Research Road Map

April 2020 Research Contracts Issue

In This Issue

http://www.kingstonhsc.ca/research

Contact:

kghri@kingstonhsc.ca

(613) 549-6666, ext. 8171

CONTRACTS IN RESEARCH

Research projects can involve a range of contract types. A contract is an agreement between two or more parties that is enforceable by law. This roadmap aims to illustrate how contracts are administered, reviewed, negotiated and executed. It will give you an overview of the roles and responsibilities of the Queen's University Partnerships and Innovation (P&I) - Research Legal Services (RLS), Kingston Health Sciences Centre (KHSC), Kingston General Health Research Institute (KGHRI), the Principal Investigator (PI) and their project team. It also will give context to the research contract flow within other required approval processes that are needed in order to initiate your project.

DEFINITION OF RESEARCH CONTRACT

A contract is an agreement between two or more parties that is enforceable by law. A research contract specifically details the rights and obligations of the parties over the course of a research study, and often includes specific deliverables and milestones.

TYPES OF CONTRACTS

There are many types of research contracts:

- Confidential Disclosure / Non-disclosure / Confidentiality Agreements
- Data Sharing / Transfer / Access Agreements *(inbound or outbound)*

- Material Transfer Agreements *(inbound or outbound)*
- Clinical Trial Agreements
- Site Agreements / Sub-agreements
- Participating Centre Agreements
- Visiting Scientist Agreements
- Collaboration Agreements
- Sponsored Research Agreements
- Equipment Loan Agreements
- Network Agreements
- Contribution Agreements
- Intellectual Property Agreements and Intellectual Property Assignment Agreements
- License Agreements
- Inter-Institutional Agreements
- Facility Access Agreements
- Memorandums of Understanding
- Project Leader Agreements and Project Participant Agreements
- Other agreements, related to the expenditure of funds from research accounts, upon request

ADMINISTRATION OF RESEARCH CONTRACTS

At KHSC and KGHRI, the majority of research contracts are administered by Queen's P&I-RLS, with only a minority of research contracts administered by KGHRI. The administering institution manages the funds (when involved) and review of the contract. Clinical research and clinical trial contracts that are currently administered by KGHRI include the Cancer Clinical Research Team (adult oncology), Paediatric Oncology, Allergy, GI, and KHSC staff (who are not Queen's Faculty). Other research areas as designated and approved by the Vice-Dean Research (KHSC)/President & CEO (KGHRI) will also have their contracts reviewed by KGHRI. When contracts are administered by Queen's, the P&I – RLS is responsible for leading the drafting, negotiation and execution of the contract on behalf of Queen's and the affiliated hospitals and/or hospital RI. Any type of research contract may be administered by either the KGHRI or Queen's P&I-RLS.

PATHWAYS TO CONTRACT REVIEW

Whether the contract is administered by Queen's or by KGHRI, the Principal Investigator (PI) should first ensure that they have applied for the relevant certification(s) (e.g. HSREB, CTO, OCREB, Biohazard).

Once submitted, the next step to contract review is through the TRAQ DSS form process **IF** Queen's P&I-RLS will be leading the contract negotiations. A draft of the contract should be attached to the TRAQ DSS form application, and a link should be made to pending certifications on the Project Info tab. The contract review process by Queen's P&I-RLS will begin once all hospital approvals through TRAQ DSS form have been obtained.
If the contract is being administered by KGHRI, the PI should request that the Sponsor, Clinical Research Organization (CRO) or other Academic Institution

submit the contract to Hartley Borst (KGHRIcontracts@kingstonhsc.ca) via email for the contract review to begin. If administered by KGHRI, the contract review process will occur in parallel with certification and TRAQ DSS form reviews.

Following negotiation and agreement by all parties, the contract will be routed for signature execution by the administering institution. The timeline from contract initiation to execution of signatures can be from a few weeks to a few months depending on the complexity of the contract.

All contracts must be signed by authorized representatives of Queen's University and/or Hospital(s)/Hospital RI.

For confidentiality/non-disclosure agreements only, where Queen's P&I-RLS is the administering institution, the TRAQ Confidentiality/Non-Disclosure Agreement Review form, which does not require hospital approvals, should be used to initiate review.

For all other types of research contracts, **even if no funding is involved**, the TRAQ DSS form should be used. All relevant attachments and forms should be included and relevant approvals should be selected. Links to pending certifications should be created at the bottom of the Project Info tab.

For a summary illustration of the above process, please see flowmap at the end.

RESPONSIBILITIES OF PI & ADMINISTERING INSTITUTION

In general, the administering institution leads the drafting, negotiation and execution of research contracts and ensures that the terms are in accordance with university and hospital policies (for example: publication, intellectual property rights, confidentiality, insurance and liability, conflict of interest and indirect costs (overhead)).

The PI and study team negotiate the protocol, deliverables & budget with the Sponsor/CRO/other Academic Institution, create the TRAQ DSS form application, and seek departmental approval for the budget and use of resources.

Please note that amounts in the budget should be in $CAD; if not, please convert the currency. PIs need to calculate and include indirect costs (overhead). PIs are also reminded to review the contract prior to signature.

See the table directly below for the list of responsibilities for the PI/Study Team, Queen's P&I-RLS, KGHRI/KHSC/Providence Care, and Queen's Research Accounting:

Task	Who is responsible			
	PI / Study Team	P&I – Research Contracts	KGHRI / KHSC/ Providence Care	Research Accounting
Study Preparation				
- *Protocol preparation / review*	x			
- *Negotiate study budget (if applicable)*	x			
- *Regulatory documents*	x			
- *TRAQ DSS application*	x			
- *Certification application (e.g. HSREB, Biohazard, Animal Care)*	x			
Review / Approval Process				
- *Review and approve TRAQ DSS application*			x	
- *Claim TRAQ DSS application*		x*	x^	
- *Negotiate study agreement*		x*	x^	
- *Draft & negotiate site / sub-agreements (if applicable)*		x*	x^	
- *Verify certifications & overhead*		x*	x^	
- *Approve for signatures*		x*	x^	
Signature Process				
- *Queen's signatures*		x		
- *KGHRI / KHSC / PC signature*			x	
- *PI signature*	x			
- *Sponsor / Partner signature*		x*	x^	
Contract Execution and Budget				
- *Upload executed agreement to TRAQ*		x		
- *Approve research project account set-up*		x		
- *Submit budget and signing authority to Research Accounting*	x			
- *Set-up research project accounts*			x^	x
- *Communicate PeopleSoft Fund, Dept, Acct, and Project #s*				x
Reporting				
- *Financial Reports*	x		x^	x
- *Technical / Scientific reports*	x			

* University and University/Hospital/Hospital RI agreements ^ Hospital/Hospital RI only agreements

CONTACTS

For questions to Queen's P&I-RLS, please contact researchcontracts@queensu.ca.

For questions to KGHRI, please contact Hartley Borst at KGHRIcontracts@kingstonhsc.ca, cc Lisa Kozycz at Lisa.Kozycz@kingstonhsc.ca.

For questions to PCC, please contact Allison Philpot at philpota@providencecare.ca, cc Sally Lake at lakes@providencecare.ca.

Source: The Research Contract Lifecycle Presentation to Kingston SoCRA Chapter Meeting, 26 February 2020. Presented by Diana Purvis (Queen's P&I-RLS), Shari Glustein (KGHRI), & Veronica Harris-McAllister (KGHRI).

PATHWAYS TO CONTRACT REVIEW