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Outside Laboratory Genetic Test Billing and Reconciliation

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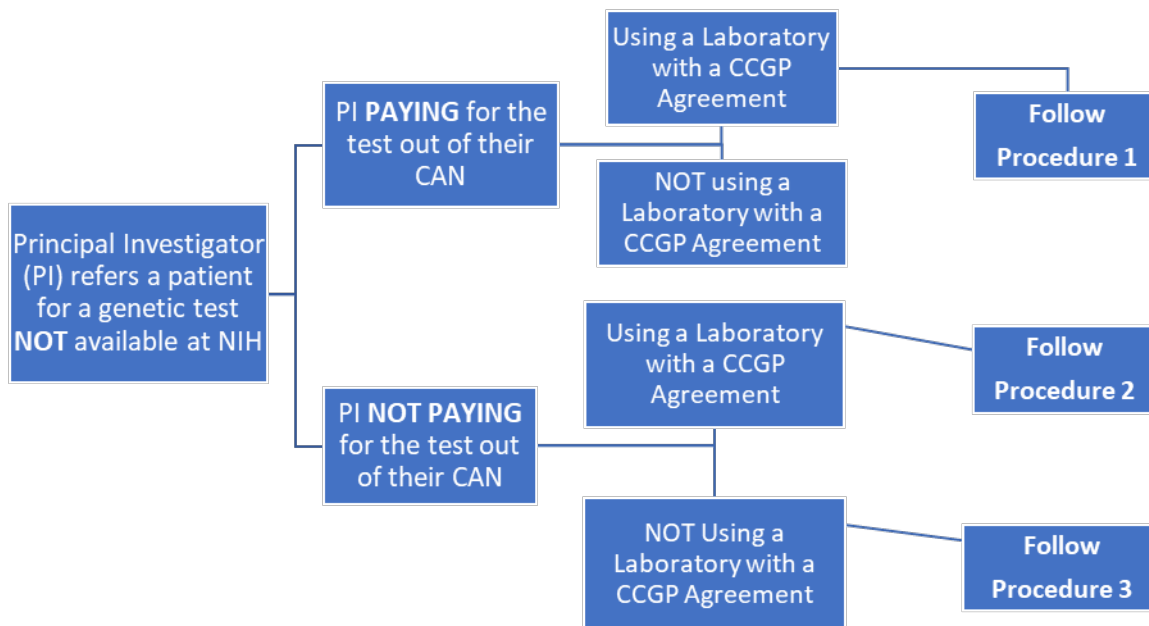
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POLICY

Patients who are candidates for genomic tests not offered at the National Institutes of Health may obtain testing from outside laboratories via the scenarios outlined in the Procedures section of this SOP. The Center for Cancer Research (CCR) Office of the Clinical Director does not centrally pay for or arrange genomic testing not available at NIH. The Clinical Cancer Genetics Program (CCGP) Genetic Counselors will work with investigators to determine the correct path to obtain genomic testing and payment options. Please see Figure 1 for a genetic test decision tree.

Additionally, CCGP will see the patient/family, complete and assessment including creating a pedigree, determine the test to order, perform genetic education and counseling, facilitate the sample collection, enter the test request with the outside laboratory selected, enter the Purchasing Online Tracking System (POTS), obtain the results, provide the results to the provider, patient/family, manage the outside laboratory invoices/payments. CCGP will also work with new laboratories to establish an agreement for tests not available through [laboratories with agreements](#). CCGP will also work with other CCR Genetic Counselors by entering POTS and managing outside laboratory invoices/payments.

Figure 1: Genetic Test Billing Decision Tree



PURPOSE

To explain the procedures for billing and payment or reconciliation of costs associated with genetic tests ordered and performed at non-NIH genetic testing laboratories, under the following three options:

1. The Principal Investigator budget will pay for a test that uses one of the laboratories with which the CCGP has an existing agreement. Please see [Procedure 1](#) of this SOP.
2. The Principal Investigator is **UNABLE to pay** the cost of the test regardless of whether or not testing will be performed by one of the laboratories for which there are existing agreements. In this scenario, the PI will be required to submit a request via the Office of the Clinical Director to request that the cost of these tests using SOP ADCR-14 *Authorization of Outside Medical Services (AOMS) for Research Participants* be paid centrally. For that procedure, please see [Procedure 2](#) of this SOP.
3. The Principal Investigator is paying the cost of the test AND is not using one of the laboratories that the CCGP has an existing laboratory agreement with. Please see [Procedure 3](#) of this SOP.

RESOURCES

- Laboratories with ongoing agreements
 - Invitae
 - GeneDX
 - Fulgent
 - For prices from the above laboratories, please contact Hermi Mesfin hermi.mesfin@nih.gov
- Center for Cancer Research Standard Operating Procedures [website](#)
- [CCR Office of the Director](#)
- Center for Cancer Research Clinical Cancer Genetics Program
 - NCI Genetics Consult Service NCI_GeneticConsult@mail.nih.gov
 - Outside Medical Services NCICCROutsideMedServ@mail.nih.gov

PROCEDURES

There are three procedures based on the nature of the test, the laboratory used, whether there is an agreement with the laboratory, and whether the Principal Investigator will be using their budget to pay for the test. Figure 1 provides a decision tree that points you to the applicable procedure.

There are three mechanisms for a patient to be seen and tested by a genetic counselor:

- A. CCR Genetic Counselor which is currently limited to the Pediatric Oncology Branch and Neuro Oncology Branch.
- B. CCGP Genetic Counselor which covers all other Branches within CCR.
- C. Non CCGP/CCR Genetic Counselor (i.e. another NCI Division or another Institute).

PROCEDURE 1: Principal Investigator Paying Genetic Test Costs and Using an Outside Laboratory With and Without a CCGP Agreement

There are **two testing options** for using a CCGP Genetic Test Laboratory Agreement:

1. Patient seen by a CCGP/CCR Genetic Counselor
2. Patient is seen by any non-CCGP/CCR Genetic Counselor from another Division or Institute

PATIENT SEEN BY A CCGP/CCR GENETIC COUNSELOR

CCR Genetic Counselor

Step 1: Patient will have already seen the CCR Genetic Counselor who will determine the test/laboratory to use and submit the order to the testing laboratory.

Step 2: Email Hermi Mesfin using the consult email mailto:NCI_GeneticConsult@mail.nih.gov and include the following information based on whether using a laboratory WITH or WITHOUT an agreement per Table 1.

Table 1: Required Information for using Laboratories WITH or WITHOUT an Agreement

Laboratory WITH a CCGP Agreement	Laboratory WITHOUT a CCGP Agreement
<ul style="list-style-type: none"> • Patient name and MRN • Diagnosis; • Name of the Principal Investigator; • Indication of test; • Laboratory selected for the test; • Specific test ordered; • Any specific billing instructions; • Principal Investigator CAN number and Administrative Officer name. • Name/affiliation of Genetic Counselor seeing patient. • Confirmation the Genetic Counselor has established an account with the specific laboratory being used to enter the test request form. 	<ul style="list-style-type: none"> • Patient name and MRN • Diagnosis; • Name of the Principal Investigator; • Indication of test; • Laboratory selected for the test; • Specific test ordered; • Specific test code; • Specific test price; • Any specific billing instructions; • Principal Investigator CAN number and Administrative Officer name. • Name/affiliation of Genetic Counselor seeing patient. • Confirmation the Genetic Counselor has established an account with the specific laboratory being used to enter the test request form.

Step 3: Hermi Mesfin will enter the POTS.

Step 4: Laboratories with and without agreements will submit an invoice that includes all tests ordered with that laboratory in that billing period to John Lueders.

Step 5: John Lueders will submit the invoice to Hermi Mesfin to reconcile with Genetic Counselor tests ordered.

Step 6: John Lueders will pay the invoice using the CCGP Kathleen Calzone CAN.

Step 7: Melissa Shue will contact the Principal Investigators AO three times/year (December, April, and August) to initiate a Budget Management System (BMS) Transfer to reimburse the CCGP Calzone CAN for all tests ordered in that interval.

CCGP Genetic Counselor

Step 1: Email Hermi Mesfin using the consult email NCI_GeneticConsult@mail.nih.gov to schedule an appointment including all information as required in Table 1:

Step 2: Patient will be seen by a CCGP Genetic Counselor who will determine the test/laboratory to use and submit the order to the testing laboratory.

Step 3: The Genetic Counselor will notify Hermi Mesfin of the laboratory and test ordered and any specific billing instructions per Table 1.

Step 4: Hermi Mesfin will enter the POTS.

Step 5: Laboratories with and without agreements will submit an invoice that includes all tests ordered with that laboratory in that billing period to John Lueders.

Step 6: John Lueders will submit the invoice to Hermi Mesfin to reconcile with Genetic Counselor tests ordered.

Step 7: John Lueders will pay the invoice using the CCGP Kathleen Calzone CAN.

Step 8: Melissa Shue will contact the Principal Investigators AO three times/year (December, April, and August) to initiate a Budget Management System (BMS) Transfer to reimburse the CCGP Calzone CAN for all tests ordered in that interval.

PATIENT SEEN BY A NON-CCGP/CCR GENETIC COUNSELOR

Step 1: Obtain pre-test permission if using a Laboratory Agreement* by emailing Hermi Mesfin hermi.mesfin@nih.gov including all information required as listed in Table 1.

Step 2: Hermi Mesfin will enter the POTS and confirm the entry with the team.

Step 3: Laboratories with agreements will submit an invoice that includes all tests ordered with that laboratory in that billing period to John Lueders.

Step 4: John Lueders will submit the invoice to Hermi Mesfin to reconcile with the Genetic Counselor the test(s) ordered.

Step 5: John Lueders will pay the invoice using the CCGP Kathleen Calzone CAN.

Step 6: Melissa Shue will contact the Principal Investigators AO three times/year (December, April, and August) to initiate a Budget Management System (BMS) Transfer to reimburse the CCGP Calzone CAN for all tests ordered in that interval.

*Non-CCGP/CCR Genetic Counselors using a laboratory without an agreement does not involve CCGP.

PROCEDURE 2: Genetic Tests Using an Outside Laboratory With a CCGP Agreement and Principal Investigator Not Paying Test Costs

There are **two testing options** for using a CCGP Genetic Test Laboratory Agreement:

1. Patient seen by a CCGP/CCR Genetic Counselor OR
2. Patient is seen by a non-CCGP/CCR Genetic Counselor.

PATIENT SEEN BY A CCGP/CCR GENETIC COUNSELOR

- Step 1: Email Hermi Mesfin using the consult email NCI_GeneticConsult@mail.nih.gov to schedule an appointment for the patient to be seen by a CCGP/CCR Genetic Counselor (if not already arranged) and include all information listed in Table 1.
- Step 2: Hermi Mesfin will schedule the patient with a Genetic Counselor if not already arranged and notify the team of the date of the appointment.
- Step 3: The referring team will be notified by Hermi Mesfin or the Genetic Counselor that saw the patient of the test and laboratory to be used with instructions to contact Outside Medical Services using SOP [ADCR-14 Authorization of Outside Medical Services \(AOMS\) for Research Participants](#) to obtain permission for the test. Testing **CANNOT** commence until Outside Medical Services has provided approval.
- Step 4: The Principal Investigators team and/or Outside Medical Services will notify Hermi Mesfin of the approval and provide the POTS number generated by Outside Medical Services.
- Step 5: Laboratories will submit an invoice that includes all tests ordered with that laboratory in that billing period to John Lueders.
- Step 6: John Lueders will submit the invoice to Hermi Mesfin to reconcile with the Genetic Counselor the test ordered.
- Step 7: Hermi Mesfin will email a redacted version of the invoice that **ONLY** reflects the Outside Medical Services charge to OMS via NCICCROutsideMedServ@nih.gov.
- Step 8: Outside Medical Services team will work with OCD purchasing agent to pay the invoice.

PATIENT SEEN BY A NON-CCGP/CCR GENETIC COUNSELOR

- Step 1: Obtain pre-test permission if using a Laboratory Agreement by emailing Hermi Mesfin hermi.mesfin@nih.gov including all information listed in Table 1.
- Step 2: The team will be notified by Hermi Mesfin to contact Outside Medical Services using SOP [ADCR-14 Authorization of Outside Medical Services \(AOMS\) for Research Participants](#) to obtain permission for the test. Testing **CANNOT** commence until Outside Medical Services has provided approval.
- Step 3: The Principal Investigators team and/or Outside Medical Services will notify Hermi Mesfin of the approval and provide Hermi Mesfin the POTS number generated by Outside Medical Services.
- Step 4: Laboratories with agreements will submit an invoice that includes all tests ordered with that laboratory in that billing period to John Lueders.
- Step 5: John Lueders will submit the invoice to Hermi Mesfin to reconcile with the Genetic Counselor the test ordered.

Step 6: Hermi Mesfin will email a redacted version of the invoice that ONLY reflects the Outside Medical Services charge to OMS via NCICCROutsideMedServ@nih.gov.

Step 7: Outside Medical Services team will work with OCD purchasing agent to pay the invoice.

PROCEDURE 3: Genetic Tests Using an Outside Laboratory Without a CCGP Agreement and Principal Investigator Paying Test Costs

Seeing a CCGP/CCR Genetic Counselor is the **only option** when **NOT** using a Laboratory Contract.

PATIENT SEEN BY A CCGP/CCR GENETIC COUNSELOR

Step 1: Email Hermi Mesfin using the consult email NCI_GeneticConsult@mail.nih.gov to schedule an appointment for the patient to be seen by a CCGP Genetic Counselor including all information listed in Table 1.

Step 2: Include in the referral email the Principal Investigator CAN number and name of the Administrative Officer.

Step 3: Hermi Mesfin will schedule the patient with a Genetic Counselor and notify the team of the date of the appointment.

Step 4: Patient will be seen by the CCGP Genetic Counselor who will determine the test/laboratory to use and submit the order to the testing laboratory.

Step 5: The CCGP Genetic Counselor will notify Hermi Mesfin of the laboratory and test ordered and any specific billing instructions.

Step 6: Hermi Mesfin will enter the POTS.

Step 7: Contract laboratories will submit an invoice that includes all tests ordered with that laboratory in that billing period to John Lueders.

Step 8: John Lueders will submit the invoice to Hermi Mesfin to reconcile with Genetic Counselor tests ordered.

Step 9: John Lueders will pay the invoice using the CCGP Kathleen Calzone CAN.

Step 10: Melissa Shue will contact the Principal Investigators AO three times/year (December, April, and August) to initiate a BMS Transfer to reimburse the CCGP Calzone CAN for all tests ordered in that interval.