Protocol Flow

1) Faith Fortune (Administrative Coordinator) will upload new protocol on the TCRC website.

2) Studies can be found under the **Trial Management** > **Studies**. A new study will appear with a blue square indicating TCRC submission.

3) Study specific information such as study type, IRB review type, sponsor name and funding source can be found under each studies SPID number tab

4) Protocol Nurse will complete the review forms in Harvard Catalyst as done previously

5) RN, RD, and Amanda Griffin (Lab Manager) will use this website to create order sets. See "Creating MD orders" manual on the website under **Trial Management** tab → **TCRC Forms and Documents.**

6) Once RD, RN, Amanda, and Study Coordinator have reviewed the order sets, click the "Send for Approval" button. Each morning, the system will then send out an email to everyone who has outstanding activities, called the "Daily Digest". (See Email Notifications guide on changing email settings for immediate notifications)

   a. Daily Digest will include trainings/attestations, orders to approve, orders that have been approved, and orders that have been rejected

   b. Faith will no longer generate the approval email for orders.

📋 0000   👥 Contacts   📒 Orders   💱 Funding   📄 Documents   🔍 Scientific Reviewers   📊 Trainings

Edit Order

Edit | Delete | Copy | Print Preview | Back | Send for Approval

Information

Visit name	Start date	Due date	Approved date
Gap			

7) <mark>One signature from each role group is required for approval</mark>. Each visit will require a complete set of signatures. The hourglass represents the need for a signature from that role group. The stamp signifies that a representative from that role group has signed.

Signatures

8) After 4 days, Faith will then send a final reminder to sign orders.

9) To confirm an order has been approved, look for the "Approved Date", under the Orders Tab.

10) NOTE: Protocol RNs will still need to build visit templates with RD and Sarah Luthern before study visits can be scheduled. After the template is built, Faith will send out the final TCRC study approval letter.

11) To print a current order, click the document icon next to the Approved Date, or click
"Download" and print from within the individual MD Order.

Home ▾ Conducting A Study ▾ Trial Management ▾ Events ▾ Administration ▾ Account ▾   Logout (Lu) Account

📋 0000   👥 Contacts   📋 Orders   💲 Funding   📄 Documents   🔍 Scientific Reviewers   📖 Trainings
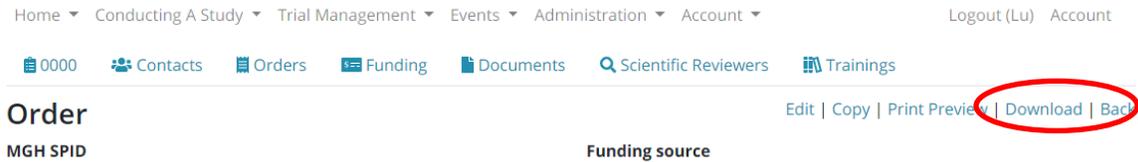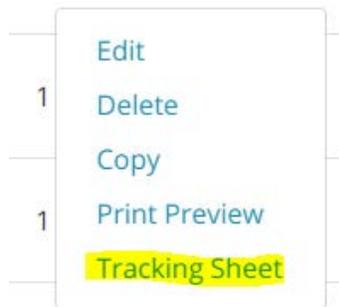
Order   Edit | Copy | Print Preview | Download | Back
MGH SPID   **Funding source**

12) You will also need to print the Tracking Sheet. There are 2 places to find this:

    a. Using the dropdown arrow in the main MD Orders tab

    b. Within the individual MD Order links list

1   Edit

    Delete

    Copy

1   Print Preview

    Tracking Sheet

Documents   🔍 Scientific Reviewers   📖 Trainings   ✏️ Edit Study

Edit | Delete | Copy | Print Preview | Tracking Sheet | Back | Send for Approval

13) If this is the first visit to the TCRC, print a Contact

Page, located under the "Contacts" tab

📋 1362 👥 Contacts 📋 Orders 💲 Funding

Contacts

| Active ▾ | Search | Reset |

Download: CSV | PDF

Role	Name

    a. Please contact Faith Fortune to request any
edits/changes. This may include change in
staff, updated phone numbers/pagers, or
special information like "contact for Baseline
visits only"

    b. A new Contact page will need to be printed and placed in the patient chart
after any changes are made
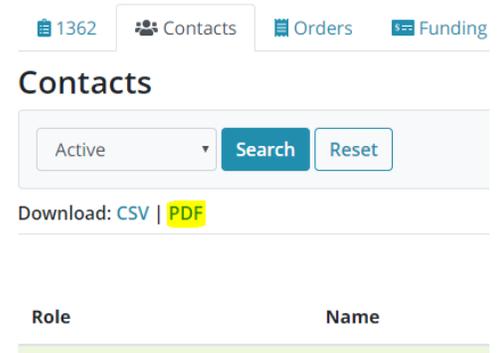
To Reject Orders:

If a role group would like to make an edit to a set of orders which have been sent out for approval, the signatures of the role groups who have previously signed need to be removed. Edits can only be made after signatures have been removed.

Signatures

ald39
a. Griffin
TCRC Lab
2020-01-15

Study
Coordinator

Protocol
Nurse

Protocol
Dietitian

🗑 Remove Signatures   🔧 Sign as Associate Protocol Nurse   🔧 Sign as Protocol Nurse

Example- If Amanda signed a set of orders, but a nursing edit is required- select Remove Signatures, made the edit and then Send out for Approval. (Amanda will be notified by email that her signature was removed)

Once **all** role groups have approved, signatures cannot be removed. If new edits are required, the set of orders will need to be copied, revised, and then sent out for approval. The original set of orders will be stored in the system as an older version.

NOTE: If a set of orders is approved in ERROR or significant protocol changes have occurred and the approved order is no longer needed, it can be set as INACTIVE. This prevents anyone from printing the MD order by accident but can be REACTIVATED if needed in the future.

Extra Helpful Information

1) Orders can be filtered by All/Approved/Not Approved in drop-down.

2) The above standard form and protocol synopsis template can be found under Trial Management> TCRC Forms and Documents.

3) Send protocol synopsis to RD to complete nutrition section before final submission to Faith.

4) The completed protocol synopsis is to be emailed to Faith Fortune who will upload under the document tab of the study and will send out for training.