

Contracts

Research Contracts, Research Agreements or Clinical Trial Agreements are agreements that are negotiated with an industry/commercial sector and/or granting or other funding agency, with the Principal Investigator and the Institution at which the research study is being conducted (i.e. Queen's University and/or the Board of Governors of Kingston Hospital, *commonly referred to as* Kingston General Hospital). If research is being conducted within a Queen's affiliated teaching hospital, then the hospital will be a party on the contract, otherwise if research is conducted outside a hospital setting, only the University will be a party on the contract.

All research contracts are required to be reviewed by the Queen's University's Office of Research Services' Contracts Office. In special circumstances, contracts may be reviewed by the Kingston General Hospital's Office of Health Sciences Research, at the sole discretion of the Vice-President of Health Sciences Research. The Office of Research Services' Contract Office, in consultation with the Researcher, will provide advice and assistance to ensure that the University's and Hospital's (if applicable) policies are followed and the interests of the Researcher are protected. When dealing with the government and private sector, institutional overhead is applied to all contracts to cover indirect costs associated with the research study, these including but not limited to, occupancy cost, building use, central administration, library costs and central computing services costs. The amount of institutional overhead applied to the total direct costs associated with conducting the research study is as follows:

Private Sector: The minimum is 40%. Higher rates will be negotiated where warranted. For work performed off campus, a lower rate of 20% may be accepted.

Clinical Trials: The minimum is 30% for studies funded by industry or the commercial sector.

Ontario Government: The rate is 30% (15% for work performed off campus) and this is applied to direct payroll costs including salaries and benefits, consulting fees, per diems and honoraria to the Researcher for work conducted on campus, 30% on materials and supplies expenses, and 2% on travel and subsistence expenses. This applies to all provincial funding except the Ontario Centres of Excellence in which the overall rate is 35%.

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Federal Government: The rate is 40% for work performed on campus and 20% for work performed off campus. However, the University is willing to accept the traditional calculation: 65% (30% for off-campus) on direct payroll costs including salaries and benefits, and including consulting fees, per diems and honoraria to Researchers, 30% on payments to graduate students, including benefits (15% for work off campus) if the work forms part of their thesis research and 2% on travel. If the work is not part of a student's thesis, full rates apply.

Off-Campus: Reduced rates apply to off-campus research since it does not include elements such as depreciation for buildings and equipment, operation and maintenance of the physical plant, library expenses, or student administration and services. This policy would apply to contracts in which the research activities are performed in facilities not owned or operated by the institution and to which rent is directly allocated to the project(s), *and* research activities in which all project personnel are located at that facility for a minimum of 75% of total grant supported effort for a continuous period of no less than six months or the life of the project, whichever is shorter.

Other Canadian Agencies: Certain major government agencies and other large organizations may negotiate specific indirect cost recovery with a group of universities or with the University Associations.

United States Government: A rate of 51.4% is applied to salaries (excluding fringe benefits), and applies to U.S. government grants, contracts, and other agreements. There is no indirect cost awarded on grants from the Department of Health and Human Services (except NIH which carries a rate of 8% of total direct costs less equipment).

Specialized Services: A rate of 15% is applied on the total income received from external private sector and governmental users. Specialized Services provided to collaborators within the university and from other universities will not be subject to recovery of indirect costs.

Hospital Research Grants: Affiliated hospital research grants flowing through Queen's will be levied a 10% overhead rate in recognition of financial and payroll services.

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Contracts under \$3000.00: Contracts less than \$3,000 will not be charged indirect costs. Subsequent agreements, amendments or extensions will revert to the standard formulas mentioned above.

Throughout contract negotiations there are several key themes or terminology that is usually required to be in contracts. These include, but are not limited to:

- ✓ All identified names/addresses of the parties negotiating the contract;
- ✓ Parties rights, duties, and obligations;
- ✓ Definitions of key terms used throughout the agreement;
- ✓ Contract commencement and duration;
- ✓ Ethics approval obtained;
- ✓ Confidentiality;
- ✓ Monitoring of study, if industry-sponsored;
- ✓ Publication rights;
- ✓ Registering a clinical trial on a publically-funded registry;
- ✓ Intellectual property rights;
- ✓ Ownership and access to data;
- ✓ Indemnification;
- ✓ Limitations on liability and warranties;
- ✓ Insurance (sponsor, institution and researcher);
- ✓ Subject compensation for injury;
- ✓ Privacy;
- ✓ Governing law and jurisdiction;
- ✓ Federal and provincial laws and regulatory requirements (i.e. Tri-Council Statement, International Conference on Harmonization (ICH) Good Clinical Practice Guidelines, the Declaration of Helsinki);
- ✓ Termination of agreement;
- ✓ Serious adverse event reporting (clinical trials only);
- ✓ Force majeure;
- ✓ Assignment;
- ✓ Language;
- ✓ Signature of all parties agreeing to the terms;
- ✓ Appendices (i.e. protocol, budget, schedule of payments).

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For more information regarding the medical-legal issues for clinicians enrolled in the Canadian Medical Protective Association (CMPA) to consider when negotiating clinical research agreements or contracts, please consult with Canadian Medical Protective Association's *General Information on Clinical Research Contracts* (<http://www.cmpa-acpm.ca/cmpapd04/index.cfm>).

For more information regarding the recommended minimum standard requirements for Ontario academic hospitals when negotiating a clinical study agreement, please consult the Council of Academic Hospitals (CAHO)'s *Statement of Principles to be Considered When Negotiating a Clinical Studies Agreement* ([http://www.caho-hospitals.com/docs/CAHO Clinical Studies Agreement Statement of Principles Version 2-0.pdf](http://www.caho-hospitals.com/docs/CAHO_Clinical_Studies_Agreement_Statement_of_Principles_Version_2-0.pdf)) or contact:

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