THE FUNDAMENTALS OF NON-FEDERAL RESEARCH:
THE GOOD, BAD AND UGLY.

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LEARNING OBJECTIVES:

1. TO BE ABLE TO IDENTIFY THE COMPONENTS OF NON-FEDERAL RESEARCH

2. REVIEW BEST PRE-AWARD PRACTICES TO PREVENT POST-AWARD UGLY
## INDUSTRY/UNIVERSITY PARTNERSHIPS
### MOTIVATION & DIFFERENCES

<table>
<thead>
<tr>
<th>University</th>
<th>Industry</th>
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<tbody>
<tr>
<td><strong>Motivation</strong></td>
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<tr>
<td>• Funding of laboratory including supplies and equipment</td>
<td>• Increased Profits/Return on Investment to Shareholders</td>
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<td>• Funding of graduate students</td>
<td>• Staying Ahead of the Competition</td>
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<td>• Publications</td>
<td>• Professor is the Foremost Authority in the Field</td>
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<td>• Leveraging of industry funds (especially with federal funds)</td>
<td>• Professor salary is lower than industry salary</td>
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<td>• Tenure and promotion</td>
<td>• Labor and Use of University Laboratory facilities is less expensive than operating an industry based R&amp;D facility</td>
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<tr>
<th>Differences</th>
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<tbody>
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<td>• Academic calendar</td>
<td>• Standard calendar year</td>
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<tr>
<td>• Research for the public good</td>
<td>• Product development and ownership</td>
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<td>• Results and reports</td>
<td>• Proprietary/Deliverables/Milestones</td>
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<td>• Dissemination of results</td>
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COMPONENTS OF NON-FEDERAL RESEARCH

Sources of Support
IDENTIFYING SOURCES OF SUPPORT
FUNDING OPPORTUNITIES DATABASE-FOUNDATION CENTER

• Database includes funding opportunities from many sponsors
• Search based on deadlines, keywords, categories, funding type and more
• Includes funding opportunities for students and post docs
• Can search from any computer (after registration on a computer in the Emory network)
• Individual, one-time searches as well as saved searches
• Funding Opportunity Alerts sent via email listing the new or revised funding opportunities that match the criteria of all saved searches.
• You determine frequency of alerts
FUNDING OPPORTUNITIES DATABASE-FOUNDATION CENTER

• A thorough database, comprising more than 140,000 grantmakers, that is updated weekly so you can count on the accuracy of results

• Multiple filters and an assessment tool help you quickly identify your best potential funding sources

• A prospect management platform that automates much of the grantseeking process and stores your data for you
FUNDING OPPORTUNITIES DATABASE-
PROPOSALCENTRAL

- An e-grantmaking website that is shared by many government, non-profit, and private grant-making organizations.
- The site allows you to search for Funding Opportunities and apply through their portal.
Components of Non-Federal Research Mechanisms
Funding Mechanisms

- Grants and Cooperative Agreements
- Contracts
- Gifts

Funding Announcements

- FOA, PA, RFA
- BAA
- RFP, RFQ
- Unsolicited
- Restricted Programs

SPONSORED OPPORTUNITIES
COMPONENTS OF NON-FEDERAL RESEARCH

Basic Components of a Proposal

- Prepare
- Implement, Evaluate, Continue
- Focus on Priorities
- Develop the Project
- Research Funders & Grants
- Write the Proposal

Grant Cycle
BASIC ELEMENTS OF A NON-FEDERAL PROPOSAL

• Sponsor Identifies Institution
• Sponsor driven agenda
• Proposal Development/Industry Procurement
• Ownership IP
• Non-Disclosure Agreement
• Use of Proprietary Data

• Internal Authorization(s)
• Certifications and Representations
• Proposal Readiness
  • Statement of Work: confer with sponsor
  • Budget
  • Milestones
  • Start and End Date
• Proposal Submission
• Contract
What are the typical components of a proposal with a commercial sponsor?

Protocol
Investigators either present concept papers (not fully developed protocols) to a potential funder or they may have developed a protocol in its entirety.

Protocols follow the same format (not an inclusive list):

- Short summary (If a sponsor wants more information than what is in the protocol, they'll ask.)
- History of previous research on that topic and conclusions from previous research
- A hypothesis, supporting material for their hypothesis
- Inclusion/exclusion criteria
- Plan or schedule
- Measure of effect
- Statistical analysis plan
What are the typical components of a proposal with a commercial sponsor?

**Budgets** - Industry sponsored clinical trials have a per-patient budget.

**Investigator Initiated Studies** - In an investigator-initiated study, the prospective budget must include all possible charges for clinical items and administrative items. Typically, those budgets are basically asking for a fixed amount of money, so it is imperative that all charges are identified. It is rare to have an ‘invoiceable item’ type budget where the institution can invoice if something occurs – a scan, a biopsy, a test, an IRB renewal, increases in effort for the PI or other research staff. All of that must be projected upfront or the budget will end up in deficit.

**Industry Initiated** - Alternately, when an industry-sponsored trial comes to an institution the industry sponsor provides a budget and the amounts have to be negotiated. Those trials frequently have invoiceable items with terms. Examples: CT scan of the chest at screening if not standard of care”. Big pharma is typically the biggest sponsor of industry-funded trials and probably industry sponsored research studies as well.
What are the typical components of a proposal with a commercial sponsor?

Clinical Trial Agreements
An NDA is usually established first. Emory's OSP/OTT group does that for investigators, and investigators know to seek this assistance. After protocol approval and during budget negotiation, contract terms that delineate publishing, patents, proprietary info—all of that is included in contract language and ironed out between Emory (or other entity) and the funder.

Some major things we watch out for in a research contract are:
- The ability for the Institution to use the results of the study for internal noncommercial (research and education) purposes;
- Payment terms;
- Making sure we’re not agreeing to keep sponsors’ information confidential indefinitely (we have to put a cap on it, 5-10 years);
- The duty of the Sponsor to notify the Institution in the event they learn of adverse events in their monitoring of the study so that we can alert the patients and the IRB (in keeping with our AAHRPP accreditation);
- Making sure the sponsor isn’t unreasonably attempting to limit their liability in the contract; patient information protection; and
- Overall compliance with the law.
IMPORTANT CONTRACTING ISSUES

- **Amendments, ‘no-cost extensions’** – any change in terms to the contract (contractual obligation, PI, agency name, term, budget, scope of work, etc.)

- **Signature authority** – Emory signature policy

- **Intellectual Property** – primary issue for Sponsored Research Agreements or investigator-initiated research agreements

- **Budget/Payment schedule** – check for of IRB, set-up fees (non-refundable if non-federal), total amount and frequency of payments (including hold back provisions)
Indemnification: Defend/hold harmless in event of lawsuit

- Who is covered? (only patient)
- What is covered? (only drug or device events)
- Exceptions (negligence, failure to follow protocol or regs, etc..)
IMPORTANT CONTRACTING ISSUES

- **Confidentiality** – “everything we give you and everything you do for the study”, length of time, patient confidentiality, exceptions, reciprocity, HIPPA

- **Publication** – right to publish independently and without restrictions, “approval” vs. “review”, non-profit status (IRS)
Excerpt from our CTA Template

Sponsor agrees to indemnify, defend and hold harmless the University, its trustees, officers, agents and representatives and employees, including the Principal Investigator from any and all losses, injuries, harm, liabilities, claims, actions, suits, costs and expenses, including, reasonable attorney’s fees, for personal injury (including death) or economic loss arising out of or connected with the performance of the Study, including the use by Sponsor of Study results.

The obligation of indemnification under this Section shall not apply to the extent that liabilities are caused by (i) failure of the University and/or Principal Investigator to use the Study Drug/Device in accordance with the Protocol or other written instructions of Sponsor or (ii) the negligence and willful misconduct of Principal Investigator or any other employee of University. Deviations from the Protocol for reasons of patient safety that may arise out of medical necessity shall not nullify Sponsors indemnification obligations hereunder; provided that University’s actions related to such deviations do not constitute negligence.
Do you allow commercial entities to restrict the Indirect cost other than possibly off campus or OSA determination?

Indirects are based on OTT/OSP’s guidelines. They are not negotiable.

Emory has standard and published Facilities & Administrative rates http://www.osp.emory.edu/facts/fac-rates.html

Emory has standard and published facilities and administrative rates. Any deviations from these from these must be documented, justified, and approved by the School of Medicine.
Are there some that you make special agreements with or that you can’t come to an agreement with?

Some sponsors just say no. They can’t or won’t fund what is needed. Sometimes we may agree to less than stellar terms depending on the circumstances. Rarely are we unable to come to an agreement with a sponsor and have to walk
Indirect Costs

Do you allow them to restrict the IDC?

Other than possibly off campus or OSA determination we won’t let a commercial entity restrict our idc as we don’t want it to be seen that the university is supporting or giving a break to a commercial.
OTHER IMPORTANT CONTRACTING ISSUES

- **Termination** – reciprocal right, incurred expenses coverage

- **Data ownership** – critical for Sponsored Research Agreements and investigator-initiated projects

- **Use of name** – Generally prohibited except for federal registries (clinicaltrials.gov), required reporting and some publications. Commercial purposes almost always prohibited

- **Special issues** – non-disclosure provisions preserving the ability to publish. We have to follow International Committee of Medical Journal Editors (ICMJE standards) ([http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html](http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html));

- **Indemnification and subject injury reimbursement coverage** (here’s our subject injury policy online: [http://irb.emory.edu/documents/SubjectInjuryCT.pdf](http://irb.emory.edu/documents/SubjectInjuryCT.pdf))
Do you try to encourage using your template for agreements over the company’s? Do you involve Legal?

They request their templates often. They’ll consider an institution’s template and, then, will ask that everything be put in their template. We usually use/review/negotiate the sponsor-provided template. But we have our own templates available in the event a sponsor (usually a smaller-scale/newer sponsor) doesn’t have a template of their own

http://www.osp.emory.edu/forms/index.html
Special things to consider when the company is owned or has heavy PI involvement; how do you manage conflict of interest?

eCOIs are mandated by all IRBs (Emory, WIRB, federal CIRB, etc.)

It must be clear who owns what and that is considered by the IRB in their review.

Conflict of Interest is managed internally by Emory’s Conflict of Interest Office. All studies are reviewed by the COI office and all study staff have to be reviewed for COIs.
What are some things that you need to watch for?

- Restrictions on publishing
- Confidential or proprietary information
- Patents
- Non-disclosure agreements

Give the PI in your institution heads up on not to sign or do anything before consultation. The PI will only sign at the contracts office's direction since OSP/OTT negotiates the contract language. PIs do not bind Emory in research agreements.
BEST PRACTICES FOR PRE-AWARD

Organization and time management are keys to SUCCESS!

- Start early!!
- Create a Grant Tracking List/Calendar
- Coordinate Your Grant Team Responsibilities while Staying on Schedule
- Read sponsor instructions, guidelines, and/or requirements
- Identify the Key Information
- Assemble Supporting Documents
- Internally route for approval and report on your progress at key intervals
- Confirm submission mechanism
POST AWARD CONCERNS
What kinds of reports or requirements do they normally have? How do you report expenditures or get approvals?

They want deliverables. They want patients accrued to the studies and they want reports filed. They usually require Emory’s W9, the FDA Form 1525, a payment information form, a Conflict of Interest Disclosure Form.

With the contract terms:
-Sponsors usually provide a study drug and the funding so in exchange they want the rights to any discoveries/improvements/inventions that may come out of the study. We assign all IP rights and ownership of the study data to the Sponsor. Emory’s IP policy: http://policies.emory.edu/7.6
-preserving the right to come to Emory to monitor/audit our site for performance and compliance;
-obligations of Emory maintaining their information confidential; the ability to review and comment on proposed publications, especially in Multi-center studies because they are trying to coordinate the data from all the sites;
-cooperation with their obligations to meet federal reporting obligations (sunshine act, transfers of value, conflict of interest disclosures, record maintenance); and
-assurances Emory and study staff are not debarred.
What typical kinds of post award reports or requirements do non-federal sponsors normally have? Financial status report are required. The report can be interim, annual or final. Requirements will depend on the sponsor. Foundations tend to have more restrictions so the administrator will need to be familiar with the agency.

What would you advise a pre-award administrator to ensure is documented in order to avoid ‘ugly’ post award management of non-federal sponsors? Some common areas are cost share, administrative salaries, overhead, effort, vendors vs. subs, and participant support.

How do you report expenditures or get approvals? We provide reconciliations to the PI's. Industry best practices would be monthly or bi-monthly at a minimum. Obtaining approvals on expenses will depend on the institution or how the department is setup. At Emory, some departments have an internal approval process wherein the lab personnel will order the products and they send an email to the PI for approval. The email triggers the finance area to review for allocability, allowability and reasonableness before approving.

Are there special things that you need to be aware of and watch for in the post award administration of the agreement with non-federal sponsors? You will need to know the sponsor’s terms and conditions. They will vary according to sponsor. It is best practice to visit the agency’s website for any updates that you may not be aware of. An administrator should not be in the habit of managing by last award received from sponsor.
SUMMARY

COMPONENTS OF NON-FEDERAL RESEARCH SOURCES, MECHANISMS, BASIC PROPOSAL ELEMENTS, COMMON CONTRACTING ISSUES, DIFFERENCES BETWEEN INDUSTRY AND NON INDUSTRY, THINGS TO WATCH OUT FOR

BEST PRACTICES

(WHERE CAN THINGS GO WRONG, HOW TO PREVENT THE UGLY, POST AWARD CONCERNS)
Thank You