The Agreement Process

McMaster University
Faculty of Health Sciences
Health Research Services
When Do You Need an Agreement?

You need an agreement when:

- When you are engaging an investigator at another institution (includes HHS and St. Joes) to be part of your project. (even if there are no $$ involved)

- When you are being engaged by an investigator at another institution to work on their project

- When you receive funds from a granting agency or industry to perform a specific project
What am I doing?

✓ Ensuring compliance with University / Hospital policy

✓ Looking at potential liability and conflict of interest issues

✓ Making sure that the agreement accurately reflects the obligations and the intentions of everyone involved in the research
Why?

- Not all agreements are created equal.
Main Areas of Negotiation

- Confidentiality clauses
- Publication clauses
- Indemnity and Insurance clauses
- Intellectual Property Rights and Ownership
- Termination rights
- Governing law clauses
Confidentiality

- We check to ensure that the provisions are not overbroad, that they will allow you to publish the results and

- That you are not bound “in perpetuity” to an oath of silence
Indemnity and Insurance

- We make sure that everyone is obligated to carry a certain amount of insurance coverage (not just the Institution and the PI) and

- That the indemnification clauses (designate to hold harmless) against any lawsuits that arise as a result of the conduct of the work in accordance with the protocol are reasonable and fair.
Termination Rights

- Make sure that at a minimum, McMaster and our Investigator retain the right to terminate the study should the relationship not work out.

- Make sure that if it is terminated early, that there is fair settlement for all parties in the payment for work done up to the termination date.
CMPA has stated that the governing law clause must be a Canadian province or the country of Canada, because the CMPA is not structured to provide assistance to members who are involved in medico-legal matters outside of Canada.
What are the steps?

1. If you are receiving money or your services have been requested ask the investigator from the lead institution to send you an agreement for review
   Or
2. if you are sending money or requesting services contact Caroline Woods at Health Research Services (HRS) to arrange a draft agreement to send to your party for their review.

3. Submit your draft agreement in electronic format to HRS for review. We will assist you with drafting of the agreement and negotiation with the other parties to the agreement.

4. After negotiations are complete obtain authorized institutional signatures of McMaster and the other parties through HRS.

5. Complete the signature process before beginning the work. A fully executed original will be kept for HRS’s files.
How Do I Get an Agreement?

Contact the Appropriate Office:

- Health Research Services
- McMaster Industry Liaison Office
- Office of Integrated Research Services – Hamilton Health Sciences
- Research Administration - St. Joseph’s Healthcare
- McMaster Office of Research Services
- McMaster Purchasing
Health Research Services

Working Specifically for the Faculty of Health Sciences

- grant agreements,
- subgrant agreements
- Inter-institutional agreements
- McMaster co-ordinated Clinical Trial agreements,
- Letters of Intent
- MOU’s for the Faculty of Health Sciences
- Amendments to any of these agreements
McMaster Industry Liaison Office (MILO)

MILO working for all McMaster Faculties

- research contracts,
- industry sponsored agreements,
- service agreements,
- confidentiality agreements,
- non-disclosure agreements,
- data transfer agreements
- material transfer agreements
- intellectual property related issues
McMaster-Affiliated Hospitals

- All research agreements where either Hamilton Health Sciences or St. Joseph’s Healthcare Hamilton is a Party

- Clinical Trial agreements where subject recruitment is taking place within an HHS or SJHHH hospital/facility

- Works co-operatively with HRS to handle Clinical Trial Agreements
McMaster Office of Research Services

- ORS handles all research agreements for all other McMaster Faculties

McMaster Purchasing

- Purchasing handles any service agreement or contract not related to research that involves the purchase of an item or service from an outside provider.
Who Do I Contact?

- Health Research Services – Caroline Woods cwoods@mcmaster.ca
  x 22006, HSC 1B7
- McMaster Industry Liaison Office – 905-525-9140 ext.28646, McMaster Innovation Park
- Office of Integrated Research Services – Hamilton Health Sciences – Katie Porter x 74559 researchagreements@hhsc.ca
- Research Administration – St. Joseph’s Healthcare Hamilton – Mary Jane Sayles x32993
- Office of Research Services  Gilmour Hall, 3rd flr., ste. 305 x 26974
- Purchasing - Administrator  Carol Fletcher x 24297 fletchc@mcmaster.ca
Please Don’t

- Start any work without checking to see if you need an agreement and without the agreement being finalized.
- Transfer any funds to an outside party without an agreement in place.
- Sign an agreement without McMaster Institutional review and approval.
How Long Does it Take?

Currently, 2-3 weeks on average
The Process

- Once review is completed by HRS, a red-lined contract is sent to the PI

- If requested by our PI, HRS will negotiate directly with the other Parties

- Once it has gone out, it is up to the other Parties to respond
The Process

- Final documents forwarded to the other Party(ies) to begin the signature process
- Other Party sends the executed copy to McMaster PI for his/her signature
- The PI forwards the executed copy to HRS for final signature by authorized official of McMaster
- The fully executed documents are returned to the McMaster PI – 1 copy for his/her file and 1 copy to return to Other Party
Types of Agreements: To Name a Few

- Subgrants
- Grant Agreements
- Collaborative Research Agreements
- Non-disclosure Agreements/Confidentiality Agreements
- Inter-institutional agreements (Co-PI grant procedures to follow)
- Clinical Trial Agreements (special procedures to follow)
- Memorandums of Understanding
- Letters of Intent
- Amendments to any of the above type of agreement
Inter-Institutional Agreements

When you are a designated Co-Principal Applicant on a Grant (ie CIHR) an Inter-Institutional Agreement is Required
A Principal Applicant

- Has the responsibility for the intellectual direction of the proposed research as well as administrative and financial responsibility over the grant.

- Accepts the terms and conditions of the grant or award as set out in the sponsor's policies and guidelines.
The Institution Agrees to:

- Provide the committed resources
- Abide by the sponsor’s policies and guidelines
- Have the necessary accounting systems and financial controls
- Have a process in place for the ethical review of research
- Ensure the project conforms with regulatory requirements
Co-Principal Applicant

- In applications where the responsibility for the intellectual direction of the research is shared more or less equally between two or more individuals, there may be two or more Principal Applicants.

- By mutual agreement, one of the Principal Applicants must be the nominated PI on CIHR applications.

- The Nominated Principal Applicant and their Institution assume the administrative and financial responsibility for the grant.
What is an Inter-Institutional Agreement?

- An agreement between two or more institutions whose faculty are listed as Co-Principal Applicants that:
  - Describes the terms of a jointly held award
  - Lays out responsibilities of each institution involved with regards to:
    - administration,
    - insurance,
    - liability and
    - oversight of other sites involved in the study
Why an Inter-Institutional Agreement?

- Where the Co-Principal Investigators share the responsibility for the protocol design and direction of a study so do their respective institutions share the responsibility for the management, administration and associated risks for the conduct of the study both at their own institution as well as others involved in the study
Institutions holding funds are strongly advised to have in place liability insurance that protects them and their researchers from actions arising as a consequence of the research activity.

An inter-institutional agreement ensures that everyone including the institutions are aware of their respective roles and responsibilities in regards to the entire study.
Clinical Trial Agreements

Special Processes are in place for the review of Clinical Trial Agreements
Clinical Trial Agreements (CTA’s) are required when subjects are administered a new (not approved by Health Canada) procedure, drug, or device, or when subjects are administered an approved procedure, drug or device that is outside of the approved parameters or when there is an intervention with the subject.
Clinical Trial Agreements and Requests for CTA templates are submitted electronically to researchagreements@hhsc.ca where they are tracked in a database and assigned to a reviewer.

Agreements where McMaster is the lead institution are assigned to Caroline Woods in Health Research Services.
## McMaster or HHS the Lead Institution?

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<thead>
<tr>
<th>Scenario</th>
<th>Institution</th>
<th>Lead Institution Signing Agreement</th>
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<tbody>
<tr>
<td>Where the funds for the Clinical Trial Study are being held at McMaster</td>
<td>McMaster</td>
<td>Signing the agreement.</td>
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<tr>
<td>Where the funds are held at McMaster and the subjects are being recruited in HHS or SJHH hospitals</td>
<td>McMaster</td>
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**Note:** McMaster University cannot be a site that includes patient recruitment. It can be a co-ordinating centre.
Thank You!

Should you need any more information or would like to request a presentation for your group or department please contact:

- Caroline Woods cwoods@mcmaster.ca  x22006
  Or
- Wendy Hollinshead whollins@mcmaster.ca  x 22466