Getting to Know Business & Industry
Presenters: Bridget Foss, April Anderson, Tom Schouweiler & Sarah Danner
Team 5, Sponsored Projects Administration
Who is the Business and Industry (B&I) Team?

Team 2
Public Health
Dentistry
Pharmacy
AHC Shared
Carlson School Law

Jason Jacobs (PGA)
Karen Sachi*
Anjeanette Roy
Derek Krogstad

Cody Gallagher (floater GA)

Team 3
Science & Engineering
College of Liberal Arts
Education
Humphrey
Continuing Education

Amy Rollinger (PGA)
Pat Jondahl
Danielle Billington
Nic Allyn
Jon Klaphake

Team 4
CFANS
Extension
University Libraries
OVPR
System Acad Adm.
Biological Sciences
Vet Medicine
Design

Team 5
Business and Industry (All Campus)
MTAs (All Campus)

Laura Williams (PGA)
Bridget Foss
April Anderson
Duane Oyen
Tom Schouweiler
Sarah Danner
Brianna Graham

Award
Set-up Team
Karen Sachi (PGA)

Frances Werner
Riana Fletcher
Chris Coyne
Lorrie Awoyinka (PGA)
Tanya Walton
Renee Frey
Eri Knudsen
TBD

Nancy Benson
Michael Harris
Jean Delutri
Robert Delutri
Dembo Darboe
Karen Merrill
David Thao
Kristin Engstrand
Jonathan Hansen
Whousia Vang

Andrea Marshall (PGA)
Amy Bicek-Skog
Brett Carlson
Kim Makowske
Rylee Pelzer

Subaward
Jennifer Thissen
Lesley Schmidt
Sindberg (Subaward Compliance Officer)
Most Common B&I Questions and Concerns

• F&A Rates
• Agreement Negotiation
  • Research
  • Clinical Trials
• Master Agreements
• Unfunded Research Agreements (UFRAs)
The University does **not** negotiate F&A rates with industry sponsors.

A reduced F&A rate can only be used on an industry award if an F&A waiver has been approved.

### University F&A Rates

<table>
<thead>
<tr>
<th>Activity</th>
<th>Fiscal Year(s)</th>
<th>On-Campus</th>
<th>Off-Campus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organized Research</td>
<td>2016 - 2017</td>
<td>52.0%</td>
<td>26.0%</td>
</tr>
<tr>
<td></td>
<td>2018</td>
<td>53.0%</td>
<td>26.0%</td>
</tr>
<tr>
<td></td>
<td>2019</td>
<td>54.0%</td>
<td>26.0%</td>
</tr>
<tr>
<td>Other Sponsored Activities</td>
<td>2016 - 2019</td>
<td>33.0%</td>
<td>26.0%</td>
</tr>
<tr>
<td>Industry-Funded Clinical Trials (Total Direct Costs)</td>
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Agreement Negotiation

• Negotiation begins after a signed PRF is received at SPA; however, SPA will provide copies of template agreements to sponsors prior to receiving the PRF.

• The University has policies and liability limitations that need to be addressed in sponsored agreements.
  o Openness in Research Policy http://policy.umn.edu/research/openresearch
  o MN-IP Create http://www.research.umn.edu/mn-ip/programs.html
  o AAHRPP http://www.aahrpp.org/
  o Liability, MN Statute 3.736 https://www.revisor.mn.gov/statutes/?id=3.736

• Agreement review may include groups outside of SPA (i.e. OGC, OTC, IRB).
**MN-IP Create**

**Option A**
Pre-pay 10% of sponsored research agreement (or $15,000 whichever is greater) for exclusive, worldwide rights to all inventions arising from the research project with pre-set terms.

**Option B**
- No upfront fees
- No pre-set royalties
- Sponsor and university negotiate a royalty-bearing license once the IP is developed
- Sponsor manages and directs all patenting activities and pays all costs associated with patent prosecution (collaborating with the university on patent claims)

**Option C**
Pre-pay 10% of sponsored research agreement (or $10,000 whichever is greater) for a non-exclusive, royalty-free license to all inventions and any copyrightable materials arising from the research project.
Sponsor also receives a time limited option to negotiate a royalty-bearing exclusive license once the IP is developed.
Clinic Clinical Trials

• Expedited PRF process allows SPA to negotiate the CTA while the department is completing budget negotiation.

• Expedited PRF Package Includes:
  o Draft PRF signed by Principal Investigator
  o Draft Protocol
  o Agreement (if available)

• Advance Account (optional)
  o sponsored chart string for costs incurred prior to execution of the agreement (i.e. IRB fee)

• Prior to execution, an updated and fully approved PRF is required.
Accelerated Clinical Trial Agreement

• Why was the ACTA created?

• ACTA must be signed “as is”
  o This allows for quick implementation

• See other registered organizations at https://www.ara4us.org/acta/
Main Differences Between Research Projects and Clinical Trials

**Research**
- Administrative
  - Full PRF needed
  - Full F&A Rate - MTDC
- Terms & Clauses
  - MN-IP Create
- Agreements
  - Domestic Research Agreement

**Clinical Trials**
- Administrative:
  - Expedited PRF can be utilized (full PRF is required once budget is complete)
  - Reduced F&A Rate - TDC
- Terms & Clauses
  - AAHRPP
- Agreements
  - ACTA or sponsor template
Master Agreements

• Purpose is to expedite contracting.

• Most practical when there are multiple studies in the pipeline.

• Negotiations can be lengthy.
  o OGC reviews all master agreements
  o Terms must meet the University’s standard policies

• A PRF, work scope and budget are required for each study under a master agreement.

• Master Research Agreement template is available for use
UFRA: Unfunded Research Agreements

Research agreements in which no money changes hands

• Material transfer agreements (MTA), confidentiality agreements (CDA, NDA), research collaboration agreements (RCA), data use agreements (DUA) and memoranda of understanding (MOU)

• Reviewed and signed at SPA

• Complete an MTARF and send to ufra@umn.edu
MTARF: Material transfer agreement routing form

- Analogous to a PRF, provides data needed for review
- Completed in EGMS (http://egms.umn.edu)
- For instructions on completing, email ufra@umn.edu
- Not needed for confidentiality agreements
Material Transfer Agreements (MTAs)

A contract that defines the terms of transfer of research materials from one institution to another

- **Outgoing**: UMN materials being sent to someone else
  - Handled by UMN’s Office for Technology Commercialization
    - otcagree@umn.edu

- **Incoming**: Someone sending something to UMN
  - Handled by SPA
  - Create an MTARF, notify us via ufra@umn.edu
Material Transfer Agreements (MTAs)

Materials

• Chemical compounds
• Biological materials (e.g., cultures, cell lines, plasmids, nucleotides, proteins, transgenic animals or plants, or pharmaceuticals)

Issues

• Ownership of the materials and new things derived from the materials
• Limits on recipient’s use of the materials
• Rights to inventions made from or using the materials
• Confidentiality and publication
Other UFRA Agreements

Data use agreements (DUAs)
- Like MTAs, but the materials are data, databases
- HIPAA and other privacy concerns

Confidentiality agreements (CDAs, NDAs)
- Potential sponsors can send proprietary information for UMN to review before a research agreement or clinical trial agreement is contemplated

Research collaboration agreements
- A research agreement without funding
- All the same rules apply

Memoranda of understanding
- Vary from simple agreements to work together to very complex agreements involving specific terms
- Most common is agreement to help submit a proposal when UMN is a potential subcontractor
UFRA Questions

General questions: ufra@umn.edu

MTAs

• Outgoing materials: http://www.research.umn.edu/techcomm/request.html
• Incoming materials: http://www.ospa.umn.edu/policiesandprocedures/MTAs/index.html

MTARFs:
http://www.ospa.umn.edu/policiesandprocedures/MTAs/mtarfinstructions.html
Helpful Hints

- It is essential that a sponsor contact is included on the PRF.
- Still send the PRF and coordinating documents to proposal@umn.edu like with a federal/state/non-profit study
- If it’s a true proposal with an industry group, it should still be submitted through SPA
- Correctly identifying sponsor initiated vs. investigator initiated on the PRF (PRF Question #10) for clinical trials helps with agreement negotiation, compliance review, etc.
Helpful Hints

• Answering “yes” to the IP questions (PRF Question #16) on the PRF does not slow down negotiation and can actually help.

• Use the “notes” field on the PRF! (PRF Question #25)
  o Is the submission truly a proposal or should SPA contact the sponsor with a draft agreement?
  o Are there special instructions or background information that would be helpful to the B&I grant administrator?
Questions?
THANK YOU!