Agenda

- Research Administration Announcements
- New COI Policy: Update
- Industry Initiated Clinical Research: Pre-Award
  - Pre-Award Overview
  - IRB Basics for the Administrator
  - Prospective Reimbursement Analysis Compliance Perspective
  - Clinical Trial Agreement Negotiation: Subject Injury Clauses
  - Clinical Research from a Contracting Perspective
  - Q&A
RA Announcements

- Google Search Boxes

- ORA Events Calendar

- Research Administration
REVISED EMORY POLICY 7.7
MANAGING FINANCIAL INTERESTS RELATED TO RESEARCH

Brenda Seiton
Asst. VP Research Administration
May 17, 2012
New PHS Regulations – Major Changes

- Lower threshold for reporting and review of financial interests
  - $5,000 annually aggregated – remuneration, royalties & publicly traded equity
  - Zero threshold for privately traded equity/ownership
  - Includes income from non-profits (Professional societies, international institutions) for seminars, lectures, etc.
    - Excludes income from US government sources
    - Excludes US academic, medical, or research institutions
- Sponsored travel must be reported
  - Excludes government sources
  - Excludes US academic, medical, or research institutions
New PHS Regulations (con’t.)

- **Change in Responsibilities**
  - Investigators must report all financial interests related to Institutional Responsibilities & update within 30 days
    - Consulting already covered by Faculty Handbook
    - New: Investments, honoraria, and sponsored travel
    - Institution determines which are related to a specific project

- **Wider Scope** – includes training, fellowship, construction, and conference grant proposals

- **Subrecipient Monitoring**

- **Detailed Reporting to Funding Agency**

- **Public Reporting of Investigators (including subs) with FCOI**

- **Mandatory Training for all Investigators**

- **Retrospective Review for non-compliance with policy or management plan**
Impact at Emory-PHS Investigators

Schools & Units FY2011 – all PHS funded Investigators

- SOM: 835
- EC: 55
- Grad: 24
- RSPH: 143
- Yerkes: 78
- SON: 33
- Other: 12
Implementation of Regulations at Emory

- One Policy – same thresholds but disclosure of sponsored travel will not required for non-PHS activities
- Different Forms for annual and transactional disclosure
- Training: included in eCOI system
- All Significant Financial Interests will undergo institutional review and management plans issued as needed
  - Three review levels: Administrative, Expedited, Full Committee
- Quality Assurance review for awarded grants
- Determination of “Financial Conflict of Interest” will be made only for PHS & NSF
- Public Reporting only for PHS awards
- SBIR/STTR Phase I and GRA awards exempt from disclosure requirements
- Subrecipient oversight only for PHS awards
WE NEED YOU

- Beta Testers needed in June
- Please contact us if interested, and we can send you the link for testing:
  - COI-OFFICE@LISTSERV.CC.EMORY.EDU
Industry Initiated Clinical Research

Pre-Award
Presentations

- Pre-Award Overview
- IRB Basics for the Administrator
- Prospective Reimbursement Analysis
  Compliance Perspective
- Subject Injury Option
- Clinical Research from a Contracting Perspective
Industry Initiated CT Process

Documents needed in EPEX before OSP can sign a contract:
- OCR Budget Approval
- SOM Approval
- COI Summary Sheet
- IRB Approval

OSP Contract Signed

OSP

IRB Approval

eIRB

eIRB Protocol

COI Management Plan

COI Summary Sheet

eCOI

Individual Financial Interests Report

PI Certifies

Dept/Ctr Approval

PI/Admin

Dept/Ctr Approval

SOM

OCR

OSP Negotiation Begins

Subject Injury Option (generated by OSP Contracts)
Say ‘Yes’ to Question 15!!!

PRIOR to hitting the button.

Why?

- EPEX automatically initiates the workflow to OSP and OCR at the same time. If this does not occur, the negotiation of the contract WILL be delayed.

- Indicating ‘Yes’ to Question 15 after the button has been selected will not initiate the workflow correctly.

PLEASE NOTE: At this point, Ad-Hoc’s must be inserted and the process becomes linear.
IRB Basics for the Administrator
Objectives

- Highlight resources to define requirements for human subjects' research
- Identify documents to submit a new study
- Understand the IRB review process
- Recognize PI or Sponsor-Investigator (S-I) responsibilities
- Provide guidance specific to administrators
• Established to protect the rights and welfare of human subjects participating in Emory University research studies
• Emory has 2 IRB committees—one sociobehavioral, and one biomedical (with 7 subcommittees)
• Committees are made up of a diverse group of physicians, scientists, nurses, pharmacists, non-scientists and community members
IRB Roles

- Evaluates risk/benefit ratio
- Approves, disapprove, or require changes to studies
- Continuing reviews (for example, yearly)
- Provides oversight and monitoring (site visits)
- Rarely, may suspend or terminate approval
- Provide education and advice
- Acts as HIPAA Privacy Board for:
  - Patient authorizations for research
  - Waivers
Regulations and Guidelines followed by the IRB

- **Belmont Report, 1979**
  - Three fundamental ethical principles guiding human subjects research:
    - **Respect for persons** (voluntary, informed consent)
    - **Beneficence** (maximize benefits, minimize harm)
    - **Justice** (equitable subject selection, fair distribution of benefits and burdens)
Regulations and Guidelines followed by the IRB

- **OHRP: Office for Human Research Protections**
  - A DHHS agency (not “part of NIH”)
  - Oversees federally-supported human subjects research
  - Grants Federal Wide Assurances (FWAs) to organizations who commit to follow Federal policy
    - Like a “driver’s license” for doing human subjects research with federal support
  - 45 CFR 46 Subpart A (the Common Rule)
  - 45 CFR 46 Subparts B, C, and D (additional protections for vulnerable populations)
    - B: pregnant women/fetuses
    - C: Prisoners
    - D: Children
Regulations and Guidelines followed by the IRB

- **FDA (Food and Drug Administration)**
  - A DHHS agency
  - Oversees research, regardless of funding source, using FDA approved drugs, devices, or biologics, or investigational products used under INDs or IDEs
    - IND: Investigation New Drug application
    - IDE: Investigational Device Exemption
  - 21 CFR 56 (IRBs)
  - 21 CFR 50 (informed consent)
  - Responsibilities of Investigators
Required Training and Certifications: Research Staff

- CITI certification (human subjects protections)
  - Biomedical or Sociobehavioral modules
  - Basic then refresher every 2 years

- eIRB account
  - How-to on our website
  - eIRB training (it’s not very user-friendly)

- HIPAA Privacy training
  - HIPAA Security training if required by the department or role
First Steps for Submission of a New Study

- Prepare documents:
  - Protocol, Lay Summary
  - Consent/Assent forms
  - HIPAA Authorizations
  - Recruitment materials
  - Data & Safety Monitoring Plan
  - Other documents as applicable

For templates and guidelines please go to:
http://www.irb.emory.edu/researchers/formstools/formstools.cfm
Data Monitoring

- Important to consider when working on study budgets
- The IRB requires a data monitoring plan for all studies that are more than minimal risk, which may require:
  - Data & Safety Monitoring Board or Committee (DSMB, DSMC, DMC)
  - Medical monitor
  - Quarterly study monitoring by a contract research organization (CRO) or self-auditing
IRB Review Process

Meeting: review, discussion, vote

- Defer
- Pending Approval
- Approve
- Table
- Disapprove

**Note:** No HSR activities before getting your final approval in hand!
Also, check with OSP and OCR

Exception: physicians should treat patients
• The Office of Quality at EHC has two initiatives to help drive patient safety and help study teams get ready before they start a trial:
  ○ Clinical Research Readiness Checklist must be complete
    ✷ Laura Deane of OoQ will email the team and the IRB when complete
    ✷ Laura Deane issues exemptions (not the IRB)
    ✷ If these are missing, the IRB can still approve the study but we will NOT release stamped ICF and HIPAA forms until the items are in place or an exception is granted.
  ○ Key Points Summary
Study Funding

- IRB needs information for each funding source for the research project
- The federal grant document (if applicable) needs to be uploaded
  - TIP: Be sure to include this information, even in draft state, so that it doesn’t hold up review!
Study Funding

• The IRB needs the current copy of the federal grant to match the consent documents. **We do not need the eNOA**
• In case of questions regarding the budget or contract process, please contact the Office of Clinical Research and/or the Office of Sponsored Programs
• Note: There is active communication between OSP, OCR, and the IRB during the review phase
Investigator Responsibilities in Research

Include the following:

- Define who is engaged in the research
- Train study staff
- Disclose conflicts of interest (all study staff)
- Assure study staff are competent and licensed
- Conduct research in accordance with the Belmont Report, Federal regulations, IRB P&Ps, GCP (as applicable)
- Ensure adequate informed consent
- Ensure compliance with the IRB-approved protocol
- Track and trend adverse events
- Monitor literature
- Data monitoring
- IRB submissions, reports to sponsors and FDA
- Effort reporting and budgets
- Ensure paperwork is complete!

Ultimate responsibility rests with PI!
Sponsor-Investigators

- FDA-regulated clinical trial where the Emory PI is the IND/IDE holder
- Study responsibilities at Emory and other sites
- Be aware of cost associated with multi-site studies (i.e.; Monitoring)
- For guidance, please contact Margaret Huber with ORC

Responsibilities are huge!
Western IRB

- The largest IRB in the world
- Commercial IRB
- Benefits to sponsors leading multisite trials
- WIRB-eligible studies per Emory-WIRB agreement: Phase III, industry-designed, initiated, and sponsored
- Form A and B to Emory IRB, then we will send the packet to WIRB
Important Considerations for Administrators

• **PI transfers:**
  - Ensure that PI information is changed in e-IRB
  - Alert the sponsor BEFORE the PI leaves Emory. Alert OCR, OSP, and the FDA (if applicable)
  - Make sure there is a back up plan to ensure a smooth transition
  - Consider budget issues (i.e.; PI takes grant)

• **Coordinators vs. Resident/Fellows:**
  - Awareness of appropriate functions
  - Completed required training
  - Have adequate time to focus on responsibilities
Important Considerations for Administrators

• Determine who is responsible for regulatory submissions, including reportable events

• Make sure your department has provisions to ensure study is going according to plan:
  ○ Ongoing budget review
  ○ Internal monitoring
  ○ SOP’s for conducting clinical trials
Important Considerations for Administrators

- Robust orientation process for study team members:
  - e-IRB access
  - CITI certification
  - HIPAA training

- Consider the following before approving/reviewing new study proposals:
  - Do you have qualified personnel: CRCs, PI expertise, etc.
  - Budget limitations vs. PI expectations
  - Study responsibilities: Is PI aware of time commitments?
  - Review of new submission before going to IRB
    - Considered resources required to conduct the study
    - Internal review of proposal (ex. CTRC in WCI)
How to Contact us

- Ask questions! We are here to help.
  - Call us at (404) 712-0720
  - Email us at irb@emory.edu
  - Come to Helpdesk on Fridays 11 AM -1 PM
  - Make an appointment with staff
  - Log comments in eIRB
Want hands on Training?

- Maria G. Davila
  (404)712-0724 or maria.davila@emory.edu
- Shara Karlebach
  (404)712-0727 or shara.karlebach@emory.edu
- Martha Copplestone
  (404)712-0736 or martha.copplestone@emory.edu
Clinical Research at Emory

Prospective Reimbursement Analysis
Compliance Perspective

Sheila O’Neal, RN, CCRC
Clinical Research Finance Supervisor
Office for Clinical Research, Pre-Award
Prospective Reimbursement Analysis (PRA)

- Foundation for research billing compliance
- Review of study documents to determine which services are billable to third party payers.
- Any study which has billable items or services which could incorrectly be billed to third party payers needs a PRA – Dean’s mandate 6/11/2007
- Based upon Medicare guidelines—National Coverage Determinations (NCDs) & local coverage determinations (LCDs).
Pre-Award Development of PRA

- The CRC should submit to the listserv (www.ocr.emory.edu) or through EPEX concurrently with IRB submission

- Required documents for PRA:
  - eIRB number
  - Protocol
  - Draft CTA
  - Draft budget
  - Draft informed consent document
  - Request for PRA and Budget Development Form
  - IND/IDE documentation
  - PI effort form for all PIs
  - EPEX submission – check “YES” to question #15
    - See decision tree for guidance
The PRA

Pre-Award Development of PRA

- Determine if qualifying clinical trial. If not, nothing can be billed to third party payer.

- What is promised free in the consent?

- What is sponsor offering to cover/pay (draft budget/CTA)? Study medication(s), device?

- Research each item and service to determine:
  - If routine care, can bill to third party payers.
  - If not, sponsor needs to pay.
Pre-Award: Development of the PRA

• Work collaboratively with PI, CRC & ancillary depts. to ensure all CPT/CDM driven items & services identified.

• Verify how study operationalized since may impact budget.

• PRA sent to the PI and CRC for review and approval.

• PRA used to develop budget to cover costs.
  – Budget includes:
    • Items to be billed to grant ("S" on PRA)
    • Effort
    • Start-up costs
The PRA

Pre-Award: Development of the PRA

- Study staff must follow PRA for billing purposes for every research patient, regardless of patient’s situation.

- Once the PRA is final, only Pre-Award can change the PRA. Needs changed if:
  - additions or deletions to billable items & services in the protocol or
  - changes to the location where items & services are performed, e.g. central lab vs. EML
The PRA

Proprietary and Confidential
Emory University School of Medicine
Office for Clinical Research

NAME OF PROTOCOL

This Prospective Reimbursement Analysis (PRA) is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, coverage determinations, and federal guidelines. All items and services that are billable to Medicare must be supported by medical necessity. This PRA was prepared by Emory University for its own internal business operations. As such, this PRA does not create or obligate any third party and Emory makes no warranties as to its accuracy. For budgeting purposes, with the exception of investigational devices, the PRA assumes that the Medicare program and commercial insurers will cover at least as much as Medicare covers. Insurance policies vary, however, and there is no guarantee that a commercial insurer will cover or pay for all items/services designated on this PRA as billable to Medicare. Research subjects should be advised to contact their own insurance providers concerning their coverage.

<table>
<thead>
<tr>
<th>Items &amp; Services</th>
<th>Item/Service Location</th>
<th>CPT Code</th>
<th>Enrollment</th>
<th>Pre-Ablation</th>
<th>Ablation Procedure</th>
<th>Pre-Discharge</th>
<th>10 Day Follow Up</th>
<th>3 Month Follow Up</th>
<th>NA</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-Lead EKG</td>
<td>p. 8·, 20, 21, 25, 27, 29, 31, 33, 34</td>
<td>CRH</td>
<td>5</td>
<td>5 (42)</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>The department has their own EKG machine and will perform all protocol required EKG's.</td>
</tr>
<tr>
<td>Transthoracic Echocardiogram</td>
<td>p. 20, 21, 25, 27, 29, 31, 33, 34</td>
<td>2211</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>1,234 Sponsor is covering the cost of this exam at both visits.</td>
</tr>
<tr>
<td>Transesophageal Echocardiogram</td>
<td>p. 29, 57</td>
<td>NA</td>
<td>MOG</td>
<td>MOG</td>
<td>MOG</td>
<td>MOG</td>
<td>MOG</td>
<td>MOG</td>
<td>MOG</td>
<td>A transesophageal echocardiogram (TEE) will be required within 48 hours prior to the ablation procedure for those patients in persistent atrial flutter or those that are in atrial flutter on the day of the procedure, unless they have been adequately anticoagulated with an INR &gt; 2.0 for at least 11 days. If an abnormality suggestive of the presence of a clot is recorded by the TEE, the patient will be classified as an intent patient and appropriately withdrawn from the study with a Patient Status CRF.</td>
</tr>
</tbody>
</table>
The PRA

<table>
<thead>
<tr>
<th>Items &amp; Services</th>
<th>Item/Service Location</th>
<th>CPT Code</th>
<th>Intake Visit</th>
<th>Screening #1</th>
<th>Screening #2</th>
<th>Administration Testing</th>
<th>Admission to CIN*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical exam</td>
<td>p. 10, 11, 16, 17</td>
<td>N/A</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical History/Depression History</td>
<td>p. 10, 11</td>
<td>N/A</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatric exam</td>
<td>p. 11, 12, 17</td>
<td>N/A</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>Neuropsychological Assessments</td>
<td>p. 11, 12, 17</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>hs-CRP</td>
<td>p. 11, 15</td>
<td>85141</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBC with auto diff</td>
<td>p. 11</td>
<td>85025</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comprehensive metabolic panel</td>
<td>p. 11</td>
<td>80053</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANA</td>
<td>p. 11</td>
<td>85038</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EKG</td>
<td>p. 11, 15</td>
<td>93000</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV Ag/Ab</td>
<td>p. 11, 16</td>
<td>86703</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hep B Ag, Hepatitis C ab</td>
<td>p. 11, 10</td>
<td>86803</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thyroid Stimulating Hormone (TSH)</td>
<td>p. 11</td>
<td>84443</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine Drug Test</td>
<td>p. 11</td>
<td>N/A</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine Alcohol Test</td>
<td>p. 11</td>
<td>N/A</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admission/Overnight Stay to EUH CIN</td>
<td>p. 10</td>
<td>N/A</td>
<td></td>
<td>CIN</td>
<td>CIN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meals in CIN</td>
<td>p. 10</td>
<td>N/A</td>
<td>CIN (x1)</td>
<td>CIN (x3)</td>
<td>CIN (x2-3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intravenous Catheter For Blood sampling</td>
<td>p. 10</td>
<td>UNK</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum pregnancy test (vasculature)</td>
<td>p. 10</td>
<td>84703</td>
<td>S/LL</td>
<td>S/LL</td>
<td>S/LL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*This procedure will be performed by the study staff as indicated from the CRC in an e-mail dated 9-28-10. Therefore, no CPT code will be generated.

This will be performed by the research staff.

Psychiatric Exams will be performed by trained study staff.

Neurocognitive tests will be performed by trained study staff.

This item will be paid for by the grant.

These items will be paid for by the grant.

This item will be paid for by the grant.

This procedure will be performed by the study staff as indicated from the CIC in an e-mail dated 9-28-10. Therefore, no CPT code will be generated.

For CIN Letter dated 8/18/10, inpatient rooms will be covered.

These are part of the subjects stay in the CIN.

These are part of the subjects stay in the CIN.

These items will be paid for by the grant.
These are some of the non-billable items the research staff perform not listed in PRA.

This is our legend to define what entity is covering an item/service or where it is tested.

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**The PRA**

<table>
<thead>
<tr>
<th>Item/Service</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum Creatinine</td>
<td>p. 9, 24, 76, 96</td>
</tr>
<tr>
<td>Trans - Telephonic Monitor</td>
<td>p. 16, 25, 36, 56</td>
</tr>
<tr>
<td>Radio Frequency Catheter Ablation</td>
<td>p. 30</td>
</tr>
<tr>
<td>Procedural Data</td>
<td>p. 25, 52, 53</td>
</tr>
<tr>
<td>Anticoagulation Medications</td>
<td>p. 9, 22, 56</td>
</tr>
</tbody>
</table>

*Items/services on protocol schema which are performed by study coordinator and do not require a charge are included but are not included in the following: Informed Consent, Medical History, Demographics, 1 & 6, Aforementioned collection/assessments, questionnaires, and/or performance status (NHRA Classification, Symptom Checklist, and Patient Death Data, if applicable), enrollment assessment, and monitoring/consultant evaluation.*

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**Office for Clinical Research**
What can **YOU** do to facilitate?

- Send study documents to [ocr@emory.edu](mailto:ocr@emory.edu) or route in EPEX. Make sure all required documents are submitted.
  - Be sure to check YES to question #15 in EPEX so it will route automatically to OCR.
- Submit concurrently to IRB, OCR & OSP/EPEX.
- Submit amendments for review if changes in billable items or services.
- Respond timely to questions or requests for PRA or budget approval (within 24-48 hours).
The PRA

What **YOU** can do to facilitate?

- Determine how protocol will be operationalized in department before submission to OCR:
  - Where will the subjects be seen? TEC, MOT, WCI, ER, Grady, research room, CIN, in-patient, CHOA, ECC, etc.
  - Who will be doing which procedures? Are there enough qualified staff to safely conduct study?
  - Are there sufficient potential patients to enroll in the study at Emory? Some studies compete for same patient population.
The PRA

What **YOU** can do to facilitate?

• Verify PI salaries and effort.
  • Must send updated PI effort if not routed by September 1st.

• Notify OCR if know of FDA or sponsor delays.
  • IND/IDE issues, departmental changes or sponsor communications.

• Notify OCR if the PI has changed.
  • Or will have to re-start EPEX submission.
The PRA

For General Information:
Call: 404-778-4960 or
Email us at: ocr@emory.edu or
Go to our web site at:
www.ocr.emory.edu
Clinical Trial Agreement Negotiation

Subject Injury Clauses
Photos of Severe Adverse Reactions Produced by Negotiating Subject Injury Clauses in Clinical Trial Agreements
What’s All the Fuss?
Battle of the Titans

- Medicare/Medicaid
- Research Institution
- Pharmaceutical Company
What Institutions Want

• To limit subject’s exposure to paying for costs associated with subject injury by getting others to pay in a way that doesn’t run afoul of Medicare/Medicaid rules.
What Medicare/Medicaid Wants (Actually, Requires)

• **Medicare Secondary Payer Rule:** Comes into play if Sponsor promises to pay for subject injury.

• **What the Rule Says:** If a clinical trial sponsor pays for subject injury, then Medicare considers the sponsor to be just like an insurance company that is the primary payer for costs associated with the injury. Medicare is a secondary payer only.
  – If sponsor pays for subject injury, it must register with Medicare as a payer.
What Pharmaceutical Companies Want

• To pay for subject injury after the subject’s insurance company has paid:
  – Sponsors want to bill subject injury to Medicare or insurance company first, and then pay only for those expenses that insurance did not cover.

• They want to be the secondary payer too!
Overall Options

• **Option 1:** Sponsor does not pay for subject injury for any subjects – informed consent must advise subject that he/she is responsible for these costs

• **Option 2:** Sponsor can choose to pay for Subject Injury Costs for all subjects. – informed consent must let subject know any requirements for payment, e.g., injury caused directly by drug or device.

• **Option 3:** Sponsor can choose to pay for subject injury for uninsured subjects and subjects with Medicare, but for patients with private insurance, Sponsor can pay only for any subject injury costs not paid for by the subject’s insurer.
Problems We Encounter

• Pharma companies want language that says they will pay only for costs associated with subject injury after subject’s insurance has paid.
  – For Medicare/Medicaid patient this is not permitted.
• Option 3 is difficult to administer.
  – Emory prefers Option 1 or 2.
Document Harmonization

- Clinical trial agreement should state whether or not Sponsor will pay for subject injury.
- Informed consent document must be consistent with clinical trial agreement.
- If sponsor is paying for subject injury, HIPAA authorization and informed consent should make clear that sponsor may require PHI in order to pay for claim.
Can confrontation be avoided?
We Can’t Roll Over On These Clauses
What to Do:

- Let investigators know that if sponsor pays for subject injury, sponsor is primary payer.
- Whatever option is selected, research site must be able to administer it.
  - Tell subjects who to contact in event of patient injury.
  - Have process to make sure bills get to sponsor if appropriate.
  - Include appropriate clauses in informed consent/HIPAA authorization.
Clinical Research: From a Contractual Prospective

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5/17/2011
Clinical Trial Agreement (CTA)

- Most common contractual document governing sponsored clinical research; specifically clinical trials involving: investigational drugs, medical devices and biologics.
Clinical Trial Agreement (CTA)

- Summary of sponsor, Emory and Principal Investigator (PI) obligations for performance of trial.

- Generally executed after a proposed non-disclosure/confidentiality agreement is in place.
  - Emory, on behalf of its employee(s), agrees not to disclose sponsor’s protocol and other proprietary information.
CTA Components

- Reporting, monitoring, and safety obligations:
  - Compliance with Emory’s subject injury and related policies,
  - Emory’s AAHRPP Accreditation,
  - Applicable federal regulations (including FDA, DHHA),
  - IRB, and
  - Sponsor’s requirements.
CTA Components

- **Indemnification**: Shifting legal risk/obligation
  - Hold Emory harmless against manufacturing and/or formulation of study drug/device
  - Assumes Emory acted in accordance with protocol and/or sponsor instructions
  - We specifically reserve our right to deviate from protocol or sponsor instructions for patient safety or medical necessity purposes
Other CTA Components

- **Publication**: Rights and Restrictions
  - Reserve Emory’s/PI’s rights to use and publish study results for its own teaching, research, clinical and publication purposes provided such publication does not breach confidentiality provisions of CTA.
  - Agree to submit proposed publication for sponsor’s review and comment (not edit) to ensure sponsor’s confidential/proprietary info is not in proposed publication.
  - Related to this, we will agree to delay publication of research results for a “reasonable period” after study closes or after database lock.
Some CTA Components

- **Payment Terms:**
  - Inappropriate Incentive?
  - Undue Influence?
Some CTA Components

- We don’t agree to “[p]ayment terms which are conditioned upon a particular research result or tied to successful research outcomes; including payments or other incentives tied to target enrollment numbers or target enrollment accrual timelines; or “finder fees” or any form of bounty for identification of eligible research subjects.”

Source: OSP Clinical Trial/Clinical Research Contract Negotiation/Checklist Manual
Items Required for CTA Execution

- Final OCR Negotiated Budget (via EPEX)
- SOM (school level) Approvals (via EPEX)
- COI Certification Summary (via EPEX)
- IRB Approval (via eIRB)
Master CTAs to date

- Abbott Labs
- Abbott Vascular
- Alpha
- Amgen
- Aptium Oncology
- Bayer Healthcare
- Beckman Coulter
- Biogen Idec
- Bristol Myers Squibb
- Calypso Medical
- Celgene
- CytoDome
- Dupont Pharmaceuticals
- Eli Lilly
- Evalve
- Genzyme
- Guidant
- Hoffman LaRoche
- ImClone
- Medarex
- Medtronic
- Merck
- Millennium
- Moffitt Research Institute
- Novartis
- Novo Nordisk
- Purdue Pharma
- Roche Labs
- Sanofi Adventis
- Schering Corp
- Schering Plough Research Institute
- Seattle Genetics
- Sekisui
- St. Jude Medical

Emory Research A-to-Z
Q&A: All

It's QUESTION TIME!!