Sponsored Research Contracts: Management and Issues

Contracts and Industry Agreements

Office of Sponsored Programs
Contract Management

- OSP comprises two separate Units:
  - Contracts Unit
  - Grants Unit
## Contract Types by OSP Unit

### (Grants and Contracts)

<table>
<thead>
<tr>
<th>CONTRACTS UNIT</th>
<th>GRANTS UNIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry sponsored Clinical trial and clinical research contracts</td>
<td>Federal Grants with terms and conditions</td>
</tr>
<tr>
<td>Confidentiality Agreements related to Clinical Trials</td>
<td>Foundation grants with terms and conditions</td>
</tr>
<tr>
<td>Clinical Material Transfer Agreements</td>
<td>Outgoing subawards under federal grants (both FDP and non-FDP)</td>
</tr>
<tr>
<td>SBIR/STTR subawards</td>
<td>FDP incoming subs</td>
</tr>
<tr>
<td>Incoming and outgoing subcontracts under <strong>federal contracts</strong></td>
<td></td>
</tr>
<tr>
<td>Non-FDP incoming subs</td>
<td></td>
</tr>
<tr>
<td>State contracts (including county and city contracts)</td>
<td></td>
</tr>
<tr>
<td>Purchased service agreements</td>
<td></td>
</tr>
<tr>
<td>Federal Request for Proposals (RFPs)</td>
<td></td>
</tr>
</tbody>
</table>

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*Emory University | Research Administration*
Contracts Generally NOT Reviewed by OSP Contracts Unit

- Personal Consulting Agreements (Faculty/staff not performing or serving in capacity of university employee)
- Agreements to establish Academic Programs/Accreditation
- Teaching/Training Agreements where faculty are paid directly
- Agreements to purchase equipment to be used for Patient Care (Emory Healthcare generally handles these agreements)
- Vendor Agreements for the purchase of goods and services (University Procurement generally reviews these agreements)
- Licensing Agreements (OTT generally reviews these agreements)
Management Statistics

How many contracts did the OSP Contracts Unit receive for review/negotiation during calendar year 2013?
Guesses?
## Total Number of Contracts received for review/negotiation in 2013 (Jan 1 – Dec. 31)

<table>
<thead>
<tr>
<th>Contract Type</th>
<th>Number of Contracts Received by Contracts Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trials</td>
<td>326</td>
</tr>
<tr>
<td>Research Agreements</td>
<td>238</td>
</tr>
<tr>
<td>Confidential/Non-Disclosure Agreements (CDAs)</td>
<td>285</td>
</tr>
<tr>
<td>Amendments</td>
<td>388</td>
</tr>
<tr>
<td>Data Use Agreements</td>
<td>10</td>
</tr>
<tr>
<td>Material Transfer Agreements (MTAs)</td>
<td>6</td>
</tr>
<tr>
<td>Other (Research Services, State Agreements, etc.)</td>
<td>218</td>
</tr>
<tr>
<td>Research Service Agreements</td>
<td>22</td>
</tr>
<tr>
<td>Master Clinical Trial Agreements</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total Contracts</strong></td>
<td><strong>1497</strong></td>
</tr>
</tbody>
</table>
Master and Template Agreements

- **Purpose**: Reduce/eliminate lengthy negotiations

- **Function**: Predetermined terms and conditions already agreed upon by parties for

- **Benefit**: Allows award set-up (NOA issuance) faster assuming all other requirements are met
Drawbacks to Master Agreements?
One Notable Drawback

Terms agreed by the parties will be “locked” for a few years which may present some challenges if/when Emory policies/positions changes, or new laws/regulations are enacted during the course of existing master agreement period, etc.

Examples:

• Subject Injury Policy
• University Accreditation Requirements (AAHRPP)
• FDA or other federal regulations/law, etc.
End Result

***May have to go back and negotiate to amend existing master agreement w/ sponsor
Master and Template Agreements to Date
Master Agreements

By Sponsor

- Abbott Laboratories
- Abbott Vascular
- American Foundation for Aids Research
- Amgen
- Bayer
- Biogen
- Calypso Medical Tech
- Celgene
- Cerus
- Children’s Hospital and Regional Medical Center
- Cytodome
- DuPont
- Eli Lilly
- Evalve, Inc. (division of Abbott)
- Emmes
- General Electric
- Genzyme
- Georgia Core
- Guidant
- Hoffman-LaRoche
- ImClone
- IND 2 Results, LLC
- Medarex
- Medtronic
- Merck
- Millennium
- Moffitt Research Institute
- Myriad Pharmaceuticals
- Novartis
- Novo Nordisk
- Purdue Pharmaceutical
- Schering Plough
- Sekisui
- St. Jude Medical
- Siemens
- SMO-USA, Inc.
Master Confidentiality Agreements

- Abbott Laboratories
- AstraZeneca
- Celgene
- Oak Ridge
- Array Biopharma
Template Agreements

- Georgia Department of Community Health (formerly Georgia Department of Human Resources)
- Children’s Healthcare of Atlanta Subcontract (outgoing)
- Oak Ridge MOU & Teaming Agreement
Template Agreements (OSP Website)

- Clinical Trial Agreement (CTA)
- Sponsored Research Agreement
- Research Services Agreement
- Non-Disclosure Agreement (NDA or CDA)
- SBIR Subcontract Template
- STTR Subcontract Template
How Contracts are Routed to OSP
Emory Proposal Express
EPEX

What is Emory Proposal Express (EPEX)?

- The Purpose of EPEX is to assist in budget development, electronic routing, and institution approval related to extramural funding at Emory. **EPEX replaces the SPAF** (Sponsored Programs Approval Form) and is a necessary accompaniment to any Grant or Contract requiring Institutional endorsement.

When to Route through EPEX

- All extramurally sponsored projects requiring Institutional review/approval (i.e. Dept, School, OSP, etc.), including **industry and cooperative group funded clinical trials** to be conducted at Emory or Emory affiliate sites must be routed through EPEX.
- This includes: new projects/studies and **Budget Amendments** that **increase** or **decrease** per patient costs (to be covered later)
- This does not include Budget Amendments to increase the number of patients with no change in the amount per patient (to be covered later)
Clinical Trial Model

Clinical Trial Agreements represent the majority of agreement types reviewed/negotiated by OSP Contracts Unit
Routing Federal/Foundation Trials – A Basic Federal Proposal Model

1. PI Prepares Proposal
2. Routes Proposal (EPEX)
   - Division
   - Department
   - School
   - OSP
3. OSP Reviews/Submits Proposal
4. PI Receives indication of possible funding (JIT request)
5. OSP receives award
6. DMC Issues NOA once all final documents received
7. PI Routes to OCR
8. OCR Conducts Medicare Coverage Analysis
9. OCR provides MCA results to PI/Dept/DSM/OSP
10. PI Should submit to IRB when JIT Request received if submission not yet made
<table>
<thead>
<tr>
<th>Type of Amendment:</th>
<th>EPEX Needed</th>
<th>School Approval</th>
<th>OSP Approval</th>
<th>OCR Review</th>
<th>IRB Approval</th>
<th>Sponsor Approval</th>
<th>Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change of PI</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>TG</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Requires OSP Prior Approval Form</td>
<td></td>
<td>Copy of new IRB Approval with new PI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in contract provision, not involving the project length or any monetary aspect of the Agreement (i.e. contract terms, Protocol Amendments)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Current IRB Approval Required</td>
<td>Analyst</td>
</tr>
<tr>
<td>Budget Amendment that increase or decrease the awarded budget (including pass-through items).</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Current IRB Approval Required</td>
<td></td>
<td>Analyst</td>
</tr>
<tr>
<td>*Exceptions: Budget Amendment to increase number of patients to be enrolled</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Current IRB Approval Required</td>
<td></td>
<td>Analyst</td>
</tr>
<tr>
<td>Budget Amendment that changes payment schedule.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td>Analyst</td>
</tr>
<tr>
<td>Extension of budget/project end dates or specified end date in the contract.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td>Analyst</td>
</tr>
<tr>
<td>Extension of budget/project end dates or no specified end date in the contract.</td>
<td>Yes</td>
<td>Yes</td>
<td>Requires OSP Prior Approval Form or Email</td>
<td>Yes</td>
<td>Current IRB Approval Required</td>
<td></td>
<td>TG</td>
</tr>
<tr>
<td>Extension of budget/project end dates or no specified end date in the contract.</td>
<td>Yes</td>
<td>Yes</td>
<td>Requires OSP Prior Approval Form</td>
<td>Yes</td>
<td>Current IRB Approval Required</td>
<td></td>
<td>TG</td>
</tr>
<tr>
<td>Change in Sponsor/Sponsor Address Changes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Current IRB Approval Required</td>
<td></td>
<td>TG</td>
</tr>
</tbody>
</table>
Contract Tracking

Contracts Database

- **Purpose:** To track the status of contract negotiation from receipt to completion

- **Function:** Stores data elements. Interface w/EPEX (some data). At-a-glance view of status

- **Benefit:** Reporting, follow-up, management tool to measure performance and campus access (coming soon to faculty/designated staff)
Contract Tracking (con’t)

Web based application coming soon for faculty/staff, IRB, and Controller’s Office access to retrieve needed information:

- Status of Contract
- Subject Injury Option per Emory Policy
- Private Use/UBTI for IRS compliance
OSP Contracts Dept.
Assignments
To be Distributed
Additional Resources

EPEX

- **Training**
  - Training is available 24/7 via PeopleSoft UPK on the Compass Training Page: Compass> Training> Grants: [http://compass.emory.edu/training/index.html](http://compass.emory.edu/training/index.html)
  - Instructor-led is available bi-monthly. Dates and Times for the instructor-led EPEX course can be found on the Training page of the OSP website: [http://www.osp.emory.edu/communication/training/index.cfm](http://www.osp.emory.edu/communication/training/index.cfm)

- **EPEX and OCR**
  - Information regarding OCR and EPEX can be found on the EPEX page of the OSP Website: [http://www.osp.emory.edu/forms/epex.cfm](http://www.osp.emory.edu/forms/epex.cfm) and includes:
    - Required Attachments
    - Clinical Trials Procedures and Workflow

- **Other Available Information**
  - EPEX FAQs: [http://www.osp.emory.edu/OSP_other/EPEXFAQs.cfm](http://www.osp.emory.edu/OSP_other/EPEXFAQs.cfm)
  - Compass Grants Help: psgrants@emory.edu
Contract Issues
(some)
Some Issues Requiring Negotiation

- Publication
- Confidentiality
- Intellectual Property
- Subject Injury/adverse effects
- Indemnification/hold harmless
Publication

Rights and Restrictions

Do the terms of the contract allow the University/PI to use the research results (data, etc.) for teaching, training, or patient care?

- Why is this important?
- Impacts on University tax-exempt status
- Multi-site considerations
- Confidentiality Considerations?
- Acknowledgment of sponsorship
Questions?
Issue or non-issue

A term in a contract requires the University/PI to submit a copy of any proposed publication of the research results/data no less than 30 days prior to the date of publication for review and approval by the sponsor.

This is an issue. True or False?
Answer

True

False
Discussion

...for “approval” is an issue

“....for review and comment is acceptable”
Confidentiality

*Non disclosure, duration, exclusions, etc.*

Do the terms of the contract contain a non-disclosure provision?

Generally acceptable if:

- to protect sponsor’s confidential/proprietary info. Research results/data should be excluded to reserve publication rights
- duration for non-disclosure period is “reasonable”
- does obligation of non-disclosure do not include any of the generally acceptable exclusions:
General Exclusions to Confidentiality/non-disclosure

- Information which, at the time of disclosure, is in the public knowledge;
- Information which, after disclosure, becomes part of the public knowledge by publication or otherwise, except by breach of this Agreement;
- Information which was in the possession of recipient at the time of disclosure and which was not acquired directly or indirectly by recipient from the disclosing party, and which prior possession can be proven by documentary evidence;
- Information received from third parties, provided such information was not obtained, to their knowledge, by said third parties, directly or indirectly, on a confidential basis;
- Information which is independently developed by University personnel not privy to Sponsor’s Confidential Information disclosed under this Agreement;
- Information which is required to be disclosed by applicable law, rule, regulation, judicial order or subpoena; or
- Information which is necessary to provide patient care for any Study subject participating in the Study under this Agreement.
A term in a contract states, “University/Principal Investigator shall not disclose any confidential or proprietary information identified as such and provided by the sponsor pursuant to this Agreement. Any Confidential Information furnished by the Sponsor must be submitted to the Principal Investigator and clearly marked as Confidential.

The obligation for confidentiality shall not apply to:

- Information which, at the time of disclosure, is in the public knowledge;
- Information which, after disclosure, becomes part of the public knowledge by publication or otherwise, except by breach of this Agreement;
- Information which was in the possession of recipient at the time of disclosure and which was not acquired directly or indirectly by recipient from the disclosing party, and which prior possession can be proven by documentary evidence;
- Information received from third parties, provided such information was not obtained, to their knowledge, by said third parties, directly or indirectly, on a confidential basis;
- Information which is independently developed by University personnel not privy to Sponsor’s Confidential Information disclosed under this Agreement;
- Information which is required to be disclosed by applicable law, rule, regulation, judicial order or subpoena; or
- Information which is necessary to provide patient care for any Study subject participating in the Study under this Agreement.

The obligations of this paragraph shall not restrict the ability of the University to use Research results and to publish as described in Article ___ of this contract.

This clause is an Issue. True or False?
Answer

True

False

✓
Discussion

The obligation of non-disclosure in the proposed clause does not contain a “reasonable” non-disclosure period. In fact, it does not contain a period at all.

Thus, it could be interpreted that the University/PI’s obligation is perpetual.
Does the contract limit the University’s ownership of intellectual property/inventions created as a result of the research performed or services provided?

As a general position, the University will not require ownership of inventions resulting from a Clinical Trial. Ownership to inventions are looked at more fully when the Protocol or statement of work is written by an Emory PI.
Intellectual Property (con’t)

The use of data and work products (deliverables) relating to the University’s/PI’s performance under the contract should be retained for teaching, research, clinical and publication purposes, as well as to comply with federal, state or local laws or regulations.

- Work-for-Hire obligations are generally not acceptable. Impact on University’s tax-exempt status. UBTI/Private Use
License: Sponsor will generally grant University a non-exclusive license to use a Sponsor’s Invention (subject to confidentiality provisions) for internal, non-commercial research and educational purposes.
A term in a proposed contract requires University to grant ownership of inventions created by University or PI prior to and during the period of performance of the contract.

This is an Issue. True or False?
Answer

True ✅️

False ☐
Discussion

As a general rule, ownership of inventions existing prior to the Effective Date of the contract, are the separate property of University/PI, and should not be affected by current contract. Thus, sponsor shall not have any claims to or rights in such intellectual property. (background IP)
Subject Injury

Payment, Adverse Affects, and reporting

Does the contract require the Sponsor to pay for medical costs in the event of patient injury?

Language in the contract must be consistent with one of three options per University’s Subject Injury Policy.
Subject Injury Policy

- **OPTION 1:** The sponsor may choose not to pay for Subject Injury Costs for any subject, no matter if the subject is insured, or how he/she is insured.

- **OPTION 2:** The sponsor may choose to pay for Subject Injury Costs for all subjects, no matter if the subject is insured, or how he/she is insured.

- **OPTION 3:** The sponsor may choose to pay for Subject Injury Costs for uninsured subjects or subjects with Medicare/Medicaid and to pay any part of Subject Injury Costs for privately insured subjects that are not covered and/or paid by their private insurance.
Subject Injury (con’t)

Does the contract require the sponsor to notify all study sites of issues that may potentially negatively affect research subjects?

**AAHRPP:** Association for the Accreditation of Human Research Protection Programs
Subject Injury (con’t)

- **Sponsor will promptly report to the Principal Investigator and to University, at the notice address indicated in the notice section of this Agreement, any findings that could,**
  
  (i) affect the safety of research Subjects during and after the Research
  
  (ii) their medical care or their willingness to continue participation, (iii) influence the conduct of the Research, or
  
  (iv) alter the IRB’s approval to continue the Research.

- **Sponsor shall monitor the data to ensure the safety of research subjects and timely provide University and Principal Investigator with a copy of all medical monitor or safety monitoring committee reports generated for the Research**
Indemnification/hold harmless

General definition: means to allocate risk of claims by third-parties (i.e. research subjects) to shift liability to a specific contractual Party.

Clinical Trial Contracts:
With the exception of University/PI negligent actions, we generally require sponsors to indemnify the University/PI from liability with respect to the use of study drug/device or protocol procedures.
Indemnification (con’t)

Sponsored Research Contracts:

With the exception of University/PI negligent actions, we generally require sponsors to indemnify the University/PI from liability with respect to their use of data, research results, and deliverables (subject to governing law)

Mutual Indemnity is also generally acceptable.
Questions?