



The 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 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

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

PERFORMANCE IN THE PAST YEAR

General Contracting Group:

- The ORA General Contracting Group handled 1,842 incoming contract files and 1,078 outgoing subawards in FY18. Total incoming contract volume increased 9.4% from FY17 to FY18. *Appendix 1* is a table showing total contracts for FY16, FY17, and FY18 by record type, attached for comparative purposes.
- Sponsored Research Agreement volume increased 9.5% from FY17 to FY18; accounting for 49% of total contract volume in FY18 and 51% in FY17.
- Materials Transfer Agreement volume increased 78% from FY17 to FY18; accounting for 16% of total contract volume in FY18 and 10% in FY17.
- Data Use Agreement volume increased by 43% from FY17 to FY18; accounting for 10% of total contract volume in FY18 and 8% in FY17.

Clinical Research Contracting Group:

- The ORA Clinical Research Contracting Group handled 1,253 incoming contract files in FY18.
- Total contract volume increased 1.4% from FY17 to FY18. After a period of sharp growth from FY12 to FY16 (nearly doubling), CRC volume has remained stable in the 1,200-to-1,300 range for three consecutive years (FY16/17/18 -- see *Appendix 2*).
- Contract file breakdown for FY18 is 371 “Standard” agreements (comprehensive agreements with funding and/or drugs/devices for a specific clinical research project), 411 contract amendments, 18 “Master” agreements, and 453 nondisclosure agreements.
- During FY18, Clinical Research Contracting handled files for 361 different Principal Investigators from 65 different departments/institutes/units within JHM.

CHANGES IN THE PAST YEAR

Throughout FY18, we have continued to update sponsored agreement templates in concert with the Office of General Counsel to maintain compliance with a changing regulatory environment. Along with JHURA, we have completed testing on our new subaward management system (SWiFT) with a pilot launching on 7/24/18. SWiFT will provide an automated platform for entering subaward requests, reducing data entry on the department side and reducing ORA processing times for issuing subawards. SWiFT will also offer increased transparency and accountability to research teams by providing a real-time status of their subaward requests as they move through the process.

Staffing Changes in the Past Year

General Contracting Group:

Major staff changes on the General Contracting team in FY 18 included the departure of Melody Snow, Assistant Director for Outgoing Awards. Final arrangements have been made for the hiring of her replacement, Marissa Pio Roda, who is scheduled to start in August.

Ian Round, Sponsored Projects Specialist, also left JHU in June and Brian Line was hired in July to fill the vacancy.

Cherise Hursey, Sr. Sponsored Projects Specialist, has accepted a position on the grants team and we will be posting the requisition to fill the upcoming vacancy.

Clinical Research Contracting Group:

The Clinical Research Contracting Group faced significant staff changes in the second half of FY18 with the departure of two experienced Contracts Associates, Anthony Maranto in February and Sara Pettit in May.

Contracts Associate Suzanne De Deyne joined us in April and is already a productive member of the team; our newest Contracts Associate, Jennifer Williams, is slated to start in August.

NEW DEVELOPMENTS FOR THE UPCOMING YEAR

ORA, along with other research-related offices at SOM, will be launching a new website format that will contain up to date information to assist faculty and staff with their grant and contract needs. We will also be rolling out the SWiFT system to the entire SOM in Fall of FY19. SWiFT will provide a user-friendly platform on which to submit subaward requests and to upload accompanying documentation. ORA is also working 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.

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 PIs 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:

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

Full staff listings for ORA contracting staff are available here:

https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/ORA_EB_Contact.html

And here:

https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/FP_Contact.html.

APPENDIX 1 Contracts/Agreements handled by SOM ORA (MRB) by Agreement Type FY16-FY18

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

*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.

Shaded rows indicate steady increases over previous years.

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

