



# Clinical Center Genomics Opportunity (CCGO) Protocols Ordering and Viewing Exome Secondary Findings Analysis

**Background:** Once you have gotten approval for a protocol to be part of the CCGO project the ability to order in CRIS starts with ensuring the patient is on a protocol that is part of the CCGO Project. Below are steps to ensure that the patient is on a CCGO protocol.

## 1. Steps to Ensure that your Patient is on an Approved CCGO Protocol:

1. Locate and select your patient.
2. Click the **Patient Info** tab.
3. In the **Summary Views** box, select **Health Issues** and review the list of protocols displayed.

Type	Code	Health Issue	Status	Scope	Onset Date	Entered
Visit Reason	93-CC-0094	1993-CC-0094	Active	This Visit	02/04/2014	02/04/2014
Protocol	12-N-0095	2012-N-0095	Confirmed	General	12/03/2014	12/03/2014
Protocol	13-CC-0000	2013-CC-0000	Confirmed	General	02/04/2014	02/04/2014

4. If the protocol is listed, enter a Service Request to request a protocol assignment change:
  - a. Select the **Enter Order** icon.
  - b. Using Manual Entry, type change.
  - c. Locate the **Change Protocol Assignment**. Click **Add**.

Manual Entry Searching for ...

change

Order	Cost
<b>Change Physician Assignment (Change Provider Assignment)</b> Use to request an update to a patient's Primary Provider or Attending Physician. Call the MRD for any questions (301) 496-2292.	
<b>Change Physician to Receive Reports (Change MD to Receive Reports Request)</b> Please make your edits to the existing information and submit the service request. Use the website <a href="https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome">https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome</a> to look up phone, address information for the physicians. Call the MRD for any questions (301) 594-3493	
<b>Change Protocol Assignment</b> Use to add or remove a Protocol, or change a patient's Visit Reason Protocol. Changes must be approved in advance by the Principal Investigator and must be discussed in advance with the patient. Call the MRD for any questions (301) 496-2292.	
<b>Change Provider Assignment</b> Use to request an update to a patient's Primary Provider or Attending Physician. Call the MRD for any questions (301) 496-2292.	

- d. Enter the appropriate information.
- e. Click **OK**.

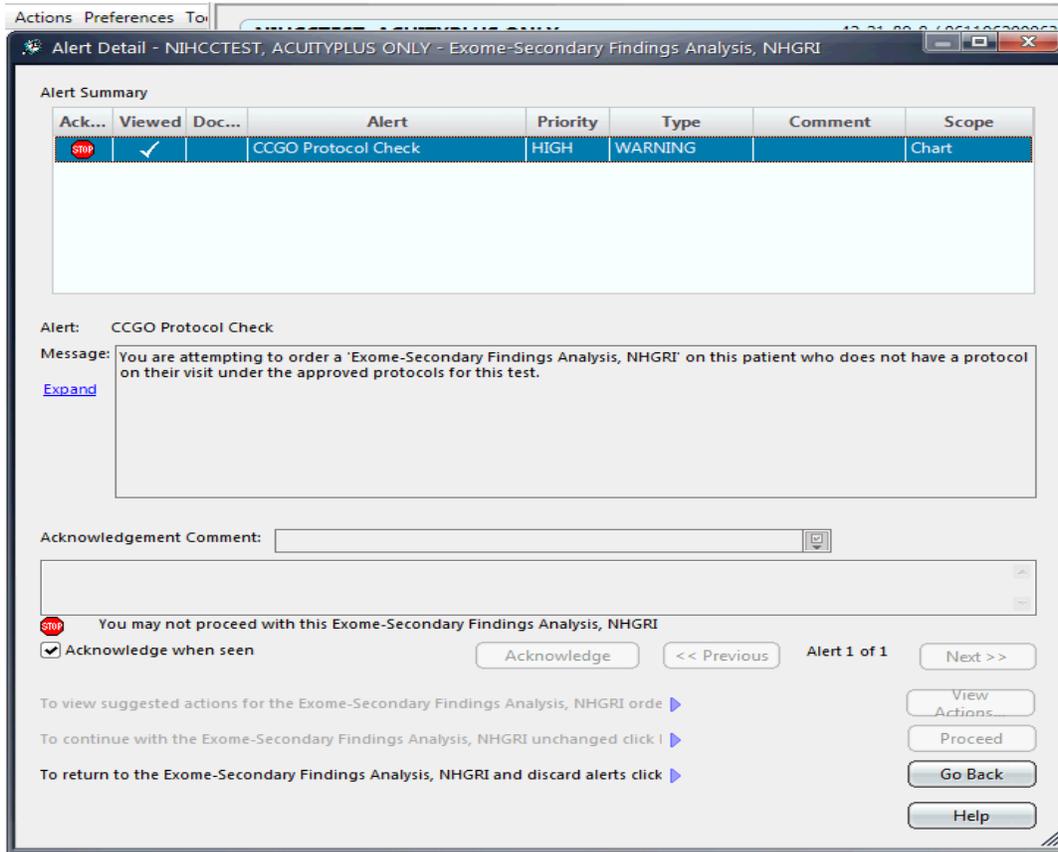
*Note: Protocol Assignment requests are sent to the MRD and are updated in CRIS. If MRD does not yet have the signed protocol consent documents then the protocol will show up in CRIS in the health issues section with an "unconfirmed" status. Once the patient is discharged and MRD receives the signed protocol consent, that status will be updated to a status of "confirmed" and the onset date field will reflect the date the patient signed the consent.*

**II. Steps to Place Order:**

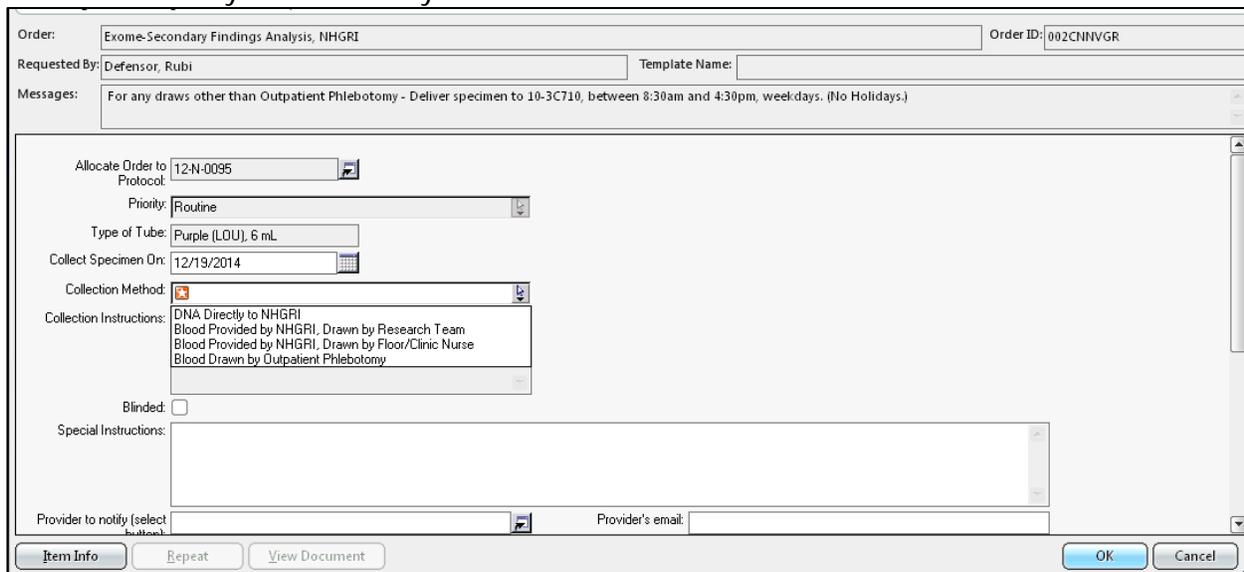
- 1. Select the **Enter Order** icon.
- 2. On the Start of Browse, click Outside Labs >> Laboratory >> NHGRI

- 3. Select the **Exome-Secondary Findings Analysis, NHGRI** order. Click **Add**.

- If the protocol under Health Issues is not a CCGO protocol, an alert message will display and stop you from proceeding with order entry.



- Continue with your order entry and click **OK**.



### III. To Review The Results

1. Locate your patient.
2. Click the **Results** tab.
3. Select appropriate filters, if applicable.
4. Select the **Image Viewer** icon. This will display the PDF Report.

5. The reports are available, along with the VS files, in BTRIS Identified Data for the PIs and their designees.

**ACMG Secondary Finding Report**

**Patient Name:** [Redacted] **Date sample received:** 01/23/2009  
**DOB:** [Redacted] **Sample type:** Blood  
**Lab Accession No:** [Redacted] **Request date:** N/A  
**Report date:** 01/06/2014

**Test Indication:** Exome sequence analysis for variants in 56 genes as recommended for report of incidental findings by the American College of Medical Genetics (ACMG).

**Results:** The following alteration was found to exist in the heterozygous state in this individual:

Gene Name	Genomic Position	Reference cDNA	Alteration	Disease	Pathogenicity	Reference
BRCA1	chr17:q.7128292G>A	NM_000018.2	c.184G>A p.Arg615Gln	Breast and Ovarian Cancer	Pathogenic	PUBMED 10077518

No other **REPORTABLE** variants were identified in the ACMG set of 56 genes (Table 1).

**Interpretation:** This alteration in *BRCA1* is considered pathogenic. Evidence for pathogenicity of this variant includes three prior reports in individuals with Breast and Ovarian Cancer. Pathogenicity refers to the ability of this variant to cause disease, however, penetrance is not expected to be 100% and this individual may not develop disease. There is a small but real risk of false results due to sample mixup, to control for this a second independent sample should be tested for this variant before using this information for clinical purposes.

No other **REPORTABLE** variants were identified in this gene set. **REPORTABLE** variants include known pathogenic variants or variants of the kind that are likely to cause disease. This report does not imply that no variants were identified but rather that the information available for the

This test was developed and its performance determined at the NIH. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. Pursuant to the requirements of CLIA '88, this laboratory has established and verified the test's accuracy and precision. CLIA ID#: 21D1062422.

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