

Stem Cell Network Comprehensive Conflict of Interest Framework

1.0 Introduction

The core mandate of the NCE Program is the generation of social and economic benefits for Canada through promoting and funding interactions between university researchers and the private sector. In this context the appropriate management of conflict of interest through governance processes that are independent and transparent is key to maintaining public confidence in the program. For that reason the NCE has developed a Conflict of Interest Framework which has been implemented by all Networks of Centres of Excellence, including the Stem Cell Network.

Above and beyond the management of the potential, apparent or actual conflicts inherent in the nature of the program, the Board of the Stem Cell Network and Expert Review Panels have identified two specific issues with respect to the SCN that warrant special attention:

- In general it will always be important to ensure that an NCE is not dominated by participants from one group or another to the detriment of either the Network as a whole or other Network members. The SCN has to be particularly aware of this following its establishment of Aggregate Therapeutics Inc. (ATI), a company in which 37/71 SCN researchers and 16/24 member institutions are shareholders.
- The high degree of public interest in this field requires that Network processes are transparent and beyond reproach. Examples of areas where public-private interactions will be subject to particular public scrutiny include funding decisions in general, the use of human embryos for research purposes, and the advancement of clinical trials.

Given these concerns the SCN Board established a Task Force in December 2005 to review the SCN's current approach to conflict of interest, and to make recommendations to the Board about how to enable and ensure exemplary practice within the SCN. This Framework was subsequently reviewed by the SCN Board Ethics Committee and the Board as a whole, and was adopted on June 19, 2006.

This framework document reflects the recommendations of the review process and represents a comprehensive approach to the management of potential, apparent, or actual conflict of interest in the Stem Cell Network. The framework is divided into two broad sections as follows:

- Conflicts of Interest in the Governance of the Stem Cell Network
- Conflicts of Interest in activities funded through Stem Cell Network awards

2.0 Conflicts of Interest in the Governance of the Stem Cell Network

- 2.1 The first class of decisions to be considered is those taken directly by the Stem Cell Network Board. In general those decisions most likely to cause a conflict of interest relate to the funding of SCN projects or activities.

2.2 The guiding document for managing conflict of interest on the SCN Board and all of its Committees is the *NCE Conflict of Interest Policy Framework* (Appendix A). The document sets out definitions of key terms such as conflict of interest and financial interest; disclosure obligations; management processes including key principles and dealing with non-compliance; review procedures; and, a non-exhaustive list of examples of conflict. This policy has been adopted and incorporated into the *Stem Cell Network Conflict of Interest Policy – SCN Board and Committees* (Appendix B) which includes guidelines and procedures to assist in implementing the NCE policy framework. These procedures include an *Annual Conflict of Interest Declaration* by every member of the NCE Board and its committees (Appendix C). For clarity, the term “financial interest” as defined by the NCE and used in this document is as an interest in any business in the same area as the network consisting of:

- Any material stock option (e.g., 1%) or similar ownership interest in such a business, but excluding any interest arising solely by reason of investment in such business by a mutual, pension, or other institutional investment fund over which the person does not exercise control; or
- Receipt of, or the right and potential to receive, any income from such a business, whether in the form of a fee (e.g., consulting), salary, allowance, interest in real or personal property, dividend, royalty derived from licensing of technology, rent, capital gain, real or personal property, or any other form of compensation or contractual relationship, or any combination thereof.

2.3 With respect to managing the specific issues raised by the establishment of ATI, the SCN Board has sought advice from its legal counsel on how to manage situations where either directors of the SCN are directors of ATI, or directors of the SCN are directors of companies that might compete with ATI. The Board has agreed to follow the recommended protocols of legal counsel (Appendix D).

2.4 The SCN Board has also generalized a number of lessons from the establishment of ATI into governance and commercialization policies designed to minimize future potential conflict of interest situations:

- 2.4.1 The majority of the membership of the SCN Board and all of its subcommittees may not be comprised of persons with a collective financial interest (as defined by the NCE CoI Policy Framework) in the same company.
- 2.4.2 No meeting of the SCN Board or its subcommittees will have quorum if a majority of the participants in a given meeting have a collective financial interest (as defined by the NCE CoI Policy Framework) in the same company.
- 2.4.3 Where the SCN exercises control (as defined by CICA) over a for-profit corporation, no director of that for-profit corporation shall chair the SCN Board nor the SCN committee responsible for commercialization.
- 2.4.4 The SCN will not take a financial interest (as defined by the NCE CoI Policy Framework) in any corporation commercializing SCN funded research.

2.5 The SCN Board has also been particularly conscious of the special role the Research Management Committee plays in the Network, and the degree of reliance placed by the SCN Board on the RMC for advice on funding decisions. As a consequence the SCN Board have instituted a number of additional policies and procedures relating to the activities of the RMC designed to ensure integrity and transparency in the research funding process. (Note the SCN has two funding mechanisms: Core Projects are multi-year, multi-investigator awards, typically exceeding \$500,000, for which a competition is held every 2-3 years. Catalyst Projects are one year awards for one or more PIs, with a maximum value of \$50,000, and applications are reviewed at each RMC meeting.)

2.5.1 An International Scientific Advisory Board (ISAB) has been established which, for every funding competition, provides an independent assessment and ranking of all Core Research Projects to both the Board and the RMC. Where the RMC deviates from these rankings in its funding advice it is required to provide a justification to the Board.

2.5.2 As a matter of course, any RMC member named on a Funding Proposal must recuse themselves from RMC evaluation and recommendations regarding that proposal.

2.5.3 Where a company is named as a material partner on a Funding Proposal, any RMC member with an individual financial interest in that company (as defined by the NCE Col Policy Framework) must recuse themselves from RMC evaluation and recommendations regarding that proposal.

2.5.4 To ensure the scientific integrity of the RMC evaluation process, given these quorum requirements and the broad participation in ATI, the membership of the RMC has been expanded to now 10 Network PIs and 5 external members.

2.5.5 To ensure transparency, all research proposals awarded by the Network are disclosed, by PI as well as by project, on the Network's public website within 30 days of the funding decision.

2.5.6 To provide recourse for any PI who believes the RMC evaluation process is not functioning in a fair and transparent manner, the Board has implemented a complaint policy to allow those concerns to be heard and addressed.

3.0 Managing Conflicts of Interest on activities funded through SCN awards

3.1 The second class of decisions to be considered is those taken by researchers collectively or individually as to the use of Network research funds allocated to them by the Board.

3.2 In the first instance SCN researchers must be guided by the *Standard NCE Agreement* executed by both them and their institution as a condition of receiving SCN funds. The relevant paragraph (Appendix E) of the agreement essentially states that in undertaking SCN funded activities each researcher must follow the Conflict of

Interest rules of either their institution or of their relevant grant council, whichever is the more stringent.

- 3.3 However, in medicine and biomedical research in particular questions have been raised about whether new arrangements between investigators and research sponsors, and between public and private institutions raise potential conflicts that can be addressed procedurally by such strict disclosure requirements alone. Therefore SCN researchers are additionally required to review certain “Points to Consider” when determining whether it is appropriate for them to embark on or continue in collaborative ventures with for-profit, non-profit, or not-for profit organizations. The questions described in the Points to Consider were developed by the SCN Ethics Committee and relate to Consistency with the Mission and Mandate of the SCN; Public Accountability; Transparency; and the Distribution of Benefits. They are captured in the SCN Policy on *Conflicts of Interest and Commitment for Network PI*. (Appendix F)
- 3.4 There are additional mechanisms outside of the SCN that govern human embryonic stem cell research (hESC). Specifically, no researcher can undertake hESC research at any SCN funded institution without first gaining confirmation from CIHR’s stem cell oversight committee that the proposed research meets CIHR’s Guidelines for Pluripotent Stem Cell Research. (<http://www.cihr-irsc.gc.ca/e/28216.html>). As part of their approval process CIHR requires the ongoing disclosure of all agreements relating to the research, ranging from the consent forms of the gamete donors to any contracts with third party funders. CIHR reviews all such agreements for a multitude of issues including conflict of interest. SCN relies on this process for its due diligence on projects involving hESCs and, prior to the release of SCN funding, requires that a copy of the project approval letter from CIHR be provided to the SCN office.
- 3.5 In addition to CIHR, when the Assisted Human Reproduction Agency of Canada is formed (expected mid-2006), it will be responsible for granting licenses to undertake the derivation of new hESC lines. It is expected that AHRAC will follow a similar disclosure and review process to CIHR, and SCN will similarly require a copy of the approval letter from AHRAC.
- 3.6 Responsibility for the approval of clinical trials, including corporate involvement, rests with local Research Ethics Boards in Canada. Again the SCN relies upon this review process and requires that a copy of local REB approval be provided to the Network office before any funds that will support a clinical trial are released.

4.0 Review

This conflict of interest framework will be reviewed annually by the Ethics Committee of the Stem Cell Network, and recommendations for changes made to the Board of Directors of the SCN.



Annex C - Conflict of Interest Policy Framework

Interactions between university researchers and the private sector are an essential feature of the NCE program. For the objectives of the NCE program to be achieved, many kinds of interactions among individuals participating in the network must occur. These interactions may lead to gains and benefits to the individuals participating in the network and are desirable and natural outcomes of being involved in the network. Such interactions, however, may place individuals participating in the network in a position of potential, apparent or actual conflict of interest.

The NCE Steering Committee is the body ultimately responsible to the government, and therefore to taxpayers, for the integrity of all the networks and their operations. The responsibility for implementing and managing the Conflict of Interest Policy Framework, to ensure that network operations and decisions are not biased by conflict of interest, is delegated to each Network Board of Directors, which represents the highest authority in the management structure of the network. The Network Boards of Directors are accountable to the NCE Steering Committee for the effective implementation and management of the Conflict of Interest Policy Framework.

Individuals participating in the network such as members of the Boards of Directors and advisory committees who do not receive NCE funds are recognized as playing a unique role in the networks. They bring an important perspective as a result of their particular knowledge, often as representatives of organizations in the field of interest of the network. Nevertheless, they are still required to disclose any financial interest or position of influence, as described in Section 2.0, in any business in the same area of interest as the network, other than that of their main employer.

The Conflict of Interest Policy is intended to enable Network Boards of Directors and individuals to recognize and disclose situations that may be open to question and to ensure that such situations are appropriately resolved. The policy builds upon and is complementary to those of the organizations that make up the Network Boards of Directors, the network investigators and of the administrators.

1.0 Definitions

"Avoidance" means refraining from, or withdrawing from, participation in activities or situations that place an individual participating in the network in a potential, apparent or actual conflict of interest relative to his or her network duties and responsibilities.

"Conflict of interest" means a situation where, to the detriment or potential detriment of the network, an individual is, or may be, in a position to use research knowledge, authority or influence for personal or family gain (financial or other) or to benefit others.

"Disclosure" means the act of notifying in writing the Board of Directors, through the Network Manager, of any direct or indirect financial interests and positions of influence held by an individual participating in the network which could lead to a potential, apparent or actual conflict of interest.

"Divestment" means the sale at arm's length, or the placement in trust, of assets, where continued ownership by an individual participating in the network would constitute a potential, apparent or actual conflict of interest with the participant's network duties and responsibilities.

"Financial interest" means an interest in a business in the same area as the network as described in Section 2.1 of this document.

"NCE" means the federal Networks of Centres of Excellence program.

"NCE Steering Committee" means the committee comprised of the three granting agencies' Presidents and the Deputy Minister, Industry Canada, which has overall responsibility for the NCE program.

"Network" means a group funded under the federal Networks of Centres of Excellence program.

"Network Board of Directors" means the Board that is responsible for the overall management of the network and is accountable to the NCE Steering Committee.

"Network Manager" means the senior managerial employee of the network who reports to the Board of Directors.

"Position of influence" includes any position that entails responsibility for a material segment of the operation and/or management of a business.

2.0 Disclosure

Upon joining the network, each individual is obliged to disclose in writing to the Board of Directors, through the Network Manager, any direct or indirect financial interests and positions of influence that could lead to a potential, apparent or actual conflict of interest (examples provided in Attachment). In addition, these submissions must be updated whenever the individual's circumstances change in a way that would necessitate a further disclosure. The individual also has the obligation to disclose any potential, apparent or actual conflict of interest when it arises during network committee or Board meetings so that the committee or Board is aware of the situation and can take appropriate action.

2.1 Financial Interest

It consists of:

- Any material stock option (e.g., 1%) or similar ownership interest in such a business, but excluding any interest arising solely by reason of investment in

- such business by a mutual, pension, or other institutional investment fund over which the person does not exercise control; or
- Receipt of, or the right and potential to receive, any income from such a business, whether in the form of a fee (e.g., consulting), salary, allowance, interest in real or personal property, dividend, royalty derived from licensing of technology, rent, capital gain, real or personal property, or any other form of compensation or contractual relationship, or any combination thereof.

3.0 Management of Conflict of Interest

The Network Board of Directors or its conflict of interest sub-committee is charged with the responsibility of managing conflict of interest, and determining and implementing the appropriate course of action. This management system is based on disclosure, as described in Section 2. All disclosures constitute confidential information that will be available to the Network Board, or a sub-committee thereof, for the evaluation and resolution of any conflict of interest or allegations of conflict of interest brought before the Board or its conflict of interest sub-committee.

While it is recognized that it may be difficult to completely avoid situations of potential, apparent or actual conflict of interest, complete avoidance or divestment may be required in certain cases. Such divestment should not consist of a sale or transfer of assets to family members or other persons for the purpose of circumventing the conflict of interest compliance measures as directed by the Board.

3.1 Principles

An individual participating in the network who is involved with, or has an interest in, or deals in any manner with a third party which might cause a conflict of interest, will not be present and participate in any network decisions, including committee decisions, if the declared potential conflict of interest could influence the decision or actions of the network. It is the obligation of the individual to declare such potential, apparent or actual conflict of interest before discussions take place so that the committee or Network Board of Directors is aware of the situation in order to ensure that the individual is out of the room when the discussion and decision process on the item in question are taking place. This course of action should be recorded in the minutes of the meeting.

Any question raised by an individual or company regarding the potential conflict of interest of an individual will be raised at the Network Board of Directors level and must be documented in writing. The Network Board of Directors will determine the extent to which the question should be pursued and in such cases will consult the individual in question. If necessary, the individual will be asked to respond in writing.

3.2 Non-compliance

If an individual is discovered to be in conflict of interest where disclosure and prior approval have not been sought or granted, the Network Board of Directors will require the individual to:

- account to the network for any gain or benefit made directly or indirectly, arising from an involvement with, or an interest in, or from dealing in any manner with a third party that gives rise to a conflict of interest; **and**
- withdraw from the involvement; **or**
- withdraw from the Network; **or**
- take appropriate action as determined by the Board of Directors.

4.0 Review Process

An individual may request in writing, within 30 days, a review of a Network Board of Directors' decision on conflict of interest. In certain circumstances, the Network Board of Directors may arrange for an independent third party appointed by mutual agreement of the network and the Board of Directors, and failing such mutual agreement appointed by the NCE Steering Committee, to act as an intermediary to scrutinize scientific reports and budgetary information of research project(s) in which the individual participating in the network is involved. The intermediary would provide an opinion on the overall merit of the review, without divulging specifics of a proprietary nature to other members of the network. The ultimate decision on the resolution of the review rests with the Network Board of Directors.


In cases where there is a concern with respect to decisions or actions of the Network Board of Directors itself, this concern should be submitted in writing to the NCE Steering Committee. The NCE Steering Committee may request the Chair of the Network Board of Directors to respond in writing to the Steering Committee. Following submission of the Chair's response, the NCE Steering Committee will decide on follow-up action.

Examples of Conflict of Interest

The following examples, although not comprehensive, illustrate situations that may lead to an indirect or direct conflict of interest:

- employment in any capacity by another employer outside the participant's, administrator's or director's university, institution or company signing the Network Agreement, including self-employment;
- holding an office that puts the individual in a position to affect decisions, such as manager with executive powers, within a company, or member of a board of directors;
- participating in a research contract or consultancy relationship with a company, or serving on the board of a company;
- entering into a research contract with a company in which the participant, or a member of his or her immediate family, has a financial or other interest;
- carrying out supplementary professional scientific activities in accordance with the disclosure requirements of the participant's or director's employing organization;
- ownership of equity or other financial participation in a corporation (including stock options and shares). Participants, administrators and directors should abstain from activity in which they would have inside advantage (e.g., purchase of shares) based on the information they are privy to through membership in the Network;

- accepting gifts (other than some minor hospitality) or special favours for him or herself or a member of his or her family from private organizations with which the Network does business;
- influencing the purchase of equipment or materials for the Network from a company in which the participant, the administrator or the director has a financial or other interest.

	1. Corporate	Policy No: 1-001
Policy Title/Subject: Conflict of Interest in Governance of the Stem cell Network		
Effective Date: June 15, 2006	Reviewed Date: June 2006 By Ethics Committee	Approved by Board of Directors: Original version: March 6, 2002 Revision: June 19, 2006

1. PURPOSE

Individuals who hold positions of trust in a corporation have a legal duty to act honestly and in good faith with a view to the best interests of the corporation. This duty is referred to as a “fiduciary duty”.

As part of their fiduciary duty, directors and officers of a corporation have a duty to avoid actual or potential conflicts of interest between:

- their duties to the corporation; and
- their duties to others or their own self-interest.

Under the common law (the law as developed through judicial decisions over time), the prohibition against conflicts of interest is applied strictly. Any contract or arrangement entered into by a corporation in which a director or officer has an interest is voidable by the corporation, regardless of whether or not the contract or arrangement is to the benefit of the corporation. Furthermore, a director or officer who has profited from such a contract or arrangement must account to the corporation for such profits.

The Stem Cell Network (“SCN”) is a not-for-profit corporation organized under the *Canada Corporations Act* (the “CCA”). Directors and officers of the SCN are subject to the common law rules on conflicts of interest as set forth above. These rules are modified somewhat by the CCA, which permits directors of the SCN to have a conflict of interest provided that the director discloses the conflict and refrains from voting on the directors’ resolution approving the contract or arrangement at issue. In addition, as a Network of Centres of Excellence, Directors and Officers of the SCN are also subject to the Conflict of Interest Policy Framework established by the NCE Program.

This purpose of this policy is to summarise the specific Conflict of Interest requirements of the Stem Cell Network, and to set out the procedures adopted by the SCN to ensure these requirements are understood and complied with.

2. SCOPE

This policy applies to all members of the Board of the Stem Cell Network Board of Directors, and of any committee, sub-committee or task force of the Network (“SCN Committee”).

3. POLICY

The Stem Cell Network has adopted the NCE Conflict of Interest Policy Framework as the core component of its Conflict of Interest Policy. A copy of the NCE Framework is attached to these minutes as Schedule "A". The following specific policies supplement the NCE Framework. In all cases the same definitions as set out in the NCE Framework apply.

- The majority of the membership of the SCN Board and all of its subcommittees may not be comprised of persons with a collective financial interest in the same company.
- No meeting of the SCN Board or its subcommittees will have quorum if a majority of the participants in a given meeting have a collective financial interest in the same company.
- Where the SCN exercises control (as defined by CICA) over a for-profit corporation, no director of that for-profit corporation shall chair the SCN Board nor the SCN committee responsible for commercialization.
- The SCN will not take a financial interest (as defined by the NCE Conflict of Interest Framework) in any corporation commercializing SCN funded research.

4. PROCEDURES

The procedures set out below are designed to assist individuals participating in the SCN to comply with the requirements described above.

- 4.1. At the time of his or her appointment as a member of the Board of Directors or an SCN Committee, each new member shall review this Policy. Following such review, the new member shall complete the SCN's form of Conflict of Interest Declaration, a copy of which is attached hereto (the "Declaration"). In addition to the written Declaration, members shall declare their interests orally at a meeting of the Board or Committee. Members shall make disclosure annually at the first Board or Committee meeting following the SCN's Annual General Meeting, and thereafter from time to time as necessary. The meeting Chair shall remind Board/Committee members of their obligation at the outset of each meeting. The secretary of the meeting shall record disclosure of the interests of members in the minutes of the meeting during which disclosure occurs.
- 4.2. Board/Committee members shall update their Declarations annually. If circumstances change during the period of their appointment, Members shall immediately inform the Board/Committee Chair of the change in their situation.
- 4.3. A Board/Committee member in an actual conflict of interest shall absent himself or herself from that part of the meeting during which related matters are discussed, considered and/or voted on. The secretary of the meeting shall reflect the absence of the member in the minutes.
- 4.4. A Board/Committee member who has a potential conflict of interest shall declare it and shall seek the advice of the meeting Chair as necessary in exercising his or her discretion in regards to the potential conflict.
- 4.5. If any Board/Committee member objects that another Board/Committee member is in an actual or potential conflict of interest, or is not taking the appropriate steps to deal with the conflict, the meeting Chair will call for a vote of the Board/Committee to determine the appropriate course of action.

- 4.6. The SCN is conscious of the special role the Research Management Committee plays in the Network, and the degree of reliance placed by the SCN Board on the RMC for advice on funding decisions. As a consequence a number of additional policies and procedures relating to the activities of the RMC designed to ensure integrity and transparency in the research funding process. (Note the SCN has two funding mechanisms: Core Projects are multi-year, multi-investigator awards, typically exceeding \$500,000, for which a competition is held every 2-3 years. Catalyst Projects are one year awards for one or more PIs, with a maximum value of \$50,000, and applications are reviewed at each RMC meeting):
- a) An International Scientific Advisory Board (ISAB) has been established which, for every funding competition, provides an independent assessment and ranking of all Core Research Projects to both the Board and the RMC. Where the RMC deviates from these rankings in its funding advice it is required to provide a justification to the Board.
 - b) As a matter of course, any RMC member named on a Funding Proposal must recuse themselves from RMC evaluation and recommendations regarding that proposal.
 - c) Where a company is named as a material partner on a Funding Proposal, any RMC member with an individual financial interest in that company must recuse themselves from RMC evaluation and recommendations regarding that proposal.
 - d) To ensure transparency, all research proposals awarded by the Network will be disclosed, by PI as well as by project, on the Network's public website within 30 days of the funding decision.
 - e) In case a member of the SCN, or other individual(s) associated with the SCN in some capacity, believes that despite these measures SCN procedures governing the evaluation of a research project are not satisfactory, or the RMC may have behaved unethically granting/denying SCN funding, then the SCN will respond to these complaints in the following ways:
 1. For complaints regarding SCN procedures, the RMC will be alerted to the complaint, and with the Management team, will fully address the issue and if warranted, put in place corrective measures;
 2. For complaints by one SCN member that one or more has behaved unethically in obtaining/denying SCN funding, SCN management will:
 - a. require that the complaint be formal, in writing, and detailed;
 - b. freeze funding and expenditures on the project being contested;
 - c. submit all its records relevant to the situation to the SCN Ethics Committee for its opinion, and;
 - d. alert the Executive Committee of the Board of Directors of the issue at hand and obtain their opinion.

SCN management will then take these opinions into account, propose a plan on how to proceed, seek the approval of the Board Executive to implement the plan.

5. MONITORING

The Ethics Committee will review this policy annually and will report to the Board of Directors including any recommendations for changes or revisions, for consideration by the Board at the meeting preceding the Annual General Meeting.

6. DOCUMENTATION

NCE Conflict of Interest Policy Framework
SCN Declaration of Conflicts of Interest Form

7. Related policies:

SCN Policy CORP1-002 Conflicts of Interest and Commitment for Network PIs

Stem Cell Network Annual Conflict of Interest Declaration

Interactions between university researchers and the private sector are an essential feature of the National Centres of Excellence Program (“NCE Program”). For the objectives of the NCE Program to be achieved many kinds of interactions among the individuals participating in the Stem Cell Network (“SCN”) must occur. These interactions may lead to gains and benefits to the individuals participating in the SCN and are desirable and natural outcomes of being involved in the SCN. Such interactions, however, may place individuals participating in the SCN in a position of potential, apparent or actual conflict of interest.

Name: _____

Address: _____

Affiliation with the SCN (please select one):

Director ____ Officer ____

Committee Member ____ (please specify Committee name): _____

Other _____

Please review the following definitions used in this form. The definitions come from the SCN’s Conflict of Interest Policy, a copy of which is attached.

“Conflict of Interest” means a situation where, to the detriment or potential detriment of the SCN, an individual participating in the SCN is, or may be, in a position to use research knowledge, authority or influence for personal or family gain (financial or other) or to benefit others.

“Disclosure” means the act of notifying in writing the SCN Board of Directors, through the SCN Executive Director, of any direct or indirect financial interests and positions of influence held by an individual participating in the SCN which could lead to a potential, apparent or actual Conflict of Interest.

DECLARATION

I, the undersigned, (*print full name*) _____

(a) hereby declare and make Disclosure of the following actual or potential Conflict(s) of Interest which may arise in the conduct of my duties and responsibilities on behalf of the SCN (attach additional sheet if required).

OR

(b) am not aware of any actual or potential Conflict(s) of Interest with respect to my involvement with the SCN.

(initial) _____

I have read and understand the SCN Conflict of Interest Policy and will adhere to the Policy during my affiliation with the SCN. Specifically, if any circumstances change and/or come to my attention regarding any actual or potential Conflict of Interest, I will make Disclosure to the SCN immediately.

Signed: _____ Date: _____


Appendix D

As of March 31, 2007 the Stem Cell Network transferred control of Aggregate Therapeutics Inc. to the MaRS Discovery District (www.marsdd.com). The advice previously provided by Network Counsel is no longer directly relevant, and is being updated.

Appendix E- Extract from Standard Network Agreement executed by SCN Researchers and Institutions

D. CONFLICT OF INTEREST AND RESEARCH ETHICS

- a) The Network Investigator shall abide by the Tri-Council Policy Statement on Integrity in Research and Scholarship governing the use of grant funds and the conduct of research.
- b) Each Network Investigator shall abide by the provisions of his/her Participating Institution's policies and guidelines with respect to conflict of interest and conflict of commitment and by the provisions of the NCE Conflict of Interest Policy Framework, as outlined in the NCE Program Guide. To the extent that there may be a conflict between these policies, the more stringent requirements shall prevail.
- c) The Network Investigator shall be responsible for ensuring appropriate certification and/or institutional approval is obtained for their Network Research that involves human subjects, or requires the use of animals or biohazards.

	<p>1. Corporate</p>	<p>Policy No: 1-002</p>
<p>Policy Title/Subject: Conflicts of Interest & Commitment for Network PIs</p>		
<p>Effective Date: September 20, 2005</p>	<p>Reviewed Date: By Ethics Committee</p>	<p>Approved by Board of Directors: Original version: September 20, 2005 Revision:</p>

1. PURPOSE

“Conflict of Interest” has become a topic of intense public and professional discussion in recent years. Under the terms of the NCE’s standard Network agreement, Network PIs are required to follow the conflict of interest guidelines of their employing institution or the three Granting Councils, whichever is the more stringent.

However, in medicine and biomedical research in particular questions have been raised about whether new arrangements between investigators and research sponsors, and between public and private institutions raise potential conflicts that can be addressed procedurally by such strict disclosure requirements alone, or are so serious that they should be prevented altogether.

The SCN has adopted a “Points to Consider” approach that acknowledges these difficult issues, and guides researchers to careful consideration of all facts and values when following these existing procedural-based frameworks. This policy describes the Points to Consider, and the procedures that must be followed by SCN researchers to provide assurance to the SCN Board that these issues are being examined when appropriate.

2. SCOPE

The policy applies to Network researchers in all matters pertaining to their interactions with the Network (e.g. the commercialization of Network Supported Intellectual Property; entering into research contracts that will co-fund Network Projects).

3. POLICY

Network researchers are required to consider the following “Points to Consider” (3.1) when determining whether it is appropriate for them to embark on or continue in collaborative ventures with for-profit, non-profit, or not-for profit organizations. The questions described in the Points to Consider supplement the existing conflict of interest policies that researchers are required to follow under the terms of their Network agreement, and are intended to assist researchers identify areas of concern that should be taken into account in determining whether they are in a conflict of interest.

3.1 Points to Consider

Consistency with the Mission/Mandate of the SCN

The SCN mandate is to investigate the immense therapeutic potential of stem cells for the treatment of diseases currently incurable by conventional approaches. Researchers, regardless of the source of funding or opportunities presented, must adhere to basic principles of scientific integrity in all aspects of their work. For example:

- How will participation in the proposed venture promote or enhance SCN mandate?
- How will participation in the venture enhance the professional values of medical research?
- How will participation affect training and education of researchers?

Public Accountability

SCN Members play an important role in Canada's research community. As such they are expected to behave ethically. Particularly in the case of publicly supported ventures, like SCN, this standing in the community means that Members should be accountable for their actions. For example :

- How will these arrangements enhance (or at least, not hinder) the reputation of the SCN?
- Are mechanism(s) needed to provide the Canadian public with the assurance that any such ownership relationship will advance the mission of the Canadian stem cell research in general, and the SCN mission in particular?
- Is an exclusive relationship being sought?
- Is the Network being asked to endorse a product?
- Will the Network have appropriate control over media releases?

Transparency

No organization can establish policies and procedures that anticipate all issues. Indeed, in many instances, the best "policy" is no policy, so long as good judgment is exercised and can be described and explained openly. For example:

- Is the nature of the relationship between SCN Members and the proposed entity transparent to anyone who has an interest in it?
- What plans are there to inform patients/research participants of this relationship?

Distribution of Benefits

An important consideration in all research relationships is how the benefits arising will be distributed. In circumstances where SCN and/or its members collaborate with third parties, the idea of distribution of benefits is an important consideration. For example:

- What are the potential benefits arising from the proposed relationship?
- What plans, if any, are in place to distribute these benefits with the public?
- Is the distribution of benefits compatible with the incentives required to achieve the Network's objectives?

4. PROCEDURES

4.1 Every researcher is required, as part of their annual report to the SCN, to make a declaration that they have read and taken into consideration the Points to Consider, prior to submitting their annual report to SCN..

4.2 Where application of the Points to Consider in a specific context raises issues or concerns, researchers are required to bring the issues to the attention of their employing institution or Granting Council, as directed by with the relevant conflict of interest policy.

4.3 Where researchers require advice on the interpretation of these Points of Consider in a specific context, they may seek it from the SCN Ethics Committee, by notifying the SCN Executive Director.

5. MONITORING

The Ethics Committee will review this policy annually and will report to the Board of Directors including any recommendations for changes or revisions, for consideration by the Board at the meeting preceding the Annual General Meeting.

6. DOCUMENTATION

SCN PI Annual Reports

7. Related policies:

None