Purchasing & Using Fairview and UMPhysicians Resources

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Objectives

- Identify Fairview and UMPhysicians resources
- Explain the rationale for distinguishing research from standard of care services
- Describe purpose and proper use of: E-Form, Flowcast and patient case numbers, and encounter forms
- Identify contacts
What are the Resources?

**Fairview**
- Laboratory services
- Investigational Drug Services (IDS)
- Ancillary services: radiology, electro-cardiography, clinics, operating room, etc.
- Personnel

**UMPhysicians**
- Oncology Clinic
- Imaging Center
- Professional Fees
- Personnel
Standard of Care vs. Research

Critical exercise to delineate between standard of care and protocol driven services

- “Standard of Care” or “SOC” means any test, visit or procedure that would have occurred irrespective of study participation.
- “Protocol Driven” means its required for the study and would not have happened in the usual course of care.

*Billing grid is a helpful tool*
Sample Billing Grid

<table>
<thead>
<tr>
<th>Protocol Requirements</th>
<th>Screening</th>
<th>Baseline</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>History &amp; Physical</td>
<td>I</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Consent</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinic Visit</td>
<td>I</td>
<td>S</td>
<td>S</td>
<td>I</td>
<td>S</td>
</tr>
<tr>
<td>Chemistries</td>
<td>I</td>
<td>S</td>
<td>I</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>Pregnancy Test</td>
<td>I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematology</td>
<td>I</td>
<td>S</td>
<td>I</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>PK collection</td>
<td></td>
<td>S</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PK analysis</td>
<td></td>
<td></td>
<td></td>
<td>NC</td>
<td></td>
</tr>
<tr>
<td>ECG</td>
<td>I</td>
<td>S</td>
<td></td>
<td></td>
<td>S</td>
</tr>
<tr>
<td>Quality of Life</td>
<td></td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Drug Admin</td>
<td></td>
<td>I</td>
<td>I</td>
<td>I</td>
<td></td>
</tr>
</tbody>
</table>

I – Insurance, S – Study, NC – No charge or not performed at Fairview or UMP

*Budget template located on OCR website under “Researcher Toolbox”
http://www.ahc.umn.edu/ocr/home.html*
Considerations....

Differentiating between SOC and protocol services will help to:

- Identify services that need to be included in the study budget
- Match contract and consent language (e.g., Cost Section)
- Correctly establish study billing accounts (Encounter Forms, Lab Request Slips, Patient Case #s)
Purchasing Services

Two methods to purchase services:
- Institutional or billing account for lab, IDS, clinic or ancillary services
- Subcontract (mostly used to hire personnel)
Cost of Services

Request pricing information or a Statement of Intent via Fairview’s research e-form.

Information available at [www.fairview/research.org](http://www.fairview/research.org) (under “Forms”)

1. Use pricing information to complete budget and negotiate with sponsors
2. Include E-Form price quote or Statement of Intent in PRF package submitted to SPA
   - *May reference E-Form number directly on PRF*
Welcome to Fairview’s Research Request Form

Please read the instructions below on how to enter and submit your research request form. For detailed instructions click on the Instruction button.

Navigating in the Research Request Form

The research request form will guide you through a series of screens.

- To navigate between the screens you will click 'Next'.
- To return to a screen click 'Previous'.

How to Save an incomplete request

If you need to save the form for completion at a later time you may click the button Exit and Save Form. This will save the form in the e-forms tool. To retrieve your form for update click the Instructions button for detailed instructions.

How to Submit your request

When you have completed the entry of your request click the button 'Submit to Reseach'.

- Once you have clicked the 'Submit to Research' button the form will redisplay the data you entered in a single form where it will be edited to ensure you have completed all required fields.
- If you have missed a field it will provide you an error message.
- Once all required fields have been met your request will be submitted to Fairview’s Research office.

How to Cancel your request

If you want to cancel the request you have started or not save changes you have made to an existing form, click 'Cancel'. This will close a saved form or delete a new form.

For more detailed help click on the Instructions button located on each page of the form.
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there standard of care services that require pricing for this research?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are lab services needed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the research involve the use of a drug?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will radiology/imaging services be used for research purposes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does study protocol require an ECG for research purposes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will other tests and/or procedures be required for research purposes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are clinic services needed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does research require admission to the hospital or GCRC?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are surgical services required for research purposes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will you be asking FV personnel to perform work specifically for research purposes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is Fairview being asked to purchase special equipment or supplies from study sponsor or other vendor not already described in previous sections?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
RESEARCH PRICE QUOTE FOR FAIRVIEW SERVICES

Listed below is the research price quote for the requested protocol services.

The quote will be honored for the life of the protocol with the addition of any applicable inflation factors (e.g., 5% for patient care services excluding labs, 10% for lab work and pharmacy charges) Inflation factors for all services, except labor, are effective January 1st of each year (inflates labor May 1 of each year) and will be applied to the research billing at the time services are rendered.

Once funding is awarded, contact Research Administration for assistance in establishing your Fairview accounts. Please remember to update your research accounts if the protocol services change over the course of the study.

QUESTIONS?
Contact Research Administration: phone: 612-672-7690
fax: 612-672-7691
email: amorris1@fairview.org.
# Research Pricing

Research Request 00000000 – Study Title  
Principal Investigator: Dr. Research

<table>
<thead>
<tr>
<th>Department Name</th>
<th>Service Master Desc</th>
<th>Service Code</th>
<th>Service Master Price</th>
<th>Research Rate</th>
<th>Research Price</th>
<th>Professional Fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>4112 ELECTROCARDIOLOGY</td>
<td>EKG 12 LEAD (TRACING ONLY)</td>
<td>08010266</td>
<td>$145.00</td>
<td>24.30%</td>
<td>$35.23</td>
<td>$0.00</td>
</tr>
<tr>
<td>4066 Send Out Lab</td>
<td>OE Order Entry</td>
<td>7203532</td>
<td>$0.00</td>
<td>0.00%</td>
<td>$3.82</td>
<td>$0.00</td>
</tr>
<tr>
<td>4066 Send Out Lab</td>
<td>OPKG1 Package 1</td>
<td>7203524</td>
<td>$0.00</td>
<td>0.00%</td>
<td>$7.03</td>
<td>$0.00</td>
</tr>
<tr>
<td>4071 Lab Acute Care</td>
<td>OSS2 Spin and Save 2</td>
<td>7300106</td>
<td>$0.00</td>
<td>0.00%</td>
<td>$8.24</td>
<td>$0.00</td>
</tr>
<tr>
<td>4071 Lab Acute Care</td>
<td>OVP2 Venipuncture</td>
<td>7092133</td>
<td>$0.00</td>
<td>0.00%</td>
<td>$12.60</td>
<td>$0.00</td>
</tr>
<tr>
<td>IDS</td>
<td>Start-up</td>
<td>16085615</td>
<td>$0.00</td>
<td>0.00%</td>
<td>$1,000.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>4143 CT SCAN</td>
<td>CT THORAX W/CONT</td>
<td>12500187</td>
<td>$1,284.00</td>
<td>40.50%</td>
<td>$520.02</td>
<td>$72.00</td>
</tr>
<tr>
<td>4071 Lab Acute Care</td>
<td>HCGS HCG QUAL SERUM</td>
<td>7072085</td>
<td>$0.00</td>
<td>0.00%</td>
<td>$9.98</td>
<td>$0.00</td>
</tr>
<tr>
<td>Oncology Clinic</td>
<td>Chemo, iv infusion, 1 hr</td>
<td>n/a</td>
<td>$0.00</td>
<td>0.00%</td>
<td>$0.00</td>
<td>$192.00</td>
</tr>
</tbody>
</table>
Note

If you requested IDS services, your IDS number will be created and provided with the price quotes.
Congratulations!

You’ve received funding and SPA has established your CUFS account....

What next?
Using Services

- If subcontracting for Fairview services, SPA will automatically generate the contract based on the previously submitted Statement of Intent.
- If establishing an institutional account, obtain a purchase order (P.O.) from your departmental accountant.
Account Set-Up

- Complete a Research Account Request (RAR) form.
  Available on Fairview website or from Research Adm.

- Submit RAR form and P.O. to Research Administration via email or fax

- Research Adm. will create a Fairview institutional account - B#, route to lab for a lab account, and to UMPhysicians for the Flowcast number (as needed)
Numbers, numbers...

- Fairview institutional accounts – B# (B123456789)
- UMPhysicians study account – Flowcast # (123)
- UMPhysicians patient account – Patient Case # (123456)
- Fairview lab account – U# (U1234)
- IDS file – IDS # (0123 or 0123RO)
- MRN – patient specific medical record # (0000234567)
Accounts

- Research Adm. will send an email to the E-Form requester providing account numbers along with the study Encounter Form.
- Fairview Lab will create a study-specific lab request slip and send directly to the E-Form requester.
- Researcher must contact UMPhysicians* to establish individual patient Case numbers prior to using clinic services.

*Contact Kathy Clark at 763-782-6480, kathleenclark@umphysicians.umn.edu
Registration & Scheduling

- All patients require registration – this is a mechanism to uniquely identify the patient, emergency contacts and billing within Fairview and UMPhysicians systems.

- Most service areas require scheduling – this reserves a date/time for the encounter and ties the registration information to the visit.

* See Research User’s Manual, on Fairview website, for more info: http://www.fairview.org/Research/Resources/index.asp*
Scheduling

- If using clinic resources, you must establish a Patient Case number **before** scheduling the appointment.

*No Patient Case number - charges to insurance*

- Tell the scheduler the visit is for research and provide the study name and account numbers (e.g., B#, Flowcast #, Patient Case #)

*If you don’t know the scheduler for a particular area, contact Noreen Seeger at 612-624-2475*

- If scheduling a mixed visit – part research and part clinical care – request two visits.
Use the Forms

- Use the study-specific lab requisition whenever samples should be charged to the research account (not to insurance)
- Use the Encounter Form for all other services when they should be charged to the research account (not to insurance)

If the forms are not used, the charges go on the patient’s account and are sent to insurance.
Study involves intravenous investigational drug, use of commercial drugs, lab tests at 1, 3, 6 & 12 months and clinic visits at the same time points.

The investigational drug is provided free of charge by the sponsor. No further sponsor support is offered as the remaining services are considered standard of care and should be billed to insurance (e.g., drug administration, commercial drugs, labs and clinic visits).

You speak with the PI and determine that lab tests and clinic visits are standard of care at months 3 and 12 only.
Considerations

- Negotiate budget with sponsor to cover cost of 2 clinic visits and lab tests – standard of care often varies by region
  - Draft consent language to clearly indicate that there may be a cost to the patient if they participate
  - Consider checking with patient’s insurance to determine if they will pay for research-related services
  - Use research encounter form and study-specific lab request to direct research charges to study account when applicable
  - Document research activity in medical record
Scenario #2

Study includes use of investigational drug, radiology services, clinic visits and phone follow-ups.

The study sponsor will pay for all study related activity.
Considerations

- If study sponsor will pay for all services, do not try to extend the study money by billing some of the services to insurance.
- Compare the sponsor’s proposed budget to locally developed budget.
- Use encounter form and lab slips for all services.
Scenario #3

Study involves use of implantable investigational device.

Sponsor will provide device free of charge and the remaining services are standard of care.
Considerations

- Please complete e-form for the device even though pricing not needed. This is often the only communication Fairview has regarding investigational devices.

- Document research in the medical record

- If free, hospital needs to adjust charges to insurers

- Insurers may deny entire procedure as research-related

- If not free (e.g., Category B), need to submit documents to local Medicare office for approval
## Fairview & UMPhysicians Research Contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrienne Baranauskas</td>
<td>Fairview Research Adm., Director</td>
<td>612-672-4954</td>
<td><a href="mailto:Abarana1@fairview.org">Abarana1@fairview.org</a></td>
</tr>
<tr>
<td>Kathy Clark</td>
<td>UMPhysicians Business Office</td>
<td>763-782-6480</td>
<td><a href="mailto:Kathleenclark@umphysicians.umn.edu">Kathleenclark@umphysicians.umn.edu</a></td>
</tr>
<tr>
<td>Angie Morris</td>
<td>Fairview Research Adm., Business Sup.</td>
<td>612-672-7667</td>
<td><a href="mailto:Amorris1@fairview.org">Amorris1@fairview.org</a></td>
</tr>
<tr>
<td>Debbi Stockburger</td>
<td>Fairview Research Adm., Subcontracts</td>
<td>612-672-7797</td>
<td><a href="mailto:Dstockb1@fairview.org">Dstockb1@fairview.org</a></td>
</tr>
</tbody>
</table>