



## OFFICE OF RESEARCH ADMINISTRATION (ORA)

### ROLE OF OFFICE

The Office of Research Administration (ORA) reviews and negotiates all grant and contract proposals and awards for the School of Medicine, including commercially-sponsored clinical research agreements. This includes all federal contracts, foundation awards, all grant awards, all contracts for clinical, pre-clinical and non-clinical research, consulting agreements, unfunded collaboration agreements, data use agreements, materials transfer agreements, confidentiality/nondisclosure agreements, and all outgoing subawards/subcontracts.

Research contracting at JHU SOM is supported by two separate groups: the Clinical Research Contracting ("CRC") group handles industry-supported clinical research contracts, while the General Contracting group handles all other research contracts, including contracts with noncommercial sponsors and contracts for pre-clinical research.

ORA Leadership:

Michael B. Amey, Sr. Associate Dean for Research Affairs

Thomas F. Burns, JD, MBA, Director of General Sponsored Contracting

Sharel Brown, Assistant Director, Grants

Mont Brownlee III, JD, Director of Clinical Research Contracting

A complete list of staff for the General Contracting group is located here:

[https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/ORA\\_EB\\_Contact.html](https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/ORA_EB_Contact.html)

A complete list of staff for the Clinical Research Contracting group is located here:

[https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/FP\\_Contact.html](https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/FP_Contact.html)

## PERFORMANCE IN THE PAST YEAR

### General Contracting Group:

- The ORA General Contracting Group handled 2,262 incoming contract files and 1,250 outgoing subawards in FY19, with steady volume increases in almost every category. Total incoming contract volume increased 8% from FY18 to FY19. **Appendix 1 is a table showing total contracts for FY16, FY17, FY18, and FY 19 by record type, attached for comparative purposes.**
- Sponsored Research Agreement volume increased 3% from FY18 to FY19; accounting for 48% of total contract volume in FY19.
- Materials Transfer Agreement volume **increased 16%** from FY18 to FY19; accounting for 14% of total contract volume in FY19.
- Data Use Agreement volume **increased by 66%** from FY18 to FY19; accounting for 14% of total contract volume in FY19.

### Clinical Research Contracting Group:

- The ORA Clinical Research Contracting Group handled 1,353 incoming contract files in FY19.
- Total contract volume **increased 8.0%** from FY18 to FY19. After a period of sharp growth from FY12 to FY16 (nearly doubling), CRC volume remained stable in the 1,200-to-1,300 range for three consecutive years (FY16/17/18 -- see Appendix 2) and then increased significantly for FY19.
- CRC contract file breakdown for FY19 is 403 "Standard" agreements (comprehensive agreements with funding and/or drugs/devices for a specific clinical research project), 433 contract amendments, 13 new "Master" agreements, and 504 nondisclosure agreements.
- During FY19, Clinical Research Contracting handled files for **387 different Principal Investigators** from 71 different departments/institutes/units within JHM.

## STAFFING CHANGES IN THE PAST YEAR

### General Contracting Group:

There were a few staffing changes at MRB in FY19, mainly in our Contracts Specialists group:

Arlette Langer was promoted to Sponsored Agreements Manager, assuming supervision of the Sponsored Projects Specialists group at MRB.

Kymerly Jones, Sponsored Projects Specialist joined the MRB team to replace Abigail Logsdon who moved to the CRC office in a similar role.

Cyrus Fisher was recently hired to fill a vacant Sponsored Projects Specialist position. Cyrus joins the MRB office in September 2019.

Brian Line, Sponsored Projects Specialist, recently announced that he will be leaving ORA to take a position with JHURA so we will soon be conducting a search for his replacement.

#### Clinical Research Contracting Group:

CRC's newest Contracts Associate, Jennifer Williams, started in August 2018 and has quickly become a productive member of the team.

Sponsored Projects Specialist Jacqueline Flood retired at the end of 2018 after a 15+ year career at JHU, where she started out in with JHTV (then known as the JH Technology Transfer office) before joining ORA in 2017.

Abigail Logsdon joined CRC as a Sponsored Projects Specialist in the Spring of 2019 to help fill Jacqueline's shoes. A transfer from the General Contracting Group, Abigail was able to hit the ground running from day one.

#### **CHANGES IN THE PAST YEAR**

Throughout FY19 we have continued to update sponsored agreement templates in concert with Office of General Counsel to maintain compliance with a changing regulatory environment.

The Subaward Information Tracking System (SWiFT) is now in use by a majority of departments across the School of Medicine. As we continue to fine-tune SWiFT along with our colleagues at JHURA, we will be announcing a sunset date for the old Subawards Information Sheet as we move towards 100% SWiFT use across the School of Medicine.

#### **NEW DEVELOPMENTS FOR UPCOMING YEAR**

ORA, along with other research-related offices at SOM, is continuing to work on the launch of a new website format that will contain up to date information to assist faculty and staff with their grant and contract needs. ORA is also continuing to work with Research Enterprise Services on a new platform to streamline and simplify both the CDA/NDA and MTA request processes to provide better accountability and an overall better experience for SOM faculty and staff.

#### **INCORPORATION OF SERVICES INTO GRANT APPLICATION**

ORA does not charge any fees for contract review/negotiation.

## **BEST WAY TO WORK WITH PROGRAM**

The primary gateway for submission of research contracts is via the online COEUS system; contract submissions are automatically routed to the appropriate group within ORA for review.

Once received, the ORA Contracts Specialists team creates a record in the MyRAP (My Research Agreement Place) system, which allows for visibility of project status and activity by PI's and their delegates.

All SOM departments/institutes are serviced by dedicated ORA Contracts Specialists, based on the primary department of the Principal Investigator associated with the agreement. Contracts Specialists are the starting point for all research agreements within ORA, and they are happy to provide advice and comments.

Current departmental assignments for Contracts Specialists can be found here for the General Contracting group:

[https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/ORA\\_Deptl\\_Assignments.html](https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/ORA_Deptl_Assignments.html)

For the Clinical Research Contracting Group:

<https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/training/DeptAssignmentsPrattSt.pdf>



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Record Type	FY16	FY17	FY18	FY19
Sponsored Research Agreement	994	1,018	1,048	1,081
Materials Transfer Agreement	132	156	277	321
Data Use Agreement	108	129	185	307
Confidentiality/Non-Disclosure Agreement	243	189	190	168
Confidentiality/NDA's (Clinical)	470	420	453	504
Clinical Trial Agreements	454	382	371	403
Clinical Trial Agreement Amendments	346	412	411	433
Master Clinical Trial Agreements	21	22	18	13
Contracts- Other*	225	192	142	385
<b>Total Incoming</b>	<b>2,993</b>	<b>2,920</b>	<b>3,095</b>	<b>3,615</b>
Outgoing Subawards	1,033	1,177	1,078	1,250
<b>TOTAL</b>	<b>4,026</b>	<b>4,097</b>	<b>4,173</b>	<b>4,865</b>

APPENDIX 1 Contracts/Agreements Handled by SOM ORA (MRB) by Agreement Type FY16-FY19

\*Contracts-Other includes agreements handled by ORA from time to time but not separated by category for purposes of this report. This category may include agreements such as licensing agreements, teaming agreements, memoranda of understanding, contract/proposal application materials, various outgoing agreements and others.

APPENDIX 2 Contract Volume for Clinical Research Contract Group FY12-FY18

