Colorado Clinical and Translational Sciences Institute
University of Colorado Denver | Anschutz Medical Campus

Administrative Offices
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Dear Study Team,

Thank you for reaching out to the Adult CTRC Nursing Core regarding the initial build, updates, or changes to your MD Orders. We have transitioned to an **Adult CTRC Study Startup Dashboard System**—a centralized, HIPAA-compliant platform for creating and editing MD orders. If you also use the CHCO CTRC, please continue to build Epic Use Plans (EUPs) through the CHCO CAS team for CHCO CTRC nursing orders.

Instructions for Accessing the New Adult CTRC Study Startup Dashboard System:

<u>**For New Studies:**</u>

Prior to 12/1/2024: If you received a welcome letter from the Adult CTRC Nursing inbox before 12/1/2024 and have not yet created your MD orders, please email the Adult CTRC Research Administrator to request an updated welcome letter with a link to your new study in the Adult CTRC Study Startup Dashboard. Include the following in your email:

- IRB #
- PI name and email
- MD name and email (if PI is not the MD)
- Lead CRC Name (s) and email(s) - they will receive the communications regarding study updates
- Other Study Team Members' emails - for those who need access to the Adult CTRC Study Startup Dashboard

After 12/1/2024: New studies submitted to the HSR Portal after 12/1/2024 will receive a welcome letter from the Adult CTRC with a link to your new study in the Adult CTRC Study Startup Dashboard.

<u>**For Amendments or Changes to Existing Studies:**</u>
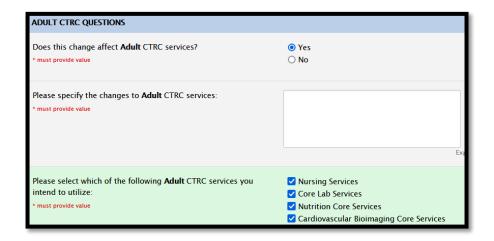
1. **Amendments:**
   If your MD order changes require an amendment to either the COMIRB and/or the HSR Portal, please follow the links below to submit or review the criteria for amendments:

   a. Colorado Multiple Institutional Review Board (COMIRB): This page provides conditions for amendments to orders and submission details.
   o Adding new documents (e.g., survey or advertisement)
   o Revising existing study documents
   o Changes to the study team, protocol, consent form or procedures
   o Changes to the study budget, contract terms, or PI

b. [Human Subject Research Portal](#) (HSR Portal): This page provides conditions required for amendments and submission details. The following changes qualify as amendments and must be submitted through the HSR Portal, which will notify the Adult CTRC of the intended changes:

- o   Change to PI
- o   Changes to budget, calendar, MCA, or financials
- o   New arm/new procedures
- o   New visit location
- o   CTRC resource requests and/or requesting a microgrant

Please ensure to:

- Select 'Yes' when prompted if the change will affect Adult CTRC services
- Check the Adult CTRC services that you intend to utilize

Once a submission is made in the HSR Portal, the [Adult CTRC Research Administrator](#) will send an email with a link to your study in the Adult CTRC Study Startup Dashboard.

2. Changes (without Amendments):

If your change/update **does not** require a COMIRB or HSR submission after reviewing the conditions in section 1, please contact the [Adult CTRC Research Administrator](#) to request a build of your study in the Study Startup Dashboard.

Note: Do not send attachments; all updates will be managed directly within the Adult CTRC Study Startup Dashboard. You will receive an email with a link to your study in the Adult CTRC Study Startup Dashboard.

Required Information when contacting the [Adult CTRC Research Administrator-](#)

- IRB #
- PI name and email
- MD name and email (if PI is not the MD)

- Lead CRC Name (s) and email(s) - they will receive the communications regarding study updates
- Other Study Team Members' emails - for those who need access to the Adult CTRC Study Startup Dashboard

Thank you for your cooperation. If you have any questions, feel free to reach out to the Adult CTRC Research Administrator or the Adult CTRC Nursing Team.

The Adult CTRC Research Team