SUNNYBROOK HEALTH SCIENCES CENTRE
IMAGING RESEARCH CENTRE CARDIOVASCULAR INTERVENTION
(IRCCI) CLINICAL RESEARCH COMMITTEE
APPLICATION PACKAGE

The IRCCI MR Research Committee is charged with allocating MR resources for funded clinical research, contract research and feasibility studies for clinical research. The following terms of reference have been developed to guide the committee and as information for investigators wishing to use MR resources for research. The committee is advisory to the Director, Heart and Circulation research and the current members of this committee include Alexander Dick (Chair), Graham Wright, John Rowlands, Normand Robert, Steve Fremes, Alan Moody, Eugene Crystal and Rhonda Walcarius.

1. Preamble

The mandate of IRCCI is the study of imaging to advance cardiovascular therapeutics. At this time the following imaging equipment is available:

- 1.5T MR scanner
- Single plane (to be upgraded to biplane in spring 2007) X-ray
- 3D ultrasound

The priorities of this equipment are:

1) Cohort study research
2) Contract research
3) Technical research

25 hours per week during normal office hours (Monday-Friday, 8:00 a.m.-4:00 p.m.) are available for funded cohort study research. When fully subscribed by funded studies, this amount of time is estimated to be sufficient to cover operating and upgrade expenses for the research equipment. Clinical research studies will be held in blocks to be released within 24hrs if no patient is booked. Technical development time in the first 3 years will be provided at reduced or no charge to the investigators.

2. Conditions

Cohort studies require the imaging of subjects to investigate a clinical condition or disease, and can include the imaging of volunteers as normal controls. Research in the IRCCI in the form of a cohort study shall be undertaken only if the following conditions are satisfied:

- There must be a valid scientific reason within the mandate of IRCCI to perform the research.
- The research must be ethical. This condition requires that the research be reviewed and approved by the Sunnybrook HSC Ethics Review Board or Animal Care Committee (if/when animal research is approved to be performed in IRCCI).
- There must be Sunnybrook HSC personnel qualified to perform the research.

- There must be adequate funding available to pay the full costs of the research

3. Priorities

Research time for cohort studies will be allocated by the Clinical IRCCI Research Committee, based on the following principles:

- The conditions in (2) must be satisfied.
- There must be adequate time and personnel to do the research. If there is insufficient time to perform all the research projects proposed, priority will be assigned in the following order:
  1. Peer-reviewed, externally funded research from major granting agencies (*e.g.* CIHR, HSF);
  2. Other peer-reviewed, externally funded research;
  3. Contract research, provided it does not displace internal research;
  4. Feasibility (pilot) studies for clinical research projects.
- Research projects for which there is insufficient research time will be postponed and reconsidered when adequate research time becomes available.

4. Supervision and Investigators

IRCCI research at Sunnybrook HSC can be undertaken when the following conditions are met:

- The principal investigator must hold a staff position (medical or scientific) with a University or hospital research institute. At least one co-investigator or collaborator from within Sunnybrook HSC, with similar standing and MRI experience, will often be involved from within Sunnybrook HSC.
- For contract research, an outside company contracts for specific studies to be done. Clinical trials of drugs are the most common example of this type of research. In this case a member of the scientific or medical staff at Sunnybrook HSC must serve as the principal investigator for the project.

5. Funding

The costs for IRCCI research resources will be recovered in the following manner:

- For cohort studies, the investigator will be charged an hourly rate for IRCCI system use. This hourly rate will include the use of the IRCCI equipment, the services of one research technologist, and the usual consumables in the usual amounts (such as linen, film and archival media). Extra personnel costs (*e.g.* reception, nursing, research assistant), use of special equipment, and contrast agent costs will be additional charges.
- There will be differential charges for research time depending on whether the research is funded by a peer-reviewed external granting agency, or a for-profit commercial company.
- The usual charge for research projects sponsored by peer-reviewed external granting agencies will be $400 per hour. Normally, the investigator will have a research grant account at Sunnybrook HSC. The investigator's account will be charged $400/hour as outlined above.
- If the research is sponsored by a for-profit commercial company, the charges will usually be

double to triple those charged to peer-reviewed granting agencies, *i.e.* $800-$1,200 per hour. This rate will be subject to negotiation between the for-profit company, the principal investigator at Sunnybrook HSC, and the Clinical IRCCI Research Committee. The allocation of funds beyond the basic recovery of $400/hour will be decided by the committee on a case-by-case basis. For multicentre research studies, Sunnybrook HSC should receive no less than the amounts paid to American sites participating in the same studies. Principal investigators at Sunnybrook HSC will normally maintain a research grant account which will be charged the IRCCI fees as the research is done. Investigators without a Sunnybrook HSC research grant account will be invoiced directly.

- All investigators will be obliged to seek granting agency or industry support for any cohort study that goes beyond the feasibility stage.
- Rates for 3D ultrasound and X-ray will be determined on a case by case basis. Some of the X-ray studies will be clinically driven procedures and therefore covered by hospital clinical budget.

6. Approval Process

All investigators must have their cohort study time allocated by the Clinical IRCCI Research Committee. This allocation must be obtained prior to committing to perform the research and cannot be transferred to another project or to another investigator. Allocation is in the form of an access code for scheduling magnet time on a web site. Investigators must comply with established scheduling etiquette, in the form of guidelines available from the Clinical IRCCI Research Committee.

In the case of peer-reviewed grant, the principal investigator are encouraged to provide a brief scientific summary, MR protocols, budget, number of subjects and timetable (hours per week), plus any other appropriate information to the committee ***prior*** to submission of the application to the granting agency. This will normally occur concurrently with submission to the Ethics Approval Board. The committee will promptly inform the investigator if there is likely to be adequate research time to perform the study and whether the investigator has estimated equipment time and expenses appropriately. If the application is subsequently funded the investigator will contact the Clinical IRCCI Research Committee ***immediately*** to confirm the availability of adequate research time and to put the appropriate scheduling and billing mechanisms in place. During the course of a research project, requests for magnet time in excess of that approved by the committee must be delivered in writing for consideration by the committee members.

In the case of contract research, the principal investigator at Sunnybrook HSC will provide a brief scientific summary, MR/X-Ray protocols, budget, number of subjects and timetable (IRCCI hours per week) to the committee at approximately the same time as submission to the Ethics Review Board. If adequate research time is available, the committee will discuss with the principal investigator the appropriate fees and their allocation. The principal investigator will be responsible for negotiating the final contract with the industrial partner, taking into account the advice from the committee. Once a contract is in place, the principal investigator will be responsible for maintaining a grant account that will be charged appropriately as the IRCCI equipment time is used.

In the case of pilot studies (5-12 patients), the principal investigator will present the scientific rationale, MR/X-Ray/Echo protocols, and timetable to the committee after approval of the Ethics Review Board has been obtained. The principal investigator must make a strong case for the project including an indication of when grant applications will be submitted and to which agencies.

Application for **IRCCI CLINICAL RESEARCH RESOURCES**
SUNNYBROOK HEALTH SCIENCES CENTRE (SHSC)

1. APPLICANT(S): _____ AFFILIATIONS (SHSC APPLICANTS LIST DEPT./DIVISION AND CLINICAL PROGRAM): _____

2. INVESTIGATOR AT SHSC: _____
TELEPHONE: _____ E-MAIL: _____

3. CORRESPONDENCE/BILLING ADDRESS (INCLUDING ROOM NUMBER):

4. SHORT TITLE OF PROPOSAL:

5. AGENCY PROPOSAL SUBMITTED TO: _____
6. REQUESTED MR TIME (MR HOURS PER WEEK): _____
7. REQUESTED X-RAY TIME (HOURS PER WEEK): _____
8. REQUESTED U/S TIME (HOURS PER WEEK): _____
7. NUMBER OF MR HOURS PER SUBJECT: _____
8. NUMBER OF SUBJECTS PER YEAR: _____
9. DURATION OF STUDY: _____

10. BILLING TYPE: ◯ Funded ◯ Pilot study ◯ Basic
CHARGE CODE: ◯ No technologist ◯ Technologist ◯ Technologist/Commercial

SHSC COST CENTRE (7241xxxxx) TO BE BILLED: _____

11. APPROVALS:
Animal Care Committee - Protocol Number: _____ Expiry Date: _____
Research Ethics Board - Project ID Number: _____ Expiry Date: _____

12. AUTHORIZED SKED USERS: _____

13. SIGNATURE: _____ DATE: _____
Individual to be invoiced for MR Research Resources

14. ATTACHMENTS:
a) A scientific summary **2 pages or less** describing project hypotheses and goals, and experimental methods. The summary should enable the committee to ascertain the demands on IRCCI resources for the duration of the project.
b) Notification of ethical approval for human and/or animal research at SHSC. Approval from other institutions is sufficient for preliminary consideration by the Committee.
c) For projects supported by external funding agencies, attach notification of award. For contract research, attach notification of agreement and budget
d) A valid MRI, X-Ray or U/S experimental protocol. Separated protocols may be required if the project encompasses multiple experiments.

Attach a brief scientific summary, budget and justification, protocols, & SHSC ethics or animal care approval
Return complete package by mail or in person to Sunnybrook Health Sciences Centre, 2075 Bayview Ave., Room S6 51, Toronto, ON, M4N 3M5, or by fax to 416-480-5714. Call 416-480-5738 for any questions.

ADMINISTRATION ONLY

COMMITTEE APPROVAL: _____ Date: _____
RATE: _____ PROFILE NUMBER: _____