AURA Meeting – 05/28/2014
Welcome

Karen Niemeier

Contracts Director, OSP
Website Spotlight

Cherrelle Duncan, MPSA
Assigning a Delegate

• Sometimes, faculty members are unavailable. Delegates can be assigned to act in their stead. Delegates can see and edit proposals the faculty member can see or edit and will get the same notifications as the faculty member does, both email and in the system. This includes the ability to route the application.

• Information on Assigning a Delegate can be found in three locations:
  • Systems & Reporting -> Cayuses424 -> Helpful Information
  • Table of Contents-> Assigning a Delegate
  • Table of Contents-> Cayuse424-> Helpful Information
Committee for the Protection of Human Subjects (CPHS)

Institutional Review Board (IRB) - Billing Procedure

Dr. Sujatha Sridhar, MBBS
Clinical Trials Resource Center (CTRC)
Executive Director Research Compliance, Education, and Support Services
Introduction

- Effective September 1st, 2013 CPHS implemented the following changes to its IRB Review Fee program. IRB Fees are collected based on the following rates for all industry sponsored projects:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Initial Review Fee</td>
<td>$2,600</td>
<td></td>
</tr>
<tr>
<td>Continuing Review Fee</td>
<td>$650</td>
<td></td>
</tr>
<tr>
<td>Admin Fee (Protocols Reviewed by a Commercial IRB)</td>
<td>$1,300</td>
<td></td>
</tr>
</tbody>
</table>

- **Effective September 1st, 2014**, the method of billing IRB fees will be changed from charging departments via Interdepartmental Billing (IB) to directly invoicing the private sponsor.
IRB Billing System

Sponsor Initiated
Project Submitted to
CPHS IRB

Application must contain
sponsor's contact info

Chesapeake (CIRB)
Review

CPHS Review

Initial Review

Continuing Review

Review info sent to iRIS
billing port

CIRB sends invoice to UT
CPHS

CPHS  confirms charges
with PI/Departments

CIRB sends invoice
directly to sponsor*

CIRB sends invoice
to Chesapeake

CPHS forwards invoice
to department to verify
charges

Invoice will cover CIRB
fees plus CPHS admin fee

Review info sent to iRIS
billing port

CPHS generates invoice in
FMS and invoices the
sponsor

Once charges are
approved, CPHS
generates invoice in FMS
and invoices the sponsor

CPHS generates invoice in
FMS and invoices the
sponsor

Sponsor process payment
to Chesapeake
Roles and Responsibilities:

- **CPHS Billing Office:**
  
  - Work with the individual departments and the IRB Office (iRIS) to determine who needs to be charged IRB fees for initial and annual reviews.
  
  - Invoice the Industry sponsor directly for IRB review fees. All invoices will be sent to the sponsor contact listed on iRIS and copied to the study team contacts at UT Health.

  - For existing research, CPHS billing department will contact the study team to obtain sponsor contact information and billing/invoicing status. All invoices will be sent to the following individuals:
    - Sponsor
    - PI
    - Project Clinical Research Coordinators (based on iRIS study contact information)

  - Assist PIs/Departments to collect outstanding payments for projects that were set up prior to September 1st 2014.
Roles and Responsibilities:

- **PI/Departments:**
  
  - Ensure appropriate terms relating to payment of IRB fees within the CTA.
    - IRB fees must be indicated as being billed directly by the IRB office
    - should be included as separated line items in the budget
    - should not be incorporated as part of any Study Startup costs
  
  - Enter accurate sponsor contact information in the IRB application for invoicing.
    - Keep CPHS informed of any changes to the contact information.
Roles and Responsibilities:

• PI/Departments:
  - Responsible for covering the costs of IRB review fees not included in CTA or and budget.
  - Report IRB payments erroneously deposited into the clinical research study’s account rather than deposited to the IRB account.
    - A valid CFS must be provided to the IRB Billing Department so that a journal entry can be processed to recover funds.
  - IRB fees are not contingent upon a signed executed Clinical Trial Agreement. IRB fees are not assessed overhead and therefore should not be invoiced for or combined/co-mingled with clinical activity payments.
Commercial IRB

- Try to work with sponsor to have Chesapeake invoice them directly.
- If UTHealth is responsible for payment and reimbursement from sponsor, when CPHS billing department receives invoices from Chesapeake, the PI/Department is contacted for review and verification of charges.
  - After charges are confirmed, the IRB billing department processes the payment to Chesapeake. CPHS generates an invoice for reimbursement.
Next steps

- Starting Sep 1, 2014 – for all new submissions, CPHS billing office will invoice sponsor directly for IRB fees.
- For existing research and during the transition to CPHS’s new billing procedure, the CPHS billing department will continue the practice of sending all invoices to the study team to request IRB fees billing/invoicing status.
- Once PI and/or coordinator receives and approves the invoice, he/she should send an email back to the IRB billing department with the approval to bill sponsors along with sponsor’s contact information.
- The deadline to send email with invoice approval and authorization is 15 days after the invoice has been received.
- After the 15th day deadline, authorization and approval will be assumed and invoice will be sent to the sponsor.
Next steps – Pending Payments

- CPHS billing office will generate invoices for pending payments going back to 2011 (for Active Industry-Sponsored studies).
  - CPHS will work with the departments to try to collect the fees from the sponsor.
  - If the sponsor declines payment the IRB office may waive the fees.
  - Documentation of any waiver or alteration of the IRB fee(s) will be noted in the study record.
Contact information

Dr. Sujatha Sridhar, MBBS
Clinical Trials Resource Center (CTRC)
Executive Director
Sujatha.Sridhar@uth.tmc.edu

Cristina Dyke, BA
CRU and CPHS
Administrative Services Officer I
Myriam.C.Dyke@uth.tmc.edu
713-704-5803

Cynthia Edmonds, MLA
Committee For the Protection of Human Subjects
IRB Director
Cynthia.L.Edmonds@uth.tmc.edu
FEDERAL REVENUE
TRANSITION FROM G TO P

Victoria Briscoe
Assistant Director, Post Award Finance
G Method

Request for Payment

Account Number: 8491G
DUNS: 800771594

Person Requesting Funds:
☐ Check here if information shown is correct; otherwise, please update.

First Name: Victoria
Initial: S
Last Name: Briscoe
Area Code: 713
Phone No.: 500 - 4940
Ext.: 
E-Mail Address: Victoria.S.Briscoe@uth.tmc.edu

Payment Due Date: 04/28/2014
Expected Disbursement Amount $: 0
Cash on Hand $: -3888444.57
Payment Request Amount $: 3888444.57

Continue
Clear
Cancel

Return To Menu
New P Method

Account Number: 8491P
DUUNS: 800771594 - ___

Name: Victoria S Briscoe
(713) 500-4927 Ext: ___
E-Mail Address: Victoria.S.Briscoe@uth.tmc.edu

Payment Due Date: 05/28/2014
Payment Request Amount: $3,888,444.57

SubAmount | Cancel
### New P Method

**Account Number:** 8491P  
**DUNS:** 800771594 - ___  
**Name:** Victoria S Briscoe  
(713) 500-4927 Ext. ___  
**E-Mail Address:** Victoria.S.Briscoe@uth.tmc.edu  
**Payment Due Date:** 05/28/2014  
**Payment Request Amount:** $3,888,444.57

<table>
<thead>
<tr>
<th>Subaccount</th>
<th>Bank Account</th>
<th>Unexpired Funds (A)</th>
<th>Expired Funds (B)</th>
<th>In-Transit Payments (C)</th>
<th>Total Funds (A+B-C)</th>
<th>Subacct Amt Requested $</th>
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Effort Reporting Update

Farrah Adegbite
Systems & Reporting Specialist
Effort Reporting Dates

- Pre-Review Period: July 7-20
- Certification Period: July 21-August 21
- Travel restrictions on uncertified cards August 25
Effort Reporting Reminders

- Please review all cards for accuracy
- Initiate any Personnel Actions, if needed
- Place incorrect cards on hold until fixed
- Guides and forms on Effort website
  go.uth.edu/effort
Effort Reporting Upgrade

- ecrt® will change from 3.0.3 to 4.5
- Improved usability for faculty & coordinators
- Trainings scheduled for June at each school for faculty and coordinators
- Notifications and more info soon
Updates

NIH resubmissions, Cayuse424/ASSIST, & Multiple PI Leadership Plan

Krystal Toups, CRA

Director, Grants
NIH & AHRQ Resubmissions

• NOT-OD-14-074 & NOT-OD-14-082
  
  

• For application due dates after April 16, 2014, following an unsuccessful resubmission (A1) application, applicants may submit the same idea as a new (A0) application for the next appropriate due date.

• The NIH and AHRQ will not assess the similarity of the science in the new (A0) application to any previously reviewed submission when accepting an application for review.

• The updated policy applies to major types of applications and activity codes.
As of April 29th, Cayuse424 supports Multi Project Applications

- P-series
- G12
- U19, U24, U10, U41, U42, U45, U56, UC7, U54, and UM1
- R24 & R28
- S06

Multiple PI Leadership Plan

Multi PI Leadership Plan Template (version# OSP41814)

- Created a separate Signature Page
- Minor changes to the language in sections (9) – (11)

Added new Multi PI application question to the R&A form

12) Is this a Multiple PD/PI application? (For NIH applications and as required by other agency’s FOA [ex. CDC & etc.] a Leadership Plan is required.)

☐ Yes  ☐ No  ☐ N/A
Clinical Research Finance

Team Members:
Heather Cody, 713-500-3983
Amaris Ogu, 713-500-3984

Email: grp-crf@uthouston.edu
CRF - Services

**Expense analysis** – Detailed breakdown of expenses applied to clinical research projects.

**Payment analysis** – Reconciliation of sponsor invoicing and payment receipts, including verification of bill and receipt of non-patient care contracted fees.

**Review of final account closeout** – Review, approve, and process project closeout requests.

**FMS Guidance** – FMS support and report/query recommendations for clinical research support staff.

*Future Services*
- Contract budget and payment terms review
- Coverage analysis review
- Third party payor review
Gifts vs. Grants

Jodi S. Ogden, MBA, CRA
Associate Vice President
Gift / Grant Determination

US or international governmental agency funding at the federal, state or local level – never treated as gifts.

Individual, corporate, or foundation funding – gift vs. grant distinction is based on the nature of the proposal, statement of work, and/or other terms of the agreement, and donor/sponsor intent.

Donors sometimes confuse the classification issue of “gift” and “grant”.

Careful consideration of the supporting documentation is critical in determining donor/sponsor intent.
Gift / Grant Determination

Private funding generally falls into one of two categories:

Philanthropic Gifts:
- Voluntary, non-reciprocal transfer of money or property from a donor to an institution.
- Donor may be an individual, a foundation, a corporation, or another non-profit organization.
- Donor does not expect anything of “value” in return and cedes control of the gift, though may restrict the use of the gift.

Sponsored Funds / Grants:
- Principal purpose is to transfer money, property, services or anything of value to a recipient in order to accomplish a public purpose.
- Generally no substantial involvement between the sponsor and recipient during the performance of the activity.
## Gift / Grant Determination

<table>
<thead>
<tr>
<th>Category of Indicator</th>
<th>Factor generally indicates a “Gift”</th>
<th>Factor generally indicates a “Grant”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposal Process</td>
<td>Generally results from a series of interactions between a donor (an individual, corporation, or foundation) and a member of the Development team, possibly with a faculty member, and is prepared and submitted by the Development Officer</td>
<td>Generally, prepared and submitted by a Principal Investigator.</td>
</tr>
<tr>
<td>Purpose</td>
<td>While the support may be accompanied by an agreement that restricts the use of the funds for a specific purpose, there are usually few other terms or conditions associated with the support.</td>
<td>The project commits the University to a specific line of scholarly or scientific inquiry, typically documented by a research plan or a statement of work.</td>
</tr>
<tr>
<td>Specific Start and End Dates</td>
<td>Typically no. However, donors may support annually funded scholarships, fellowships, etc. which generally have specific start and end dates.</td>
<td>Generally, yes.</td>
</tr>
</tbody>
</table>
# Gift / Grant Determination

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</thead>
<tbody>
<tr>
<td>Mission of and Benefit to Resource Provider (i.e. donor of a gift or sponsor of a grant.)</td>
<td>Funding is directly related to the university’s mission while only indirectly related to the resource provider’s business.</td>
<td>Funding is directly related to the recipient’s mission and often directly related to the resource provider’s mission/business activities.</td>
</tr>
<tr>
<td>Scope of Work</td>
<td>The donor typically wishes to support the broad goal of an activity rather than delineating a specific course of action.</td>
<td>A specific commitment is made regarding the level of personnel effort or specific milestones.</td>
</tr>
<tr>
<td>Cost and Budget Information</td>
<td>Line item budgets are generally not required; however, general budgets which outline categories of support may be included as part of the proposal process and/or the gift agreement. Donor typically will not pay indirect costs.</td>
<td>Line item budgets are generally required. Indirect costs are included in the budget.</td>
</tr>
</tbody>
</table>
# Gift / Grant Determination

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Award Terms and Conditions</td>
<td>The donor may request information related to the use of funds but places few or no restriction on review of results before they are made publicly available.</td>
<td>Award includes conditions for specific formal fiscal reports/audits and or invoicing.</td>
</tr>
<tr>
<td>Tax Implications</td>
<td>Qualifies for tax treatment as a charitable contribution by the donor.</td>
<td>May qualify for basic research tax credit for sponsor.</td>
</tr>
<tr>
<td>Progress Reports</td>
<td>Investigators may provide updates on research progress and/or discoveries; these may or may not be a condition of the award.</td>
<td>Programmatic reports are generally required at the award or agency level.</td>
</tr>
<tr>
<td>Financial Reports</td>
<td>Financial reports are limited to details of how, when, and to whom funds were disbursed as well as statement of earnings when applicable.</td>
<td>Financial reporting often requires detailed line item expense reporting, and is often subject to financial audit.</td>
</tr>
<tr>
<td>Unspent Funds</td>
<td>Immaterial residual gift funds generally do not have to be returned to the donor.</td>
<td>The sponsor may require that unspent funds be returned.</td>
</tr>
</tbody>
</table>
Hot Topics

Jodi S. Ogden, MBA, CRA
Associate Vice President
F&A Rate Agreement

- New agreement is expected to be finalized by the end of FY14
- Change in the way we process On and Off campus rates
  - The rate will either be On campus or Off campus, but not both
    - > 51% of the performance will determined if it’s the On or Off campus rate
  - Off campus will only be used if rent in charged to the project
Thank you!

Next meeting

July 23rd

10:00 – 11:30