|  |  |  |  |
| --- | --- | --- | --- |
| **Title:** | Procedure Guidelines for University of Colorado Hospital Inpatient CTRC | **Approval Date:** | 6.27.2025 |
| **Department:**  AdultCTRC, CCTSI | | **Required Revision Date:** | 6.27.2025 |
|  |  |
| **Approved & Reviewed by:** | Thomas Campbell, Bill Cornwell, Diane Branham, Ellen Rohan, Kyla Wulff | **Revision No:** | 2 |
| **Previous Revision Dates** | 9.24.2024  6.5.2025 |

|  |
| --- |
| **Tool: Guidelines for performing research procedures at the Inpatient CTRC** |
| **Purpose: Provide a clear description of the requirements for all research procedures performed at the Inpatient CTRC** |
| **Audience/User: All Investigators performing procedures** |
| **Description:**  **CTRC Inpatient Unit on 12 East AIP**  **For all procedures performed in the CTRC Inpatient Unit that are more invasive than phlebotomy or peripheral vein catheterization**:   1. It is the responsibility of the study Principal Investigator to verify that the clinician performing the procedure has the required privileges at University of Colorado Hospital for the procedure to be performed prior to performing the procedure. Confirmation of privileges can be viewed [here.](https://msowprodapp.uchealth.org/privinq/msopi.aspx) 2. A **UCHealth Procedure Consent** must be explained, signed and dated by the clinician performing the procedure, on the day of the procedure, prior to the procedure being performed. CTRC Nurses will provide a blank procedure consent form upon request. The signed procedure consent form should be delivered to the CTRC Inpatient Nursing station and will be uploaded to the Epic electronic health record (EHR) by UCHealth medical records (HIM). Please note that the UCHealth Procedure Consent is not the same as the consent form approved by the Colorado Multiple Internal Review Board for participation in research. View the UCHealth procedure consent policy [here.](https://uchealth-uch.policystat.com/policy/16126179/latest/) 3. The clinician performing the procedure will conduct a Time-Out before starting the procedure. View the UCHealth Lippincott guidelines for Time-Outs [here](https://procedures.lww.com/lnp/view.do?pId=2958550&hits=time,outs&a=false&ad=false). During the Time-Out, the following items will be reviewed: 4. Completion of procedure consent verified 5. Introduction of all Team Members 6. 2 patient identifiers 7. Confirmation of correct procedure and site(if applicable) 8. Safety concerns 9. Notate Time of completion of Time-Out 10. **Per UCHealth requirements as of August 1st, 2025, the Time-Out must be conducted with a UCHealth RN present. The RN will also record all details of the consent, time-out, and procedure in EPIC.** 11. Non-operative and other low-risk procedures involving light or no sedation do not require a complete H&P, but at minimum, require a procedural note. However, it is recommended to complete an H&P or to document relevant exam findings in the procedural note. Based on assessment of the study procedural risk, the CTRC Medical Directors may require a pre-procedural H&P.     1. Examples of low-risk invasive procedures include but are not limited to: lumbar puncture or percutaneous biopsy (skin, muscle, fat). 12. For those procedures requiring an H&P, a medical history and examination that was completed within 30 days prior to inpatient/observation admission may be accepted, but this must have an update performed by the study clinician within 24 hours after admission or registration but prior to a procedure requiring an H&P. Review the policy for History and Physical Examination [here.](https://uchealth.policystat.com/policy/16126139/latest/) 13. After the procedure is completed, a procedure note must be completed by the provider performing the procedure within 24 hours of performing the procedure. The procedure note will include the information below and must be placed in the Epic EHR on the day the procedure was performed:     * + 1. Date and time of the procedure         2. COMIRB protocol number and study title         3. Reason for the procedure: Research study         4. Documentation of “Pause for Safety” or Time-Out including time and those present         5. Assessment of the site (before and after the procedure)         6. Medications administered (name, strength, dose, route of administration)         7. Method of procedure         8. Type and number of sutures (if any)         9. Dressing applied         10. Tolerance of the procedure         11. Unexpected outcomes (such as excessive bleeding, pain or a hypersensitivity reaction)         12. Interventions and response to interventions         13. Instructions provided to the participant         14. Samples collected   Hospital-approved procedure note templates are available in EPIC and may be used for procedures conducted at the inpatient CTRC.  *Refer to* [*UCHealth policy*](https://uchealth-uch.policystat.com/policy/16126179/latest) *for additional guidance*  **Applicable Protocols: All**  **Timing: As soon as reviewed and approved** |
| **Best Practice Recommendations: Utilize policy for all procedures conducted on the CTRC Inpatient Unit.**  **Refer to UCHealth Policy for additional guidance.**  **Revise and Review SOP biennially** |