Research Revenue Integrity (RRI) – Who we are...

**RRI Pre-Award:** Perform coverage analysis and provide research rates for budgeting of protocol-driven items and services. Confirm that all patient care services have an identified payer source before subject enrollment.

**RRI Post-Award:** Performs detailed analysis of research accounts to ensure all technical and professional services provided under a clinical research study at any UC Irvine location are identified, coded, billed and recharged correctly. Serves as a liaison to study team, Patient Financial Services and Professional Fee Billing Departments for registration and patient billing inquiries.
Begin at the beginning...
### STUDY SCHEDULE

<table>
<thead>
<tr>
<th>Comments/Notes: KEY</th>
<th>Description/Rate Source</th>
<th>Paid for by</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>HS #1</td>
<td>Time &amp; effort</td>
<td>Sponsor or Department</td>
<td>effort, supplies, patient compensation</td>
</tr>
<tr>
<td></td>
<td>Pt. care research rates</td>
<td>Sponsor or Department (recharge)</td>
<td>room fees, tests, procedures, etc.</td>
</tr>
<tr>
<td></td>
<td>Routine patient care cost</td>
<td>Patient/3rd Party Payer</td>
<td>room fees, tests, procedures, etc.</td>
</tr>
<tr>
<td></td>
<td>ICTS service rates</td>
<td>See ICTS website</td>
<td></td>
</tr>
</tbody>
</table>

#### Patient Care

<table>
<thead>
<tr>
<th>Location</th>
<th>CPT Codes</th>
<th>Screening/Baseline (Day -45 to -1)</th>
<th>Week 0</th>
<th>Week 4</th>
<th>Week 8</th>
<th>Week 16</th>
<th>Week 24</th>
<th>End of Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>Visit 2</td>
<td>Visit 3</td>
<td>Visit 4</td>
<td>Visit 5</td>
<td>Visit 6</td>
<td>Visit 7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Informed consent
- Inclusion/Exclusion
- Medical history
- Vital Signs (includes Height & Weight)
- Physical Exam
- CT Scan
- 12-Lead ECG
- Radiograph
- Study Drug Administration
- Pharmacy Dispensing Fee
- Pregnancy Test
- Pharmacokinetics Sampling
- CBC and CMP
- Adverse Events
- Clinic Room Fee
How do you get there?

Steps required to develop a budget:

- **WHO**: Identify who on the study team is performing patient care services
- **WHAT**: Categorize the protocol events (e.g. diagnostic, laboratory, etc.)
- **WHERE**: Service areas: Pharmacy, Radiology, Pathology, Inpatient/Outpatient, Sites of Service
- **WHEN**: Determine the timeframe for patient flow
- **WHY**: Establish the items or services to be paid for by the sponsor in the contract and/or budget exhibit, including any items or services promised in the informed consent form
- **HOW**: Assemble all pertinent patient care costs to drive your budget negotiations
Additional Considerations

1. Sponsor type (i.e. federal, industry, or department funded)

2. Trial type (i.e. drug, device, observational)
   - Oral or IV drug
   - Internal or External device
   - Registry (conventional care)

3. Physician involvement, including specialties

4. Assemble your study documents for collaborative review
Resources

- Investigational Drug Services Pharmacy – Trisha Hufnagel (714) 456-7833/ thufnage@uci.edu

- Radiology Research Services - http://www.radiology.uci.edu/research/
  - Wanda Marfori (714) 456-6617/ wmarfori@uci.edu

- Pathology Services - http://www.pathology.uci.edu/services/
  - Anne Sawyer (714) 456-8975/ asawyers@uci.edu

- Research Revenue Integrity - https://intranet2.ha.uci.edu/CRFA/research01.htm
  - Paula Hilbert (714) 456-3922/ philbert@uci.edu
  - Jennifer Greenlund (714) 456-6760/ jennifg@uci.edu
  - Anya Dang (714) 456-7618/ acoultas@uci.edu

- UC Irvine Health Research Compliance - http://www.ucirvinehealth.org/compliance/research-compliance
Questions?

We are here to help!

Research Revenue Integrity

- Paula Hilbert, RN, BSN, (714) 456-3922
- Email: CoverageAnalysis@uci.edu