



Department of Clinical Research Informatics CIO Newsletter

September, 2012 - 72nd Edition

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DCRI Website

<http://www.cc.nih.gov/dcric>

CRIS Website

<http://cris.cc.nih.gov>

CRIS Training

<http://cris.cc.nih.gov/cristraining/plans.html>

CIO Remarks

Protocol Attribution

Protocol attribution is an important process used at the Clinical Center in order to align medical orders and Clinical Center Services to a specific patient and their appropriate research protocol.

Key elements include:

- Assignment of the patient to an active and approved NIH protocol, as documented in CRIS. This allows for participation in research and receiving of medical care.
- Accurate attribution/allocation to the correct protocol when placing each medical order. For example, when a patient is assigned to multiple protocols, the correct protocol must be chosen for each individual action (i.e. placing of medical order).
- Utilization of the informed consent process with each patient for each protocol to which they are assigned.
- A requirement for entering ATV requests, scheduling appointments, and placing medical orders.
- Provides clinical research teams with accurate data for analysis and hypotheses.
- Ensures and tracks delivery of appropriate medical care to patients.
- Provides patient census and clinical activity data to the Clinical Center and Institutes/Centers for resource management.
- Provides accurate data for the Biomedical Translational Research Information System (BTRIS). The process of protocol attribution is a cyclical one which follows the patient through their entire treatment at the CC. Clinicians are key to the success of this system and we thank you for your active participation.



More information and details can be found at:

http://cris.cc.nih.gov/cristraining/documents/CRIS_Protocol_Attribution.pdf

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Pharmacogenomics Testing at the Clinical Center

Part I

The CC will initiate a formalized pharmacogenomics testing program on the week of September 17, 2012.

The first part of our program is directed at improving medication safety by reducing the chance for severe hypersensitivity reactions (i.e. fever, hypotension, skin rash, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, erythema multiforme) where HLA gene variations predict for these reactions.

The first three drugs and the associated gene variations to be included in this program are:

Abacavir (HLA-B*5701)	Patients with HLA-B*5701 should NOT receive abacavir because there is a high predictive value of developing a severe hypersensitivity reaction.
Allopurinol (HLA-B*5801) Carbamazepine (HLA-A*3101 or HLA-B*1502)	For allopurinol and carbamazepine, consideration should be given to selecting other agents first. <i>Patients with these gene variations can still receive these medications, if the clinical benefit is thought to outweigh the risks. In this situation, a clinical justification is required as part of the CRIS order.</i>

HLA tests (Sequenced Based HLA-A, Sequenced Based HLA-B) can be ordered in CRIS. The tests will be done by the Department of Laboratory Medicine with an expected turn-around time of about two weeks.

Clinical Decision Support in the form of Order set forms will be used to assist with the ordering of these medications.

Please note that these orders can only be placed by a prescriber and cannot be re-ordered.

When you open the item for any of these three medications you will see a different view.

NIHCCTESTLAB, INPATIENTTWO LAB 85-19-58-4 / 121417207074 3y2m (04/17/2009) Female

CRC-7SW-N Unreviewed Allergies Herion, David W

Carbamazepine for Inpatient Use [0 orders of 9 are selected]

Allocate Order to Protocol: 99-CC-0163

Information regarding HLA testing and adverse reactions for the medication selected will appear here.

Serious dermatologic reactions, including Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome, have been reported with carbamazepine treatment. Greater than 30% of reactions occur within two to three months of treatment. Testing for HLA-A*3101 and HLA-B*1502 is recommended to assess risk.

Height/Weight/BSA/BMI: Height (cm) Weight (kg) BSA BMI

HLA Genotype Test Override Reasons: Override Reason Number:

1. Patient currently receiving medication without reaction.
2. Outside HLA genotype test result is negative and documented in CRIS.
3. Clinical justification documented in CRIS.

Date of Last HLA Test at NIH: Date and Result if available will appear here.

HLA Genotype Test:

	This order will be protected, if an order was previously placed at NIH.	Priority:	Reason for Stat/Priority Precedence:	Prescriber to Notify of Results
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Sequenced Based HLA-A,B,C	Routine	

Medication Orders:

Order	Strength	Dose:	UOM:	Frequency:	Route:	Route Modifier:	Start Date:	Priority/Time:
<input type="checkbox"/>	Carbamazepine	100 mg tablet, chewable	100	mg	every 12 hours	by mouth		T

Drug Info OK Cancel

There are three parts to the form:

1. A Place for an Override Reason

- An override reason is only needed
 - if the HLA result from NIH is pending
 - if the HLA result is positive, but the clinical benefit outweighs the risk
 - if the HLA result is available from an outside lab and the result is negative
 - if the HLA result is not yet ordered and there is clinical justification documented in CRIS

HLA Genotype Test Override Reasons: Override Reason Number:

1. Patient currently receiving medication without reaction.
2. Outside HLA genotype test result is negative and documented in CRIS.
3. Clinical justification documented in CRIS.

2. A Place to order the HLA lab test.

- If an HLA test has not yet been ordered, you can place the order from within this form by selecting the checkbox next to the lab test listed.
- If a result is pending or if the result is available, you will not be able to enter another lab order.

Date of Last HLA Test at NIH: If an HLA test was ordered at NIH, the date of the last test and result would appear here.

HLA Genotype Test:

	This order will be protected, if an order was previously placed at NIH.	Priority:	Reason for Stat/Priority Precedence:	Prescriber to Notify of Results
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Sequenced Based HLA-A,B,C	Routine	

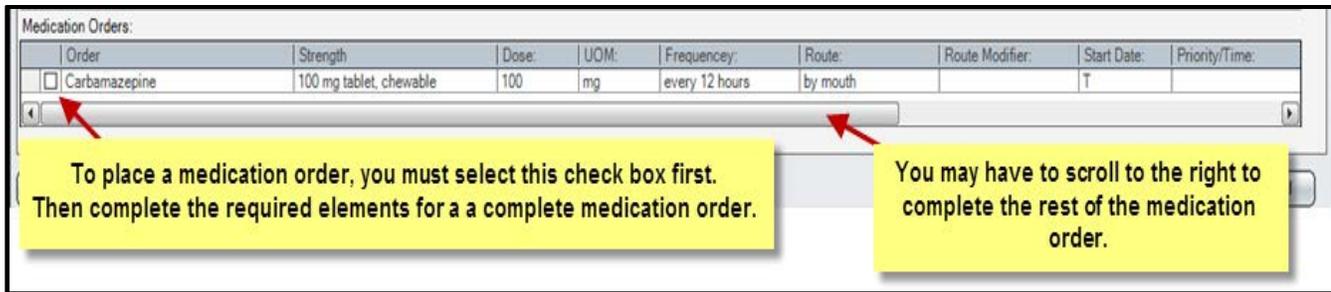
To place an order for the lab test, click in this box.

To open this order, click on the name of the test.

To receive notification that the HLA lab result is available, enter the name of the prescriber to be notified. An email indicating that results are available will be sent to the prescriber.

3. A Place to order the medication.

- a. From this order form you can enter the medication order.
 - i. Please remember to select the **correct session type before you begin** to complete the other elements.
 - ii. If you are not in the correct session type, you will have to cancel, exit the order, select the session type, and start the process again.



Questions about pharmacogenomic tests can be directed to the Clinical Pharmacy Specialist (CPS) for your unit or to the Drug Information Service (301.496.2407) if a CPS is not assigned to your area.

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Renewing PIV Card Certificates

Renewing digital certificates on your HHS ID Badge/PIV Card – PKI digital certificates on the HHS ID Badge/PIV Card are valid for 2 years for employees and 1 year for contractors. HHSIdentity will send an email reminder to users with instructions on how to renew your digital certificates 42 days before the user’s certificate expires. Please follow the instructions and contact an LWS operator to assist you. You must appear in person with your card to renew the certificates. Failure to renew your digital certificates by the expiration date provided in the email will prevent users from using their HHS ID Badge/PIV Card to login to ITAS, NIH VPN, CCCASPER for remote access and sending/receiving secure email in Outlook.

Once the certificate is renewed, it will be necessary to publish the new certificate to the GAL to continue using secure email. It will be necessary to backup or recover certificates to read old encrypted emails. Please refer to the documents that will be provided by the LWS operator for guidance or contact your desktop support person for assistance.

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NIH Password Management

Keep your NIH passwords up to date - NIH will be implementing the requirement to use your HHS ID Badge/PIV Card to login to the NIH network on Windows workstation on campus this year. Some Institutes/Centers already require this for their Windows users.

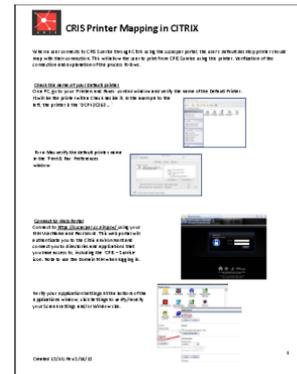
Even though you are using your HHS ID Badge/PIV Card to log in to your computer, it is still necessary to update your password to keep your AD account active. According to the NIH OCIO, as long as NIH continues to use username/password authentication with Active Directory, the password change policy will apply. AD will not allow you to login to a computer (with or without a PIV card) if your password is expired. This policy is expected to remain in effect for at least 2 more years.

CRIS Helpful Tips

CRIS Printing from CITRIX

When a user connects to CRIS Sunrise through [Citrix](#) using the [cccasper portal\(https://cccasper.cc.nih.gov\)](https://cccasper.cc.nih.gov), the user's default desktop printer should map with their connection. This will allow the user to print from CRIS Sunrise using their default printer.

Instructions on how to print from CRIS via Citrix can be found at the following URL:
http://cris.cc.nih.gov/cristraining/documents/CRIS_Printer_Mapping_CITRIX.pdf



CRIS Support

Need assistance for CRIS technical or clinical questions?

Feel free to call CRIS Support at **(301) 496-8400**.

CRIS User Support is available 24/7.

- **Business hours:** Monday – Friday from 7:00 am – 5:00 pm.
A CRIS support person will take your call and will either resolve the issue(s) OR determine if additional resources are needed to assist.
- **After hours:** After 5:00 pm – 7:00 am, weekends and holidays.
If you call CRIS Support, a recording will play directing you to either leave a message or press 1 for immediate assistance. By pressing "1" you will reach a live in-house resource people to assist in your needs.

[Department of Clinical Research Informatics](#) | [CRIS Website](#) | [CRIS Training](#)

Have a comment or suggestion about the newsletter? Contact us at CIONewsletter@cc.nih.gov