Duke Maestro Care for Research Administrators
Overview of Maestro Care for Research

Maestro Care for Research

- A clinical research study involves research using human volunteers (also called participants) and is intended to add to medical knowledge.
- For studies which recruit from a Duke Patient pool and utilize DUHS services (any orderable, schedulable, or chargeable) or spaces. Informed consent is a requirement.
- Clinical research within the SoM/SoN is organized into therapeutic areas called clinical research units or CRUs that provide oversight to most human subjects research at Duke Medicine.

The leadership structure of the CRU must include a Director, a Research Practice Manager (RPM), and a Financial Practice Manager (FPM).

There are a number of administrative groups within Duke that exist to facilitate the conduct of human subjects research for investigators and study teams and to ensure compliance with institutional and government regulatory requirements. These offices work together to assist with contract negotiations and grant awards, billing, compliance, study approvals, and other requirements such as investigational product handling and conflict of interest reporting.

Clinical Research Units (CRUs) are the operating business units responsible for the integrity, financial accountability, regulatory compliance, quality, and academic productivity of clinical research studies.

<table>
<thead>
<tr>
<th>Grants/Contracts (ORA, OCRC, DOCR, OSP)</th>
<th>Billing (PRMO, CTBO)</th>
<th>Compliance (OARC, DUHS)</th>
<th>Institutional Approvals (IRB, DOCR, ORA, OCRC)</th>
<th>Additional Groups (SOME, IDS, RIO)</th>
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</table>

Study Set Up and Institutional Approval • Duke Medicine IRB • PRMO Grant Pricing Form
Study Billing and Maestro Care • SoM/SoN Clinical Research Units (CRUs) • Maestro Care Access

Suggested Training for Research Administrators

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<td>This course helps obtain a broad understanding of the financial concepts associated with the life cycle of a clinical research study.</td>
<td>This course presents information regarding the contract approval process for industry-supported research and the associated SPS entry.</td>
<td>This course reviews best practices and provides helpful tips on developing and negotiating budgets and payment terms with industry sponsors.</td>
<td>This course teaches how to perform verification/reconciliations, run and interpret applicable reports, and reconcile them to Duke's General Ledger system.</td>
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Glossary of Terms

- **Billing Activity** – Interventions or interactions required by the research protocol to generate charges within the DUHS patient billing system. Some activity may be standard of care or research-only. All billing activity should be assessed to determine if charges should be billed to the study fund code or participant/insurance.
- **Charge Assignment Process** – DOCR works with the DUHS Compliance and PRMO-CTBO offices to develop the methodology to ensure proper routing of charges. This information is found on the Research Build Template.
- **CTBO** – Clinical Trials Billing Office, a subsection within the PRMO that is directly responsible for all clinical trial billing.
- **HAR** – Account record within Maestro Care.
- **Maestro Care** – The electronic medical record system used by DUHS that documents all patient care activities.
- **Maestro Care/Beacon Build** – During the study initiation meeting and follow up, DOCR performs an operational assessment, ensures that patient billing is set up correctly, and creates the Maestro Care build of study activities and procedures.
- **PRMO** – Patient Revenue Management Organization which is the centralized billing and collections office for the entire Duke Health System.
- **Protocol** – The document used by the PI/Study Team/eIRB that describes the clinical trial’s objective(s), design, methodology, statistical considerations, and organization of the trial.
- **Research Charge Router** – An excel spreadsheet representing all activities generating a DUHS patient charge or requiring a Maestro Care order, that covers timing of events, types of orders, and charge assignments.
- **RSH Record** – The Study Research Administration Record in Maestro Care that contains information related to the Users, Providers, Fund Code, Billing Groupers, and is linked to the Study/Billing calendar.
- **Study Calendar/Billing calendar** – The built research protocol, either through Beacon or through an order set in Maestro, combining the cycles of the protocol with detailed charge, payer and coding mapped so that as orders are fulfilled, charges are routed appropriately to the corresponding payer.
There are two requirements needed when requesting Maestro Care access for new users:

- **Maestro Care Research** (MC Clinical Research – View Only) training AND passing of the associated quiz must be completed prior to request being submitted.
- **Research Practice Manager (RPM), Assistant Research Practice Manager (ARPM), OR Financial Practice Manager (FPM)** must be the one submitting the **Duke Service Now** request.

☑ Request for access to Maestro Care can only be submitted if the end user has an active DHE account.
☑ Account activation will occur within two business days of completion of training provided that the manager has approved this request.

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1. **Log in to Duke Service Now** - select the **Service Request Catalog**
   - **Accounts & Access**
     - WebEx Access (Add/Change)
     - Account Access Order Guide - Maestro Care, Clinical & Departmental & Application Shared Drive Request
     - Password Reset
3. **When the form appears, search for the user who needs Maestro Care access**
   - Requested for: [Input Field]
   - More information: [Input Field] [Input Field]
4. **Type of Request: field select New**
5. **In the Maestro Care field, put a check mark next to Maestro Care**
6. **Scroll to the top of the page** - select **Choose options** in the right corner
7. **On the next page – Where does this user work?**
   - click on the magnifying glass – select **RESEARCH**
   - **What is the user’s role?**
     - click on the magnifying glass – select **VIEW ONLY**
   - **What is the user’s job function?**
     - click on the magnifying glass – select **RESEARCH VIEW ONLY**

8. **Choose the job role for this user**

9. **Scroll to the top of the page** - select **Checkout** in the right corner

10. **Once email confirmation of access is received, and Maestro Care is installed on Duke computer, launch the instance and log in using Duke DHE and password.**
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### Accessing the RSH Record

Research Administrators/Financial Reconcilers only have access to run reports for the projects to which they are assigned within the RSH record. Financial Practice Managers (FPM) should be assigned to all protocols within the CRU.

- Users can view who is assigned to a protocol by clicking on the Study Administration Records link from their Dashboard.

**Steps to Access the RSH Record**

1. Log in to Maestro Care and access your Dashboard – select Study Administration Records

2. Enter the protocol number, press ENTER, and select the protocol

3. Click the Users and Providers link

4. Financial reconcilers who have access to the RSH data are listed in the Research Contacts field

5. A Financial Practice Manager (FPM) can assign someone to a protocol by submitting a Duke Service Now Ticket with the person's name, DHE ID, and the list of protocols to be assigned.

### Adding Personnel to RSH Record

Adding Personnel to Maestro Care

It generally takes two business days to add key personnel to the RSH record. A Financial Practice Manager (FPM) can assign someone to a protocol by submitting a Duke Service Now Ticket with the individual's name, DHE ID, and the list of protocols to be assigned. If you need personnel added more quickly, it should be indicated on the Service Now request. In the body of the Service Now request, identify your issue as Adding personnel to RSH record so that it may be acted upon promptly.

**Steps to Add Personnel to RSH Record**

1. Log in to Duke Service Now and select the ‘Service Request Catalog’ link in the Self-Service menu.

2. Select the ‘Create a New Incident’ link.

3. Short Description - Enter
   - Assign to DOCR/Maestro PRMO Team - Addition of User to Research Study Admin for protocol.

   **Full Description** – Enter
   - eIRB: Pro00049209
   - ADD: Harry D. Potter, FPM (potte001) to RSH Record - Research Contacts
   - Assign to DHTS Service Desk

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A new fund code must be updated in Maestro for any anticipated/unanticipated expenses related to study activity. This is critical if the eIRB will remain open but the WBSE is expiring (i.e., the project receives a new budget year fund code, active enrollment or data analysis, change to PI initiated).

- These may include charge corrections, insurance refunds, project charges, ongoing study activity.
- If the IRB has been closed, a change to the fund is not needed.
- This change is accomplished by submitting a fund code change through a Duke Service Now ticket.
- Listing the Sponsor type (e.g., Industry / NIH) and indicating a WBSE change helps PRMO prioritize the request for quick turn around.

The scenarios in which a change to the fund code (WBSE) is required are:

1. During the closeout process of a project/grant (WBSE).
2. When the continuation/budget period has a different WBSE, or the PI is using a different funding source/WBSE (i.e. discretionary).
3. When both the WBSE and IRB are ending/closing, but the IRB has not yet closed the study.

Please note, if both the WBSE and IRB are closing at the same time (scenario #3), the necessary steps should be taken to notify the PRMO via a service now ticket of both the IRB and fund code (WBSE) closing.

The PRMO team will change the fund code within Maestro to xxxxxxx to block future activity to the code.

If the PRMO receives notification from DOCR directly of eIRB closure prior to any Service Now ticket being submitted, the PRMO will complete necessary steps in Maestro to ensure the study is blocked to SAP uploads by assigning an xxxxxxx number in Maestro.

However, if subsequent activity is required to be posted to a fund code that is now closed in Maestro, the PRMO will notify the study team a fund code is needed to process any outstanding activity.
### Escalation Process for Resolution of Research Charge Corrections

The process that research staff are required to follow when the usual reversal process for clinical research procedures billed to a participant's insurance is not resolved. See [Escalation Process Policy](#) for additional information.

1. If research study participant states he/she is “in collections,” contact the PRMO to determine participant’s current status.
   - If subject is indeed “in collections” due to a clinical research charge, submit a Service Now ticket to the PRMO labeling it “patient in collections” asking PRMO to pull the charge out of collections until the investigation is complete.
   - If the subject is not formally “in collections”, contact Customer Service at 919-620-4555.
2. Clinical Research Coordinator (CRC) or designee reviews Maestro Care to determine:
   - If the patient is on the trial and that the visit/encounter was linked to the timeline appropriately
   - If the billing calendar/research charge router correctly identifies that the charge is a research charge
3. If there is a problem with the visit/encounter being linked to the timeline or the charge is not directed to research, the CRC submits the Grant Charge Correction form to move the charge from the participant’s insurance to the study fund code.
   - The CRC also submits a Service Now ticket to correct an erroneous billing calendar/research charge router if needed.
   - Route the Service Now ticket to DOCR for review and approval.
4. If the problem cannot be resolved with the actions above, escalate to the Research Practice Manager/Financial Practice Manager (RPM/FPM) of the study’s CRU.

### Escalation Process for Corrections due to Closeout Timeliness

The process by which a **Financial Practice Managers (FPM)** escalates corrections in order to meet a sponsor deadline and avoid financial and compliance risk.

With the new requirements to have all project related allowable, allocable, and reasonable expenses posted to the project before submitting the closeout documentation, it occasionally becomes necessary to escalate the request for corrections to all Maestro Care charges and have it prioritized.

1. Log in to Duke Service Now and select the 'Service Request Catalog' link in the Self-Service menu.
2. Select the ‘Create a New Incident’ link.
3. **Short Description** - Enter PRMO CTBO – Federal (NIH) Award/Closeout Issue – HIGH PRIORITY-Federal Deadline– eIRB #
   - **Full Description** – Enter
   - All details regarding issue, state what needs to be done and deadline
   - **Assign to** DHTS Service Desk
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**Reports in Maestro Care for Research Administrators**

There are various reports within Maestro Care that assist a Research Administrator with the financial pieces of project management and closeout. Below are three suggested reports that will assist with the monthly management of the project.

- These reports validate enrollment, study grillendar/billing calendar, and study/insurance charges.
- Access to Maestro Care and listing on the RSH record are required for the Research Administrator to view the data.

<table>
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<tr>
<th>Report Name</th>
<th>Description</th>
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<tr>
<td>RSH010A</td>
<td>The purpose of the Research FPM Payment Reconciliation Report (RSH010A) is to determine if the service activities for the patient are accurate and have been reviewed by the PRMO and/or the clinical research study staff, to allow for proper reconciliation of the payments and/or payment reversals recorded in SAP/R3. The report can be run by protocol or Research HAR. You should run this report on a monthly basis; however, it can be run several months at a time. The Summary section of the report reflects payments that have posted to SAP/R3 Technical (HB) and Professional Billing (PB) for the time period selected. The Detailed section provides more information on the payments/payment reversals that have posted. It shows patient information, procedure codes, and descriptions for the services provided on a specific date. Also reflected are the revenue code, payment percent, and contract price by service activity, with a calculation of the amount posted to SAP/R3. For additional assistance, contact the Financial Practice Manager (FPM) within your SoM/SoN Clinical Research Units (CRUs) for guidance.</td>
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| AMB559      | All Patients Enrolled in a Clinical Trial

- This report displays all patients who are associated with a research study.
- Research billing staff may choose to specify the research study or studies for which it should run.
- This report is helpful for reconciliation of subject payments (ClinCard), travel related costs, and other items related to each study participant.
- This report should be used to verify completed status of all associated study participants prior to eIRB Closure.

The clinical research staff associated with the study are responsible for ensuring the review and accuracy of the list of enrolled study participants on the study protocol. Upon study completion, the clinical research staff should review the AMB559 report, verifying that all study participants that signed a consent form have been appropriately associated with the study and their current enrollment status has been updated to reflect the final study participation status (i.e., Completed, Terminated, Excluded). For additional assistance, contact the Research Practice Manager (RPM) within your SoM/SoN Clinical Research Units (CRUs) for guidance. |
| Research Billing Review Button | Coordinators should use the “Research Billing Review” button to review charges. From this screen in Maestro Care, coordinators can see previously missed charges, review, and “mark service date as reviewed.”

Here are a few helpful reminders regarding billing review:

- Prices displayed are the non-discounted rate.
- Charges reviewed prior to March 2014 do not need further review since they were handled by the SOM Task Force.

For additional assistance, contact the Research Practice Manager (RPM) within your SoM/SoN Clinical Research Units (CRUs) for guidance. |