Focused Problem Statement

Minimize investigator frustrations with:
- Multiple listservs
- Multiple forms
- Unclear documentation requirements
- Unclear ownership

AND

Minimize central frustrations with:
- Not receiving the appropriate documentation required
- Receiving agreements that should be managed by another team
- Unclear agreement types
- Unclear ownership
A grant includes any funding opportunity that requires the submission of an application and an institutional signature to a sponsor such as the NIH, DOD or the American Cancer Society. This includes federally funded clinical trial grant applications.

Clinical Research is conducted with human subjects or on material of human origin such as tissues, specimens and cognitive phenomena, for which an investigator directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual.

Contracts requiring an in-depth review are sent to a triage listserv. A collaborative review amongst UC, OSRA and JCTO will occur. A decision as to which office is responsible for the agreement will be provided within 48 hours.

Includes, sponsored research agreements, data use agreements, material transfer agreements (incoming), service agreements, consulting agreements, equipment testing agreements, executed biopharma alliance agreements and more.
Contracts Intake Dashboard

This application has been developed to allow WCM clinical and basic faculty and/or investigators to submit contracts/agreements through a central tool to be routed to Central for appropriate management.

Use the “New General Contract” submission function to submit all agreements to be negotiated and executed except the following: Philanthropic moneys for research, Core Service agreements, Visiting scientists/students, Compassionate Use Agreements, Grant Applications or Grant Sub-awards, Facility Use Agreement, MINT Agreement, Contract Amendments and any Qatar grants & contracts. For Qatar grants & contracts, please submit via their listerv.

Use the “New BioPharma Contract” submission function to submit all executed BioPharma agreements to be handled for administrative processing and management.

Your recent submission activity is displayed below.

<table>
<thead>
<tr>
<th>ContractID</th>
<th>Sponsor</th>
<th>Agreement Type</th>
<th>Principal Investigator</th>
<th>Submitted By</th>
<th>Submitted</th>
<th>Route</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016-04-07-140116</td>
<td>ABG Associates Inc.</td>
<td>Clinical Research/Trial/Registry</td>
<td>Ashutosh Kacker</td>
<td>Danielle Gabor</td>
<td>4/7/2016</td>
<td>OSRA</td>
<td>In-Progress</td>
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<tr>
<td>2016-04-07-141801</td>
<td>Acacia Pharma Ltd.</td>
<td>Confidentiality</td>
<td>John P. Leonard</td>
<td>Danielle Gabor</td>
<td>4/7/2016</td>
<td>Pending</td>
<td>Pending</td>
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<tr>
<td>2016-04-07-142503</td>
<td>AAB, INC.</td>
<td>Data Use</td>
<td>John P. Leonard</td>
<td>Danielle Gabor</td>
<td>4/7/2016</td>
<td>JCMC</td>
<td>Re-Routed</td>
</tr>
<tr>
<td>2016-04-07-101433</td>
<td>Clinical Research/Trial/Registry</td>
<td>Data Use</td>
<td>John P. Leonard</td>
<td>Danielle Gabor</td>
<td>4/7/2016</td>
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BioPharma Alliance Submissions

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<tr>
<th>ContractID</th>
<th>Sponsor</th>
<th>Principal Investigator</th>
<th>Submitted By</th>
<th>Submitted</th>
<th>Route</th>
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</tr>
</thead>
<tbody>
<tr>
<td>2016-04-07-131330</td>
<td>Aarhus United USA Inc.</td>
<td>Steven C. Hunt</td>
<td>Danielle Gabor</td>
<td>4/7/2016</td>
<td>OSRA</td>
<td>In-Progress</td>
</tr>
</tbody>
</table>
General Contract - Submit New Contract

1. What is/will be the funding source for your research?

2. Please Select an agreement type
   Note: If an agreement type does not fit your request, please select ‘Other’ for manual review.

3. Are/will you be performing clinical research, including a clinical trial, observation study, or registry?

Primary Questionnaire Form

4. Is/will your research be performed within a lab or facility of WCM/MeNYP?

5. Is there a high likelihood that Intellectual Property (IP) will result from your research?

6. Are you requesting to purchase or have you been requested to test the equipment?

7. Are you requesting to purchase/ trial software?

8. Are you being requested by another institution or entity to send materials and/or IP?

9. Are you being hired to provide specialized advice or services, or conduct research under the purview of your WCM employment,
   or to complete a specified scope of work using WCM resources— including personnel, space or equipment?
   Note: Answering ‘yes’ indicates that money received through this agreement will be paid to WCM.

10. Principal Investigator

11. Department

12. Division

Save Draft & Exit

Submit
General Contract - Submit New Contract

- Required fields. Submit button will be disabled until all required fields are completed.

1. What is/Will be the funding source for your research:
   - Industry (for-profit)

2. Please Select an agreement type
   - Other
   - Please explain the type of agreement
   - Testing

3. Are/Will you be performing clinical research, including a clinical trial, observation study, or registry?
   - Yes

Primary Questionnaire Form

4. Is/Will your research be performed within a lab or facility of WCM/NYP?
   - Yes

5. Is there a high likelihood that Intellectual Property (IP) will result from your research?
   - No

6. Are you requesting to purchase or have you been requested to test the equipment?
   - No

7. Are you requesting to purchase/rent software?
   - No

8. Are you being requested by another institution or entity to send materials and/or IP?
   - No

9. Are you being hired to provide specialized advice or services, or conduct research under the purview of your WCM employment, or to complete a specified scope of work using WCM resources-including personnel, space or equipment?
   - No

Note: Answering yes indicates that income received through this agreement will be paid to WCM.

10. Principal Investigator
    - John P. Leonard
    - Leonard N. Girardi
    - Leonardo Liberman

11. Department
12. Division

Save Draft & Exit
General Contract - Submit New Contract

You have successfully submitted your contract request. Based on the answers that you have provided, additional review of the request is needed. You will be contacted within 2 business days by the responsible office.
BioPharma Contract - Submit New Contract

- Required Fields. Submit button will be disabled until all required fields are completed.
1:  * Sponsor Name:  3M Pharmaceuticals
2:  * Does this agreement include outgoing subcontracts?  Yes
2.1:  Sub-site Name:
2.2:  Budget for:
2.3:  Scope of Work:
3:  * Will you be performing clinical research, including a clinical trial, observational study, or registry?
4:  * Will your research be including the use of animals?
5:  * Attach the executed agreement:
   [Click here to attach a file]
6:  * Please submit your internal budget if final budget does not include % effort, fringe and IDC:
    [Click here to attach a file]
7:  * Do you and/or any named research personnel have any interests that are disclosed/will be disclosed with this sponsor/entity?
8:  * Will this require the sharing or export of material, information, and/or technology outside the United States and/or foreign nationals within the United States?
9:  * Principal Investigator:
10:  * Department:
11:  * Division:

Submit
Next Steps

- Pilot Begins Today
- **Departments of Medicine and Radiology**
- Pilot targeted for 1 month
- Quick User Guide is being developed as well as Q&A reference