National Research Council Canada (NRC)

NRC Research Ethics Board (NRC-REB)

Standard Operating Procedures (SOPs)

1. GENERAL

The NRC Research Ethics Board (NRC-REB) helps NRC and its researchers maintain high standards in ethics in research involving human participants. These procedures support the work of the NRC-REB within the framework of the National Research Council (NRC) Policy for Research Involving Human Subjects (RIHS) (2014).

The Policy provides definitions of "research", "human participants", and "NRC involvement in research" as well as setting out expectations in respect to accountability, independence, and relevant Canadian standards as applied in this document.

The NRC-REB reports to NRC Senior Executive Committee (SEC) through the Secretary General and is responsible for:

- Reviewing applications for ethics approval of NRC research projects involving human participants;
- Advising the NRC management and individual researchers on ethical aspects of research involving human participants; and
- Providing a resource for education, guidance, and leadership in ethics relating to the conduct of research involving human participants at NRC.

Acronyms used in this document:

- NRC — National Research Council of Canada
- NRC-REB — NRC Research Ethics Board
- NRC-IRAP — NRC Industrial Research Assistance Program
- NRC-IRAP HE ITA — NRC-IRAP Human Ethics Industrial Technology Advisor
- PI — Principal Investigator
- TCPS 2 — *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2I*

2. NRC RESEARCH ETHICS BOARD MEMBERSHIP

Composition

The NRC-REB comprises:

- At least five (5) members in total
- At least one man and one woman
- At least two members with broad scientific expertise relevant to NRC
- At least one member knowledgeable in ethics; and
- At least one member knowledgeable in the relevant law; and
- At least one member external to NRC.

More than one of the areas of expertise in the list above may be satisfied in one individual.

Appointments

NRC-REB members and Chair are appointed by the NRC Secretary General. The Chair may or may not be an NRC employee and if not, may serve under contract with NRC. The Secretary General may appoint a Vice Chair to assume the responsibilities of the Chair in his or her temporary absence, or may appoint another NRC-REB member to assume these responsibilities on a per meeting basis.

The NRC Secretary General may also appoint alternate scientific, legal, or ethics experts or additional community members to be called upon, as needed, to provide expertise or to ensure meeting quorum.

Secretariat

The NRC-REB is supported by a secretariat reporting to the Secretary General.

Term of office

Members are usually appointed for a three-year term, though this term may be varied to allow for such factors as turnover and continuity. Appointments may be renewed.

Resignation

An NRC-REB member may resign from the Board by notifying the Chair, Secretariat, or Secretary General, in writing.

Vacancy

The NRC-REB Chair and/or Secretariat will inform the Secretary General if the NRC-REB membership is, or is expected to be, inadequate to meet the requirements for membership or the anticipated workloads.

Confidentiality

NRC-REB members are prohibited from disclosing any confidential information received in the context of their service on the Board. This applies to information received in writing or orally, including email correspondence, telephone calls, and presentations and print materials provided for Board meetings.

Conflict of interest

The NRC-REB shall abide by the "Conflict of Interest Considerations for NRC Research Ethics Board (NRC-REB) Protocol Review." Accordingly, NRC-REB members and staff shall declare any conflict of interest in relation to the consideration of any application and recuse themselves from consideration of applications in which the conflict is identified or seek the decision of the Chair as to whether they should recuse themselves. At the discretion of the Chair, any such member with relevant information or expertise may take part in initial discussions in order to provide information and background on the research project. However, that member shall be absent for the substantive deliberation and voting.

Indemnification of NRC-REB members

NRC-REB members are indemnified by NRC against third-party claims in accordance with relevant NRC and government policies.

Language

The NRC-REB shall review documents in either official language. Communication with applicants should always be in the official language of their choice. Meetings shall be conducted in a manner that encourages participants to express themselves in the official language of their choice.

List of members

NRC publishes the names and affiliations of the members of the NRC-REB on the NRC web site.

3. NRC IRAP HE ITAs and Portfolio Human Ethics Advisors

NRC-IRAP may appoint HE ITAs to meet operational requirements. These persons, who normally undertake this role in addition to other duties, provide support to their NRC-IRAP colleagues, advise NRC-IRAP clients, and act as a liaison between their program and the NRC-REB.

Their responsibilities include:

- Providing a resource for education and assistance to NRC-IRAP staff and investigators with NRC client firms that are planning research involving human participants;
- Working with the NRC-REB to ensure compliance with NRC's policies and procedures; and
- Working with the NRC-REB to establish criteria for the various levels of ethics consideration of human participant proposals and to review and adapt these criteria as needed.

HE ITAs work closely with the NRC-REB Chair and the NRC-REB Secretariat, receive copies of NRC-REB minutes, and are welcome to observe any NRC-REB meeting if they are not members of the NRC-REB.

The management of any NRC research portfolio may also identify a researcher or other officer to act in a similar liaison and advisory capacity within their portfolio with or without specific designation or defined authorities under these procedures.

4. APPLICATIONS FOR ETHICS APPROVAL

All NRC researchers proposing research involving human participants must make formal application for ethics approval from the NRC-REB, following the procedures set out below. A research project may not proceed to stages involving human participants before the NRC-REB has given its approval. Annex I provides a list of activities that do not require NRC- REB review.

Enquiries about human participant research projects

The Chair, Secretariat and HE ITAs welcome enquiries and questions about projects at any stage of their development or on-going conduct. However, no advice given in response to such enquiries may pre-empt the independence of the NRC-REB in its decision-making.

NRC-REB Address

All communications with the NRC-REB are made through:

NRC-REB Secretariat
National Research Council Canada
Building M-58
1200 Montreal Road
Ottawa, Ontario
Canada K1A 0R6

Email: REB-CER@nrc-cnrc.gc.ca

5. DOCUMENTATION FOR ETHICS APPLICATIONS

Applications for ethics review shall normally use the templates provided by the NRC-REB (available on the NRC public web-site). The NRC-REB may accept applications using the forms of another organization that has or will review the project, so long as it provides the same information as the relevant NRC template. In any event, Part 1 – Signature Page of the NRC-REB's application form must be completed and submitted with the other documentation. If the other REB has already rendered its decision, a copy of all related correspondence shall be included with the application.

Documents may be submitted electronically or in hard copy

PART 1 - Signature Page

Applications for all NRC research projects must identify and be signed by:

1. The Principal Investigator (PI)

   This signature certifies that:
   a) The submission accurately describes the proposed project;
   b) The PI accepts full responsibility for performing the proposed research in accord with NRC's policies, the requirements of the NRC-REB, and the commitments made in the application as approved by the NRC-REB.

2. The NRC Scientific Manager:

   The management of each NRC portfolio and program shall identify the appropriate person(s) for this responsibility. For NRC laboratory research, the relevant portfolio Research Director would normally fill this role. For NRC-IRAP projects, the Lead ITA would normally fill this role.

This signature certifies, on behalf of the portfolio or program, that:

a) The proposed research has been assessed by NRC's scientific review processes and has been found to meet NRC's scientific standards;
b) The safety of the proposed research has been evaluated and the risk to human participants meets the portfolio or program's standards;
c) The study team is competent to carry out the research in accordance with high standards of science and ethics; and
d) The needed funds and other resources will be available for the research.

Applications for projects not carried out by NRC employees must identify and be signed by:

1. The Chief Executive Officer or delegate of the organization that is performing the research. This signature certifies that the organization accepts responsibility for performing the proposed research in accordance with NRC's policies, the requirements of the NRC-REB and the commitments made in the application as approved by the NRC-REB.

2. The NRC collaborating investigator: The NRC representative who works directly with the PI must sign to certify co-responsibility with the Principal Investigator. For NRC-IRAP projects, this person should be the HE ITA.

PART 2 - Project Description

The human participant study being proposed must be described in terms that would be understandable by individuals with varied backgrounds as per the prescribed membership of the NRC-REB, recognizing that most members may not be familiar with technical concepts or terminology. This description should be prepared using the NRC-REB template or an equivalent template that provides the same range of information.

PART 3 - Consent Documentation

The information and consent documentation that is proposed for purposes of informing potential human participants about the activity and seeking their consent to participate (as research participants) should be prepared using the appropriate NRC-REB template or an equivalent template.

PART 4 - Other Information

Any other relevant documents should also be included with the application. Examples of such documents include: recruitment materials, scientific or technical protocols; terms and conditions and other documents that will be presented to participants as part of the research; technical documentation on products to be tested; documents required by regulatory authorities (e.g. Health Canada requirements for detailed documentation on pharmaceuticals, biologics, and medical devices).

6. PROCESSING OF APPLICATIONS

Correspondence with applicants

Correspondence from the NRC-REB shall normally be addressed to the PI and NRC Scientific Manager and copied to all others identified in Part 1 of the application.

Review of completeness of the application

The NRC-REB Secretariat shall promptly (one to six business days) review the application and check for completeness. If needed items are missing or inadequate, the Secretariat shall request completion. An incomplete application may, at the Secretariat's discretion, be sent for review on the condition that the full documentation can be received in time for the meeting or teleconference or, in the case of minor administrative matters, before a decision is rendered.

Notification of Receipt of Application

The NRC-REB Secretariat shall promptly acknowledge receipt of an application and inform the PI of the level of review that is planned and of any deficiencies in the documentation provided (one to six business days).

Record keeping

The NRC-REB Secretariat shall maintain a file with a unique numerical identifier for each project submitted to the NRC REB. All correspondence relating to a project should use this file identifier.

Access to Information and Privacy Acts

All NRC-REB records are subject to the provisions of the federal Access to Information Act and Privacy Act.

7. REVIEW OF APPLICATIONS

There are four possible levels of review of an application:

- Review by the Full Board
- Delegated review by a Sub-Committee
- Delegated review by the Chair
- Delegated review by the NRC-IRAP HE ITA

All applications shall be reviewed by the Full Board unless they are eligible for delegated Sub-Committee, delegated Chair review or delegated review by the HE ITA as described in this document. Projects involving only human tissues, images or data may be submitted using a simplified application form and may be reviewed by the Chair or a Sub-committee in accordance with the provisions described below.

The NRC-REB may use the Full Board even if all the eligibility criteria for Chair or Sub-Committee Review have been met when, for example, an application is received as final preparations are being made for a full Board meeting; or when any member of the Board requests review by the Full Board.

NRC-REB Review of Decisions Made on Behalf of the Board

All decisions taken by a Sub-Committee, the Chair or an HE ITA on behalf of the NRC-REB shall be reported to the NRC-REB Secretariat which shall provide a summary of these reports to the NRC-REB at its next meeting.

The collected decisions shall be examined by the NRC-REB on a regular basis, but no decisions made on behalf of the NRC-REB, pursuant to the NRC RIHS Policy and these procedures shall be overturned provided those decisions were made and reported in accordance with these procedures.

7.1 Review by the Full Board

REB meeting schedules

The NRC-REB normally schedules monthly meetings on a fixed day of the month except December and July, though meetings may be cancelled in the absence of projects to review, or re-scheduled as needed. A schedule of meetings, and submission deadlines related to meetings, shall be posted on the NRC website.

Applications requiring full NRC-REB review are considered at formally scheduled NRC-REB meetings. In exceptional circumstances (during months when no NRC-REB meetings are scheduled or in response to unforeseeable urgent situations), the Chair may convene a special NRC-REB meeting, by electronic means if necessary, provided that requirements for factors such as a quorum and time for members to consider the application are satisfied.

Agenda for NRC-REB meetings

The Chair, with advice from the Secretariat, shall determine the agenda approximately two (2) weeks before the meeting.

Providing agenda materials to members

The Secretariat provides as much of the agenda materials as possible to NRC-REB members at least seven (7) working days before the meeting.

Quorum for Full Board meeting

The quorum shall be five (5) members and shall include expertise relevant to the applications to be considered as determined by the Chair. Again, more than one of the needed areas of expertise may be satisfied by one individual. Quorum shall be noted in the meeting minutes. Participation can be in-person or by teleconference. In advance of the meeting, the NRC-REB Secretariat shall send the completed applications to be reviewed to all members of the NRC-REB requesting such materials and members anticipating their absence from the meeting may provide comments to the Chair.

Attendance using electronic technology

NRC-REB members may participate in meetings through electronic communication including web-based audio, videoconference, teleconference or similar means.

Attendance by applicants, HE ITA at NRC-REB meetings

The PI and/or the relevant HE ITA are encouraged to attend the part of the NRC-REB meeting that considers their application to clarify information and respond to questions, in person or through electronic conferencing means.

Ad hoc advice

The NRC-REB may seek advice from non-member NRC employees or other experts on specific applications or issues. Such advisors are subject to NRC's policies on confidentiality and conflict of interest, and do not vote on NRC-REB decisions.

Discussion of the application at the NRC-REB

The Chair leads discussion of the application by the Board. Board members and ad hoc advisors discuss any issues that need to be raised with the PI and the HE ITA. When the Board members are satisfied that they have the information that they need, the PI leaves the meeting. At the discretion of the Chair, the HE ITA may be present for an entire meeting.

NRC-REB decisions

After excusing applicants and any members with a conflict of interest, the Board continues the discussion to arrive at a decision. The NRC- REB may:

- Approve the application as submitted
- Determine that the application may be approved with only minor changes, with responses sent for approval to the Chair
- Determine that the application may be approved with major changes; with responses to be reviewed by the full Board; or
- Disapprove the application and invite a full re-application that addresses the concerns identified by the Board in its review.

The Chair summarizes the discussion and seeks agreement at the meeting. When deemed helpful to NRC-REB functions, the Chair may prepare a draft letter to the applicant after the meeting, email it to members seeking their comments.

In all cases, the substance of the letter to the applicant, once sent, is added to the meeting minutes as the record of decision.

7.2 Projects eligible for Review by the Chair.

The Chair is authorized to review and approve projects in the circumstances described below.

The proposed research:

- poses no greater than minimal risk, that is, the risks of participating in the research are no greater than those of day-to-day life of participants; and
- will recruit only research participants that are capable of giving their own free and informed consent; and
- involves minimal potential conflicts of interest by the Principal Investigator and the study team, which are effectively managed.

Or,

The proposed research

- involves only the secondary use of non-identifiable data, biological samples or images.

Or,

The proposed research

- involves a collaboration by NRC employees in a project carried out in the collaborator's institution and has received approval from a REB of the partner institution that is compliant with the applicable requirements of the TCPS 2 and Health Canada regulations; and in such cases, the NRC researchers shall provide the approved protocol, consent form and recruiting documents along with the approval letter and other relevant correspondence from the approving REB.

Specifically Approved Circumstances

- A research team that employs an essentially constant research design for a series of projects that involve minimal risk and non-vulnerable participants may seek NRC-REB approval of a "generic application and consent form" to expedite their work. Once the generic forms have been approved by the full NRC-REB, the Chair is authorized to approve the specific projects, basing the decision on whether the project is consistent with the approved generic forms.

- The Chair may also review and approve minimal risk research (as otherwise described above) involving minors or others not capable of giving their own consent when the Chair determines that the rights and welfare of such participants will not be significantly impaired.

7.3 Review by Sub-Committee

Selection of Sub-Committee members

The sub-committee is selected by the Chair and normally consists of the Chair and two members. The NRC-REB Secretariat checks with selected members for their ability to participate in a teleconference within one (1) week after receipt of the documents by the reviewers.

Procedures for Sub-Committee review

The NRC-REB Secretariat shall send the complete application to all members of the NRC-REB, and identifies the selected Sub-Committee members. Any other member may request to be on the Sub-Committee and offer comments, or may request that the application be reviewed by the Full Board.

Sub-Committee members first review the materials to determine whether they agree that the application is eligible for Sub-Committee review. If all members accept review by Sub-Committee, written comments will be submitted and, if requested by any member, a teleconference shall be scheduled to review the application.

Other situations eligible for Sub-Committee review

The NRC-REB may also use a sub-committee, at the discretion of the Chair, to review the responses to NRC-REB concerns, requests for renewal of NRC-REB approvals, reports of adverse events, proposed amendments, and project termination reports.

7.4 Projects eligible for Review by the HE ITA

An HE ITA may approve a project under the following circumstances:

- NRC's involvement is limited to providing funds
- No NRC personnel or facilities are involved in the project; and
- The project has been approved and is subject to on-going review by an REB that is compliant with the requirements of the TCPS 2 and Health Canada regulations, as applicable.

When a project is reviewed and approved by a TCPS 2 compliant external REB and the relevant documentation is submitted to the HE ITAs, the client will be informed the project is approved and may proceed.

However, in order to ensure that the NRC-REB is appropriately informed of all ethics review decisions, HE ITAs shall at the same time:

- Send the project protocol
- Consent form
- HE ITA attestation that all necessary documents have been received and reviewed; and
- The REB approval letter to the NRC-REB Secretariat for record keeping and reporting.

The HE ITA shall also submit to the NRC-REB all subsequent correspondence, amendments, notices, renewal and study closure documentation relating to the project sent to or received from the approving REB.

8. ADDRESSING CONCERNS RAISED BY THE REVIEW

Notification of NRC-REB decisions

The Chair may authorize the Secretariat to sign letters or memos on his/her behalf, and also to inform the applicant(s) informally by phone or e-mail of NRC-REB decisions.

Correspondence identifying concerns about an application submitted for ethics approval of research within an NRC laboratory is addressed to the Principal Investigator, with copies to all others who signed the application. For NRC-IRAP projects, correspondence is addressed to the NRC scientific manager identified in Part 1 of the application and is copied electronically to all others identified in Part 1 of the application.

Applicants are normally notified of any concerns raised by the NRC-REB within five (5) working days of the decision of the NRC-REB or Sub-Committee. The notification letter identifies any concerns raised in the NRC-REB review and invites responses, in writing, to each of the issues raised. Applicants shall submit the revised documents indicating any changes made (by "track

changes" or other similar means) to the original documentation together with a "clean" copy of the new text.

If modifications are required to any aspect of the application before it can be approved, the Chair, the Secretariat and HE ITA may help the applicant(s) to address the issues raised and help to work towards an acceptable resolution.

When the NRC-REB has found an application to be unacceptable, an entirely new application without reference to the previous one should be submitted.

Consideration of applicant responses

Responses by the applicant to concerns, issues or questions raised in the review are considered according to the mechanisms decided upon by the NRC-REB. When Sub-Committee review of revisions is appropriate, the process is similar to Sub-Committee review of an initial application. The Sub-Committee may approve revised applications, request further modifications, or refer the revised application back to the NRC-REB. When full NRC-REB review of modifications is determined, the modifications may be considered by electronic means or at the next NRC-REB meeting.

Notification of Ethics Approval

The NRC-REB Chair is authorized to directly notify the researchers of ethics approval of applications that are eligible for Sub-Committee, Chair, or Full Board Review.

The notification states that ethics approval is given for a period, which may be no longer than one (1) year, and that all human participant researches must cease unless renewal of ethics approval has been given in response to a formal application. The Notification also sets out any other conditions of approval, for example:

- Establishment of a data and safety monitoring board
- Establishment of stopping rules or other periodic reviews of the accumulating data
- Specific monitoring of aspects such as consent processes, or random audits of data
- Limitation of participant enrolment to allow re-evaluation on the basis of initial results; or
- Approval for less than one year.

9. APPEALS OF NRC-REB DECISIONS

An investigator who disagrees with the position taken by the NRC-REB should first discuss the issue with the REB Chair, who can act on behalf of the NRC-REB, and both the NRC-REB and the investigator should seek a mutually agreeable resolution. In the event of an impasse, the applicant may appeal to the Secretary General who may consider the merits of the appeal and

rule on it on a procedural basis, possibly requesting reconsideration by the NRC-REB, or may appoint a special appeal committee.

An appeal committee is composed of three persons, none of whom shall be a current member of the REB: one member is knowledgeable in law or procedural issues; and one member is knowledgeable in ethics of research involving human participants. The last member may be an administrator, a scientist or a community member. At least one of the committee members should be external to NRC.

Alternatively, the Secretary-General may enter into an arrangement with another TCPS 2 compliant REB to serve as it an appeal committee for the NRC-REB, and may enter into a reciprocal arrangement whereby NRC-REB and the other REB will serve as an appeal body, each for the other.

For purposes of the appeal, the appeal committee has the same review powers as the full NRC-REB as described above. In addition, the appeal committee may:

1) Recommend that the original NRC-REB decision be made void and direct the NRC-REB to reconsider the application on the basis of such terms as the appeal committee may recommend; or

2) In the case of protocols reviewed by delegated review, direct the investigator to submit the protocol, as a new submission, for review by the full NRC-REB.

The Secretary General will normally advise those making such an appeal of the process to be pursued in the matter within twenty (20) days.

10. CONTINUING ETHICS REVIEW

Minimum requirements

The PI or others responsible for research projects given ethics approval by NRC-REB shall comply with the following requirements to maintain continuing ethics approval.

- Notify the REB of any new information that could change the basis for the NRC-REB's ethics approval
- Notify the REB of any proposed amendments to the project as approved by the NRC-REB
- Notify the REB of any adverse events or unexpected outcomes involving the safety of participants
- Provide an annual (or earlier) renewal report as below
- Provide a final report at the conclusion of the project.

Annual renewal

The NRC-REB gives ethics approval for a maximum of one (1) year. In some cases, the NRC- REB may give its approval for a shorter period. In the absence of a current valid NRC-REB ethics approval, all research involving human participants must cease, except for continuing treatment of participants already started on medication or in other situations in which the safety of participants would be compromised.

To continue the project beyond the period approved by the NRC-REB, a request for renewal must be submitted using the Request for Renewal of Human Subject Ethics Approval form, or equivalent. The application for renewal should be submitted in time for consideration by the NRC-REB before expiry of the current approval. The NRC-REB Secretariat normally advises the applicant approximately one (1) month before the need for renewal of approval.

In accordance with the appropriate level of review, the Chair may review and approve the request of renewal or may refer it to Sub- Committee or to the full Board.

New information that could change the basis for NRC-REB's approval

The PI must immediately report to the NRC-REB any new information from the literature or from observations made during the research that could substantially change the considerations on which the NRC-REB based its ethics approval. The PI must also immediately report to the NRC-REB any sanctions imposed on the study by, for example, any regulatory agencies or bodies, trial monitors, or auditors.

The NRC-REB may request further documentation for this reconsideration. The Chair shall consider a report of new information using the appropriate level of ethics review.

Amendments to the project

The PI must propose appropriate amendments to the research or consent documents approved by the NRC-REB required as a result of new information or that involve a change to the risks and benefits to participants or change that might reasonably affect a participant’s willingness to consent, or continue to consent to participate.

These proposed amendments may not be implemented before they have been approved by the NRC-REB, unless they involve the immediate safety of the research participants in the project.

New participants may not be recruited until the NRC-REB has approved the amendment if the proposed amendments deal with a matter of patient safety or the information that is provided to potential participants.

The Secretariat shall promptly inform the Chair of receipt of a proposed amendment. The Chair determines the timeline of review needed for NRC-REB consideration. The Secretariat shall also

promptly acknowledge receipt of the proposed amendment, and indicate whether the documents submitted are sufficient for consideration, the extent to which the research may proceed pending its consideration, and the anticipated time for completion of the review.

Adverse events

A reportable adverse event is any untoward medical occurrence experienced by a research participant temporally associated with the use of an investigational intervention, whether or not the event is known to be related to the investigational intervention.

All serious adverse events (deaths, serious illnesses, hospitalizations) must be reported to the NRC-REB within forty-eight (48) hours. Other adverse events, if unexpected or occuring at a higher frequency than expected and that cause significant discomfort or stress to human participants, must be reported within fourteen (14) days. Reports of serious and/or unexpected adverse events should be reported together with an assessment of the impact(s) on the ethics of the research, and amendments that are proposed to either the project or the consent information to address the issue.

All adverse events must also be reported at the next request for renewal of NRC-REB approval, or in the termination report, whichever comes first.

Reports of adverse events shall, at the discretion of the Chair, be reviewed by the Chair, a sub-committee or the Full Board as appropriate in the light of the nature and severity of the adverse event reported.

Determining need for continuing ethics review

For projects in which the PI foresees the need for continuing ethics review in addition to those described as minimal requirements, the approval shall stipulate appropriate mechanisms of continuing ethics review of the research project as it is carried out. These mechanisms form part of the conditions upon which ethics approval of the project is based.

Termination Report

The PI must notify the NRC-REB that a project has been finished within a month of completion of the project, using the Termination report form provided by the NRC-REB Secretariat. Each project continues on the NRC-REB's files until notice of completion of the project is received and acknowledged.

Annex 1

Activities that do not need an NRC-REB review

Sensory Food Panels

- A project is exempt from NRC-REB Review if it is designed only to assess the sensory characteristics of a food, defined by the Food and Drugs Act (1953) as:
  "... any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatsoever."

The foods to be considered in this context are basic foods for which no health benefits are to be claimed and that contain permitted additives not exceeding recommended daily allowance guidelines normally associated with those foods. Sensory evaluation of foods for which health benefits will be claimed or tested shall be reviewed by the Full Board or sub- committee (or an external REB for NRC-IRAP Projects).

Anonymous or anonymized established cell lines

A project that uses anonymous, established cell lines obtained from a collection or another researcher that meet the following conditions is exempt from REB review:

- The cell lines cannot be linked to the individual from whom the tissue was originally obtained; and are broadly available to researchers.

Quality assessment, performance evaluation, and tasks that fall within normal employee responsibility

Projects of the kind listed above (and meeting the requirements as described in the TCPS 2 criteria) are normally exempt from NRC-REB review unless they clearly contain an element of research which may need ethics review.

Anonymous Market Surveys of Products & Services

A project is a market survey exempt from REB review when:

- Potential participants are competent adults; and
- Only the final cumulated data, without identifiers, will be released to the sponsoring organization.

When in doubt

The person leading the project should apply for advice in writing to the NRC-REB Secretariat describing:

- The activity to be undertaken
- The group (s) from which participants in the activity will be drawn; and
- His or her responsibilities within the organization and the relevant operating procedures.