Finding Protocols:

1. Make sure you are in your “E_SPA” role.
   a. At the top of the screen, click on the arrow in the parentheses next to your name and select the “E_SPA” role from the drop down.
   
   Kristina Solomon (E_SPA)
   University of Minnesota OnCore

   b. The “E_SPA” role allows you to search for basic protocol information across all departments without access to patient health information. For more extensive protocol information including patient health information, toggle to your default role “E_ACCT_(MG)”. The “E_ACCT_(MG)” role allows you to search protocols that have your department’s management group added (Protocols > PC Console > Management Tab).

2. Select “Protocol Search” from the “Protocol” tab at the top of the screen.

3. To search by PI, enter a name into the “Staff Name” field and select the role “Principal Investigator” in the “Staff Role” field. NOTE: be sure to check the “Pending” and “Active” boxes to limit your search to active protocols.
Requesting Access:

4. After identifying your protocol through the “Protocol Search”, click on the “Protocol No.” to enter the “PC Console” for that protocol.

5. In the “PC Console” Click on the “Staff” tab to find the “Project Manager”. Contact the “Project Manager” to request access to the study. *NOTE: when you hover over a name, you will be given the telephone number and e-mail address of that individual.*
6. You may request access in two ways:
   a. Request to be added to staff as a **Billing Contact** through the **Staff** tab. **NOTE:** This allows you to receive system e-mails and directs Fairview and UMP to contact you directly with any billing questions.

   b. Request that your management group be added to the protocol through the **Management** tab. **NOTE:** This allows all individuals in your management group to access the protocol.
**UMN Definition of Clinical Trial**

UMN defines a clinical trial as “a prospective, biomedical or behavioral research study of human or animal subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, biologics, treatments, devices, or new ways of using known drugs, biologics, treatments, or devices). Behavioral interventions are intended to prevent or treat an acute or chronic disease or condition.”[1] Pre-clinical research is not considered clinical trial activity.

[1] UMN has adopted a modified NIH definition of clinical trials to track and monitor organizational metrics. However, your trial may be subject to legal or regulatory requirements that may depend on other definitions (e.g., registering your trial and trial results in ClinicalTrials.gov.)

**Procedural Application for Industry Sponsored or Funded Clinical Trials**

For purposes of qualifying for the University-approved reduced indirect cost rate of 26% TDC, a clinical trial must be industry sponsored and/or industry funded and must meet one of the following three conditions:

- Determine the ability of a new drug, device, or biologic to diminish the symptoms, prevent recurrences, or reduce the risk of death from that disease; or
- Test drugs, devices, diagnostics, treatments, interventions, or preventive measures including testing for an unapproved indication; or
- Collect data to increase knowledge that would lead to enhanced safety and efficacy of a specified drug, a disease or device; or

and include one of the following requirements:

- involve contact with humans or animals; or
- be a retrospective review of medical records, clinical data or specimens obtained from contact with subjects.

1 This procedural application does not apply to non-industry funded clinical trials.
2 PI sponsored studies are included.
3 So called “preclinical studies” which test devices on animals for eventual human use do not qualify for the reduced rate. These projects are considered research and must bear full indirect costs.

**UMN F&A Rates**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>52% MTDC</td>
</tr>
<tr>
<td>Federal Clinical Trial</td>
<td>52% MTDC</td>
</tr>
<tr>
<td>Industry Sponsored Clinical Trials</td>
<td>26% TDC</td>
</tr>
<tr>
<td>PI Initiated Industry-Funded Clinical Trials</td>
<td>26% TDC</td>
</tr>
</tbody>
</table>
Description

TASCS is a database tool developed to help support and manage the process of compliant clinical research budgeting and billing across the University’s Academic Health Center, UMPhysicians, and Fairview Health Services.

It tracks the participation of each individual from the time they sign an initial consent form until they withdraw or the research is complete.

It can also be used in budget preparation to get Fairview and UMPhysicians research prices.

Currently, only research involving the use of Fairview or UMPhysicians services must be entered into TASCS.

Roles & Responsibilities

Every project entered into TASCS has three roles identified: Investigator, Protocol Contact and Billing Contact. The following are general descriptions of their duties:

Investigator - The Investigator enters clinical research information for each clinical research protocol into TASCS or may delegate this function.

Protocol Contact/Research Coordinator - Enters clinical research information for each protocol into TASCS if the Investigator has delegated that function to the Protocol Contact/Research Coordinator.

Billing Contact/Administrator - The Billing Contact/Administrator assists with purchase order preparation based on the budget. Monitors and reviews reports in TASCS as a tool to assist ongoing account management.

Access

Prospective users must complete training and submit a TASCS Access Application Form. A supervisor’s signature is required, except for investigators. Access is granted based on DeptIDs, which can be added and deleted as needed. Contact TASCS Support for training dates at tascs@umn.edu.

More Information

Details of how TASCS works and how it is used are explained in the TASCS User Manual which can be found on CTSI’s website http://www.ctsi.umn.edu/sites/default/files/TASCS_User_Manual_11132015.pdf
Useful Reports in Tascs

The TACS Home page

TASCS Support
email: tascs@umn.edu
phone: 612.626.4612

Recent Changes

01/05/16 - TACS will be down between 6 a.m. Saturday, Jan. 9 and noon Sunday, Jan. 10, due to maintenance on the University’s primary data center.

12/09/15 - There was a brief interruption of functionality for Google Chrome users in the accessibility of TACS menus due to compatibility issues with Google's stable release of Chrome browser v.47.0.2526.80. If you are using Google Chrome as your primary browser, and experience this interruption please clear your browser history/cache. A step-by-step reference guide can be found here: [http://it.umn.edu/how-clear-cache-cookies-in-chrome](http://it.umn.edu/how-clear-cache-cookies-in-chrome).

11/16/15 - The TACS URL has been updated. Please update any bookmarks you may have saved in your internet browser to [https://secure.ahc.umn.edu/tascs](https://secure.ahc.umn.edu/tascs).

Subject Tracking Form: Can be used to monitor patient enrollment and progress through the Study. This information is important for billing the Sponsor for enrollment.

Research Pricing: Is useful for reconciling Fairview or UMP invoices for patient visits. This report will list the current rates for Study procedures and services that are to be paid by the Study Sponsor. Note Fairview updates the research prices in TACS twice a year, in January and July.
Billing Grid: Is useful for reconciling Fairview or UMP Invoices for patient visits. This report will list all the Protocol procedures/services by Study Visit Date and will indicate if the procedure or services is to be billed to Medical Insurance (denoted by “Ins.”) or Research, “R” (study Sponsor). “O” indicates No Charge generated at Fairview or UMP.

Active Study Report: Can be used to identify all the active Protocols a given Faculty member has open. The report will also list relevant study information, such as PI, Protocol #, Epic # (Fairview) and subject activity.

Additional Resources

SOP supplemental – TASCS Workflow – Pre Award

SOP supplemental – TASCS Workflow – Post Award
Description

When purchasing UMP Staff time (Nurse, Social Worker, UMP Only Clinician) for a Research Project, certain administrative steps need to take place to setup a proper agreement. UMP is a separate legal entity from the University of Minnesota and normal CPS/PO procedures should be followed. However, UMP has an exclusion from the U of M’s “Purchasing a Professional Service” as there is a Master Agreement in place.

See Policy Library [http://policy.umn.edu/finance/professionalservice](http://policy.umn.edu/finance/professionalservice)

For a Contract under $50,000, normal QCPS process: Complete requisition in EFS and attached PSIS. No signature required

For a Contract over $50,000, complete CPS requisition in EFS. Attached PSIS and Exception to bid with Section C line 13 checked. Central will obtain signatures to execute the CPS.

Contacts for questions:

**UMP Contracting**
**Carrie Tichey**  
*Senior Director of Payer Relations and Contracting*  
612-884-0357  
Cticheyk10@umphysicians.umn.edu

**U of M Purchasing**
Jerry Taintor  
Purchasing Services  
Taint001@umn.edu  
612-525-8579