disclosure and disclosure
  - Chart notes
  - Copy of test results when disclosed.
- Letter of medical recommendations and risk reduction plan signed by the genetic counselor/nurse, physician/advanced practice nurse providing disclosure of genetic testing results should be part of patient.
  - The patient receives a copy of the medical recommendations and risk reduction plan.
  - The referring physician receives letter or progress note summarizing the patient's results and recommendations.

V Patients who receive genetic test results elsewhere but require post genetic counseling
- Follow cancer risk assessment & counseling components in section III above
  - Assess if patient has been provided the components of risk assessment and counseling.

- If patient has not been counseled provide risk assessment and counseling components.

VI Regulatory Requirements

- Institution Review Board: any regulatory responsibilities and correspondence are the responsibility of the Administrative Manager.
  - Initial submission of RAP protocol
  - Annual renewal
  - Submission of any edits/amendments

VII Quality Assurance Requirements

- Annual audit
  - FCCC will annual review RAP patient charts for compliance with FCCC RAP Procedures as well as provide quality review of cancer risk education and counseling services.
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VIII Educational Resources

- FCCC holds a weekly Pedigree review session where cases are presented and discussed. New literature is presented on a regular basis for evaluation of clinical utility.

- Continuing Education Resources:
  - American Society of Clinical Genetics – Approved for CMEs Cancer Genetics Review http://university.asco.org/cancer-genetics-review need web site link
  - National Coalition for Health Professional Education in Genetics (NCHPEEG): Approved for CME working to get CE for nurses and genetic counselors: Colorectal Cancer: Is Your Patient at High Risk? http://www.nchpeg.org/index.php?option=com_content&view=article&id=382:colorectal-cancer-are-your-patients-at-high-risk&catid=35:todays-highlights

  - City of Hope Genetics Education Programs:
    - http://www.cityofhope.org/education/health-professional-education/cancer-genetics-education-program/Pages/default.aspx

  - Johns Hopkins University Clinical Cancer Genetics Case Conference/Journal Club (Approved for CME)
    - First Thursday each Month 12:00 noon - 1:30 pm. Johns Hopkins Medical Institutions, Baltimore, MD Target Audience: Physicians, Residents, Fellows, Genetic Counselors, Nurses
    - Contact: Jennifer Axilbund, solleje@jhmi.edu

- Harvard University: Genetics of hereditary Breast Cancer (Approved for CME)http://cmeonline.med.harvard.edu/course_descriptions.asp?Course_id=118

- University of California, San Diego. PharmGenEd™ Module I: Pharmacogenomic Principles and Concepts. 1 *AMA PRA Category 1 Credits* http://pharmacogenomics.ucsd.edu/cpecme/module-i-pharmacogenomic-principles-and-concepts.aspx

- PharmGenEd™ Module II: Clinical Applications of Pharmacogenomics.. 1 *AMA PRA Category 1 Credit* http://pharmacogenomics.ucsd.edu/cpecme/module-ii-clinical-applications-of-pharmacogenomics.aspx

- Oncology Nursing Society ONS on line Genetics Course
- http://www.ons.org/media/ons/docs/education/2012CNECatalog-web.pdf
  - Cancer Genetics 101 (Approved for 16.3 CEs)
  - Genetics Online Education Series (Approved for 7.8 CE)
  - Oncology Nursing Society Meetings provide sessions on Cancer Genetics. Attending the Cancer Genetic SIG meeting at the Annual Congress also gives CE.
- International Society for Nurses in Genetics : Annual conference (Approved nursing CE) www.isong.org
- Information about other National or Regional Conferences with focus on cancer genetics will be sent as FCCC learns about them.

References:

- NCCN guidelines: National Cancer Institute: PDQ® Cancer Genetics Risk Assessment and Counseling. Bethesda, MD: National Cancer Institute. Date last modified 7-24-12.
- http://cancer.gov/cancertopics/pdq/genetics/risk-assessment-and-counseling/HealthProfessional. Accessed 8-9-12
- Genetics Nurse Credentialing Commission retrieved 08/01/2012 from: http://www.geneticnurse.org/
- American College of Surgeons 2012 accreditation standard 2.3 http://www.facs.org/cancer/coc/programstandards2012.html