Association Bilateral Meeting – Cell Therapy Stakeholder Group - Meeting Minutes - 2017-12-07

Bilateral meeting between Cell Therapy Stakeholder Group and BGTD-Health Canada

Thursday, December 7, 2017
1:00 to 4:00pm
100 Eglantine Driveway, Ottawa, Ontario

1. Attendees

Cell Therapy Stakeholders Group participants

Sowmya Viswanathan, (Co-Chair), Craig Hasilo, Martin Giroux, Gayle Piat, David Courtman, Friederike Pfau, Sandra Donaldson, Duncan Stewart, Denis-Claude Roy, Patrick Bedford, *Attending via Teleconference:* Olive Sturtevant, Karen Nichols, Deborah Griffin, Lynn Csontos, Sita Somara, Erika Kleiderman

Health Canada participants

Catherine Parker (Co-Chair), Lindsay Elmgren, Francisca Agbanyo, Ariel Arias, Gina Coleman, Anthony Ridgway, Agnes Klein, Daniel Keene, Hugo Hamel, Jian Wang, Georgette Roy, Christopher Antonio, Marie-Noël Deschambeault, Nadine Kolas, Andrea Bedard, Julie Chateauvert, Gina Radic, Maya Berci, Joelle Pinsonnault Cooper, Deborah Ashby, Wendy Burgess, Canadian Institutes of Health Research (CIHR)

2. Welcome and Introductions

Catherine Parker welcomed everyone to the meeting and noted that the agenda was quite full of significant items. BGTD is very grateful for the opportunity to meet with the Cell Therapy Stakeholder group (CTSG) as their work is a critical part of BGTD's workload. It's an exciting time for HPFB with particular emphasis on targeted funding and access to affordable medicines and therapies.

Sowmya Viswanathan thanked Health Canada on behalf of the CTSG and said that they very much welcome and enjoy these meetings. It's an exciting time in the cell and gene therapy field and they are looking forward to exchanging information.

3. Review of Agenda

Several items were moved around in the agenda. The order in which they occurred is represented in these minutes.

4. Updated Terms of Reference

C. Parker addressed the revised Terms of Reference and reiterated that the meeting was not meant to serve as discussion on any specific submissions, but rather general issues. Karen Nichols agreed, saying it is not a substitute for sponsors to speak to Health Canada, but rather an educational opportunity.

Nadine Kolas walked everyone through the proposed changes, noting that the roles and responsibilities should be looked at carefully and all members should understand their respective roles. The group should be open and transparent. Each group should have one point of contact, although multiple members may participate at the meetings.

The Terms of Reference with Health Canada does not preclude the stakeholder group from having a Terms of Reference to govern interaction and information sharing amongst themselves.

Craig Hasilo said that the formation of this group was important, especially for the manufacturers across the country. It's also important that we not lose the Pan-Canadian voice. Our mandate is to represent cell and gene manufacturers. We want to make sure there's adequate feedback.

N. Kolas added that the group would not be closed to anyone, including other non-profits. CTSG asked if the focus should go to advanced cell and gene therapies. Anthony Ridgway said that there is certainly overlap in the types of information. Not all gene therapies are cell therapies but some are and there are overlapping considerations. It was noted that as long as a gene therapy is cell- based it was already covered by the stakeholders from CellCAN, ISCT, RMAC and CCRM present at this meeting, and there wasn't a need for new call for members based on that. Gene therapy that is not cell-based was considered outside the scope of this committee.

David Courtman said that the groups should try to get input from others like the Multiple Sclerosis Society. Maybe we all have an obligation to talk to others and come back here. C. Parker said that Health Canada has a communication network with patient groups. All members of the stakeholder group should reach out to the community. The content of the meetings is considered to be public knowledge. CellCAN announces that the minutes of the stakeholder meetings are now publicly available online.

N. Kolas asked that members reflect on the role and responsibilities outlined in the Terms of Reference for the stakeholder co-chair. The stakeholder co-chair should be equipped to fulfill the agreed upon duties, which include knowledge sharing and information gathering. The CTSG should reflect on which groups are best equipped to fulfil these roles and may also wish to reflect on whether they would like to nominate a chair on a rotating basis.

D. Courtman said that S. Viswanathan was doing a great job as co-chair. There have been several rounds of internal discussion amongst CellCAN, ISCT and RMAC and Sowmya Viswanathan has been selected to continue her role and contribution as co-chair from the stakeholders. S. Viswanathan said that having ISCT as a co-chair has worked very well and a valuable way to get their input and hope it can continue. It is agreed by the stakeholder group that the co-chairs continue to be Sowmya Viswanathan and Olive Sturtevant. The representative of RMAC supports that decision.

Sandra Donaldson affirmed that RMAC wishes to keep S. Viswanathan as co-chair for the CTSG.

C. Hasilo expressed that CellCAN wishes to keep S. Viswanathan as co-chair for the CTSG for another term.

Action item: All members must agree on the ToR before it becomes finalized. Comments are due January 15, 2018.

5. Metrics related to cell therapies

Georgette Roy provided a list of gene/cell therapy Clinical Trial Applications (CTAs) issued a No Objection Letter (NOL) as of October 12, 2017, listing the sponsor, product, date of NOL issuance, and the clinical protocol.

C. Parker clarified that a Notice of Compliance (NOC) or Notice of Compliance with Conditions (NOC/c) are determined depending on the amount of data available. The NOC/c has previously been a policy, not enforceable through regulations. However, Health Canada now has legislative power to put terms and conditions to require additional tests and/or studies. A. Ridgeway said that this is a case by case issue. C. Parker suggested a workshop on this.

N. Kolas said that Health Canada has done analysis related to orphan drugs and accelerated pathways and has found that Health Canada remains competitive with the European Medicines Agency (EMA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and the US Food and Drug Administration (FDA), despite the lack of designated pathways intended to accelerate regenerative medicines and/or orphan drugs. Health Canada has the ability to have as many pre-submission meetings as required, without charge. This may shorten the time of the issuance of a NOL. Canada also has a diverse patient population and short time between issuance of an NOL and clinical trial start-up. Taken together, Canada remains competitive with countries such as Japan but greater awareness amongst industry stakeholders is needed. It was suggested that CellCAN and the CTSG could help champion this message and disseminate to the greater community.

Patrick Bedford said that people are choosing to get treatment in Japan where they have government, industry and regulations advocating the use of their special (accelerated)pathways. Recognising that part of Health Canada's mandate is to support health decision-making, he suggested that there may be an opportunity for Health Canada to work with this stakeholder community to highlight benefits of conducting trials in Canada. With respect to open cases related to autologous cell therapies, there are many misconceptions that stem cell therapies are safe or "natural" since they come from the body and that they are effective. There may be an opportunity for CTSG to address this ongoing issue through knowledge translation initiatives that promote awareness of clinicians and the general public.

P. Bedford suggested this would be an area that would benefit from clear communication from Health Canada. S. Viswanathan said that in October 2017, a paper was authored with a series of recommendations stemming from a workshop they had in March. N. Kolas highlighted that while the paper addressed minimally manipulated and homologous use of autologous cell therapy products, the issue at hand is related to more than minimally manipulated and/or non-homologous uses.

Action item: CTSG to share this paper with BGTD.

C. Parker said with regard to stem cell tourism, it's definitely a challenge as almost no legal action can be taken and would have to work it into the Criminal Code. Stem cell tourism definition is a patient leaving (or entering from other countries) the host country to receive treatment. The focus of this type of tourism is the unproven cell therapy. There is currently no legal action possible. *S. Viswanathan clarified that there will be an agenda item from ISCT's Presidential Task Force speaking to the global issue of stem cell tourism at the next CTSG meeting.* P. Bedford highlighted that other groups (PHAC) have issued communication on organ tourism in the past, and this might help to alter behaviour.

6. New Substances Notification Regulations

T. Bubela brought forward the issue of New Substances Notification Regulations and requested that Health Canada provide feedback on a draft white paper.

D. Ashby, from the Healthy Environments and Consumer Safety Branch of Health Canada, provided an overview of the New Substances Notification Regulations (NSNR) under the Canadian Environmental Protection Act, 1999 (CEPA 1999) and clarified some misinterpretations in the draft white paper. CEPA 1999 is an important part of Canada's federal environmental legislation aimed at preventing pollution and protecting the environment and human health. It outlines the Domestic Substances List as the sole basis for determining whether a substance is new for the purposes of CEPA and the NSNRs.

There are two *New Substances Notifications Regulations (NSNRs)*:

- *The New Substances Notifications Regulations (Organisms)*
    - *Organisms other than Micro-organisms;*
    - *Micro-organisms (including viral vectors, cultured cells etc.)*
- *The New Substances Notifications Regulations (Chemicals and Polymers)*
    - *Chemical;*
    - *Biochemical;*
    - *Polymers;*
    - *Biopolymers.*

New Substance Provisions ensures that no new substance is introduced into the Canadian marketplace before an assessment of its potential risks to the environment and human health has been completed. As it relates to biologic drugs, products such as vaccines (sub-unit) and enzymes are subject to the NSNR (Chemicals and Polymers). Certain mass limits must be met in order to trigger these regulations. Most biologics are not manufactured at sufficient quantity to trigger these regulations, particularly during the CTA stage of development. However, in the case of cell therapies **including unmodified** and those that are genetically modified using non-replicating viral vectors, these products trigger an Environmental Assessment under the NSNR (Organisms) when they are manufactured or imported in any amount. While options are being explored by Health Canada at this time, these products must be notified to HECSB, including at the CTA stage of development.

General advice:

- **Waivers:**
    - Only useful for info requirements requiring data:

        - Data on effects on aquatic and terrestrial plant, invertebrate, vertebrate (need 6 separate waiver rationales).
        - Antibiotic susceptibility (if virus notified, can provide antiviral susceptibility data instead of waiver).
        - Data from tests of pathogenicity valid for organisms pathogenic to humans.
    - Waiver can be requested under paragraph 106(8)(a) of CEPA (*i.e.*, the information is not needed in order to determine if the organism is toxic).
- **Surrogates:**
    - Information can be provided on surrogate organism (wild type, parent strain, species level or even genus level) with a well-documented rationale, if there isn't any information on the notified strain.
- **Literature information:**
    - Suggested databases in Guidelines. Note: Pubmed – can be used for human health info, but not a good database for environmental info requirements. Scopus covers more applicable journals and more relevant information in Scopus in general, especially for ecotox requirements. http://www.scopus.com/
    - New Substances program can provide list of recommended key words for the search. Notifier needs to provide in the NSN package their search strategy, time period used, results.
    - Need full copies of each reference supporting the NSN package (in English or French).

      Negative literature search results can be provided to meet an info requirement
- **Matched NSNs**
    - If information was previously provided by another notifier for the same strain, can simply reference information in that NSN package (will need a letter of authorization from the other notifier to use their data).
    - If information was previously provided by the notifier for a similar strain to the one being notified, can reference information that is common to both strains from that previous NSN.
- **Consolidated NSNs**
    - If importing or manufacturing a number of very similar strains at the same time, and where the technical information provided for one substance is used to address the technical information requirements for the remaining substances, notifiers can prepare one NSN master file that has all the data and the other NSNs for the similar strains can refer to the master file.
- **Pre-Notification Consultation**
    - Free service;
    - Avoids delays during the assessment of the New Substances Notification (NSN) package;
    - Notifiers can provide draft NSN package so the New Substances program can identify early on if there are any deficiencies. A request should include:

- information pertaining to the substance (substance identity supported by genetic sequence in FASTA format, explicit biological name, intended use, etc.);
- specific questions you would like answered;
- a clear indication of which information requirements you would like to fulfil with the submission of waiver requests or surrogate information (*i.e.,* information on an organism similar to the one notified or the wild-type cells or parental strain);
- a well-documented scientific rationale for each information requirement for which you wish to use surrogate data or waiver requests (should be supported with information from the literature);
- if you already have them, the test data from pre-clinical studies (full test reports) or data for the surrogate organism.

– Notifiers can then meet with the New Substances program evaluators to discuss any deficiencies (in person or by teleconference).

If you have questions concerning the NSNR for substances in products regulated under the Food and Drug Act, contact the Environmental Assessment Unit (EAU), Health Canada:

Phone: 1-866-996-9913 or (613) 948-3591

Email: eau-uee@hc-sc.gc.ca

T. Bubela said that there are a lot of questions on Schedule 1 that are very specific and would like more guidance on which sections are applicable. Currently, BGTD asks for clinical trial sponsors to obtain environmental data on shedding such through tears, urine and blood. It would be helpful to have just one consolidated review process as opposed to two processes that co-exist at the moment with different rules, different deadlines, and different government agencies.

P. Bedford said that in the US, part of the IND is filing an environmental assessment or claim of categorical exclusion, perhaps a streamlined approach to the assessment of human health and environmental perspective would be helpful.

A. Ridgway said regarding the nature of definitions, if a sponsor wants to harvest a dendritic cell, based on the definition, if one took it, cultured it ex-vivo and exposed it to proteins and put it back in the patient without genetic manipulation, according to this, it would trigger NSNR. Boundaries could possibly be negotiated.

Action Item: S. Viswanathan said that CellCAN and BIOTECanada would like to have a half day workshop with Health Canada, Environment Canada and NCC to address this uncertainty. Participants from this CTSG would also contribute to this workshop to propose practical solutions to address the current burden imposed by NSNR (organisms) on clinical trial sponsors.

7. Proposed Regulatory Framework for Environmental Risk Assessment of Active Ingredients in Drugs-Biologics

Julie Chateauvert gave a presentation on the Environmental Impact Initiative (EII) of the Health Products and Food Branch at Health Canada, which has developed proposed regulatory amendments to the *Food and Drug Regulations* (FDR) for the environmental risk assessment of active ingredients in human drugs, including biologics. Currently, this assessment is conducted

under the *New Substance Notification Regulations* (NSNR) of the *Canadian Environmental Protection Act, 1999*, whereas the safety and efficacy review of drug products is conducted under the authority of the FDR. The proposed amendments would create a single-window approach under the FDR and would align the timelines for environmental risk assessment with those that currently exist for the drug review process. Data requirements would remain the same as those currently outlined in the NSNR.

The proposed regulatory framework was created by the Environmental Assessment Working Group, which was composed of representatives from academia, industry and governments, between 2006 and 2011. At the time, the proposal did not capture biologics. Since then, the EII has added biologics to the scope of the regulatory proposal.

- Active ingredients in drugs regulated under the FDA, but does not include those whose use is solely in disinfectants, medical devices, radiopharmaceuticals and/or natural health products
- Veterinary drugs (prescription and non-prescription); and
- Human drugs (prescription, non-prescription and biologics)
- Subject to regulation if not listed on the Domestic Substances List (DSL) when one of the following submission types is submitted to Health Canada:
    - a New Drug Submission (NDS) or an Abbreviated New Drug Submission (ANDS) that requires a new drug identification number (DIN); or
    - a Supplemental New Drug Submission (SNDS) or Supplemental Abbreviated New Drug Submission (SANDS)

Data requirements in the proposed regulations would be tailored to the level of risk associated with the substance:

- A regulatory action limit would serve in screening out those active ingredients that are destined for the Canadian market in quantities that are not expected to pose a risk to the environment (Phased Approach)
- Lower risk categories of active ingredients would be exempt from environmental risk assessment regulatory requirements
- Active ingredients that are considered to pose a higher environmental risk will be automatically required to provide data regardless of their quantities/concentrations
- Active ingredients that may pose a risk to the environment but are not fully characterized by the data that is normally required would be subject to special/additional data requirements

Should this proposed framework be deemed acceptable, proposed regulatory amendments would not come into force until 2020 at the earliest.

P. Bedford noted that he was working with GE Lifesciences to encourage this at RCC, which might help to ensure this remains a regulatory priority.

8. Assist Researchers to Determine Preclinical Data Requirements for a pre-CTA meeting and CTA for Cell Therapy Products

Gayle Piat led the discussion on determining preclinical data requirements. The CellCAN manufacturing staff are often the first regulatory group approached by academic researchers when they want to translate their cell therapy products to the clinic and often have many questions about the complete Clinical Trial Application process. They question what type of preclinical data is required prior to approaching Health Canada for a pre-CTA meeting. Since much of their focus relates to efficacy in the research laboratory, they often haven't considered safety-related studies. They also question whether they can conduct the studies themselves or whether they must be outsourced to a Good Laboratory Practices (GLP) recognized facility and question which studies are considered pivotal rather than supportive. CellCAN wants to be sure that we are providing these researchers with the correct advice and information so they can confidently and efficiently move new products toward the clinic.

Although Guidance Document: *Preparation of Clinical Trial Applications for Use of Cell Therapy Products in Humans* does provide some information about preclinical requirements, it should not be read in isolation but rather as a complement to other Health Canada, ICH and FDA guidance documents. It may be beneficial to have a discussion about strategies that researchers can use to evaluate whether they have sufficient preclinical safety data. Also, is it appropriate to refer them to other guidance documents such as FDA's Guidance Document: Preclinical Assessment of Investigational Cellular and Gene Therapy Products?

Daniel Keene said that there is no pre-defined time when a pre-CTA meeting should occur. It is dependent on the question and needs of the sponsor. Some questions are best handled in a face to face meeting; while others can be done as a teleconference.

The decision as to which studies require GLP is based on the phase and purpose of the study.

As there is a great deal of intra-study variation on the reason, timing and type of the studies, it is not possible to state what are the common information gaps seen in submissions.

What needs to be done and when varies based on the type of study being done.

Long-term toxicity studies for cell-based gene therapies are dependent on the durability of the gene therapy products. Must account for this and plan ahead accordingly.

At present, there is no consensus among regulators and industry on what the most relevant animal model is or if an animal model is deemed to be required. This is decided on a case-by-case basis.

Gina Coleman gave a presentation that answered the questions posed.

What type of preclinical data are required? -The kind, duration, animal – depends on the product and the proposed clinical investigations. The review is product-based (no "one size fits all" regulatory approach). Data necessary to support development depend on the characteristics of the product. Preclinical studies are designed to support the use of a specific product for a specific clinical indication. The diversity and inherent biological properties of cell and gene therapy products necessitate a case-by-case testing strategy.

Guidance documents:

1. HC Guidance Document: Preparation of Clinical Trial Application for use of Cell Therapy Products in Humans
2. ICH S6 (R1)

How soon is too soon to schedule a pre-CTA meeting?

- Not before there is a hypothesis!

- The sooner the meeting occurs, the more general the advice will be
- Early in the development stage: general advice, recommend guidance documents
- Close to starting the development or when a clinical trial design exists: more specific advice.

How is it decided which studies require GLP?

- Pre-clinical studies that are considered pivotal for risk evaluations should adhere to Good Laboratory Practices
- Supportive pre-clinical studies do not always have to be GLP compliant
- The need for GLP compliance will depend upon the importance of the study to the overall risk assessment for the product and must be considered on a case-by-case basis.

Guidance Document: Preparation of Clinical Trial Applications for use of Cell Therapy Products in Humans

What are common information gaps seen in clinical submissions?

- Lack of proof of concept studies
- Pre-clinical data from a similar (but different) product
- No pre-clinical studies!

What is the continuum of preclinical work that goes with Ph I/II/III – what needs to be done, when?

- This is assessed on a case-by-case basis
- The expectations from pre-clinical data are:
  - To support a rationale for the first-in-human clinical trial
  - To make recommendations regarding clinical trial design
- If there are changes in the manufacturing process additional non-clinical data may be needed
- The results of the early phase trial may trigger the need for additional non-clinical studies

Address confusion about needing additional preclinical data when so much has been published already.

- Published data can be accepted if the studies are done with the same product
- The product is considered the same when the cells are processed the same way, not only when they are the same type of cells

Small vs. large animals: number of animals, route of administration?

- Mimic clinical scenario as closely as possible
- Use cells intended for clinical use…or analogous cells
- Cell viability, concentration/formulation, volume, rate of delivery, implant site, number of implants/ injections, etc.
- delivery system, timing of cell delivery, dosing regimen, etc.
- Anatomical location/extent of the diseased/injured area

Adequate numbers of animals/group to ensure statistically and biologically robust interpretation

- There is no ‘default’ to the use of nonhuman primates
- There is no ‘default’ to the use of both a rodent and a non-rodent species
- There is no ‘default’ to the use of multiple species

- Understand the limitations of the species/ model(s) used
- Scientific justification should be provided for the animal species/model(s) used

Jian Wang clarified that cell and gene therapy requirements are the same and it is case-by-case.

9. ISBT-128 labeling

Martin Giroux led a discussion on ISBT-128 labeling; the objective of ISBT-128 is to standardize internationally the terminology, labeling and barcoding of products of human origin. Since the 5th version of the FACT (Foundation for Accreditation of Cellular Therapy) standards, ISBT-128 usage is recommended and since 2017 it is a requirement.

In order to standardize terminology, the International Council for Commonality in Blood Banking Automation (ICCBBA) created a group for Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). This group develop new terminology and creates additional terminology upon request. The new nomenclature created will be transformed into a computer code and two-dimension barcode can then be created by users.

ICCBBA recommends that national consensus documents be published to integrate the requirements from regulatory, national and provincial agencies, as well as from pertinent organizations.

In January 2015, Canada's Blood groups published a common document for blood products (see supporting documentation). Equivalent documentation should be available for cellular therapy. Considering the complexity and diversity of cellular therapy products, the need for consensus terminology and components is even more important.

Francisca Agbanyo explained that ISBT128 labelling is currently not mandatory for blood for transfusion or cell-based products for transplantation. However, ISBT 128 has been voluntarily implemented by the Canadian blood establishments, who are members of Americas Technical Advisory Group (ATAG) responsible for developing the blood labelling standards. ISBT labelling is also recommended in Health Canada’s Guidance Document for the Blood Regulations. Since the naming convention in the ISBT 128 Standards provides for international consistency in product labelling, Health Canada would also encourage the voluntary implementation of ISBT 128 for cell therapy products.

F. Agbanyo said that there are many different types of cell therapy products and it is difficult for BGTD to come up with labelling standards. This is further complicated by the fact that CTO establishments also distribute a wide variety of cellular products for which there is no pre-market review so BGTD is not familiar with the labelling standards currently being used by them. This is something CTSG should explore. Health Canada can work closely together on a stakeholder-led initiative involving manufacturers of cellular therapy products. For example, BGTD could participate on a working group to help with, but not lead this initiative. It was suggested that CellCAN lead such an initiative with members of the CTSG.

Currently, establishments provide ICCBBA with a product description and ICCBBA determines if they already have the product in their database, and if not, propose a new name for the product. The final decision on product names and attributes should be made by the ICCBBA to ensure consistency at the international level.

Action Item: CellCAN and all members of the CTSG within RMAC that are impacted should consolidate efforts on this labelling issue

10. Engagement with Health Canada online and through pre-CTA meetings

Duncan Stewart led the discussion on engagement with Health Canada online and through pre-CTA meetings, saying that RMAC is interested in engaging and improving interactions between investigators/sponsors and Health Canada. They would like to provide some feedback on the website and how to engage with applicants. The format is not user friendly and it's not very clear where one needs to go to get the necessary information. They would also like to suggest that pre-CTA and CTA be two stages: stage one: online application so that HC can review and ask questions of the investigator; and stage two: the investigator can be prepared with more information for the in person meeting with HC.

N. Kolas said that Health Canada is undergoing web renewal and there are many ongoing updates. BGTD recognizes the challenges. A. Ridgway added that it's a fairly defined process, prior to the CTA filing stage. He had some concerns depending on what the online consultation system would look like. Different models may overload the system with questions, and Health Canada reviewers would become preoccupied with addressing those. The effort on BGTD's part may be a little problematic. We do develop guidance documents that tend to give guidance on the processes, what information is useful, and if there is a need for additional guidance, we may need to update them or do Q&As on them. While we can see the value in the digital age, it may not work at this time. The Office of Regulatory Affairs (ORA) tracks all communications regarding anything of that nature and is very involved. If there is a case of additional help being needed on completing the information data requirement, we're able to help but ask that sponsors refer to the guidance first.

S. Viswanathan suggested that a FAQ section may be a good idea that identifies trouble spots.

Action Item: CTSG to develop a list of suggested FAQs that Health Canada may wish to address. CellCAN offered to host this FAQ on its CTSG webpage that all members of RMAC may disseminate to their respective membership.

11. TCPS Public Consultation: Research Involving Human Cell Lines

Wendy Burgess gave a presentation on the Tri-Council Policy Statement (TCPS) Public Consultation on research involving human cell lines. The Panel on Research Ethics is proposing revisions to this. The proposed revisions reflect advice from an expert subcommittee about whether research involving human cells and human cell lines from established biobanks should undergo Research Ethics Board (REB) review.

Regarding public consultation, the panel is proposing changes to guidance regarding research involving human cells and cell lines

- Based on advice from a subcommittee of cell scientists, ethicists, and representatives from Canadian Association of Research Ethics Board (CAREB), Stem Cell Oversight Committee (SCOC) and U15
- Soliciting feedback from Oct. 17 to Jan 5, 2018
- E-mail: secretariat@rcr.ethics.gc.ca

The changes are being proposed because:

- Research involving human cells that are maintained in culture are subject to the TCPS 2 and requires REB review
- Often such research involves non-identifiable cells whose ethical provenance has already been established

The proposed changes include:

- A new exemption from REB review for research that relies exclusively on human cells or cell lines where:
  - the cells and cell lines are non-identifiable
  - the research is not reasonably expected to result in re-identification
  - the human cells and cell lines have ethical provenance

Feedback is requested:

- Is the proposed guidance clear, reasonable and feasible?
- Does the guidance raise any concerns or potential challenges regarding interpretation or implementation?

P. Bedford asked if this was for embryonic cells or all? W. Burgess clarified that it was all cells. When a scientist goes to a biobank for an assessment, they should be doing an ethics assessment as well.

Action Item: CTSG and Health Canada to review proposed changes in the context of cell therapies. Feedback to be provided directly to CIHR or through Peter Monette (Strategic Policy Branch; Health Canada).

12. Roundtable

Both BGTD and CTSG thanked one another for the meeting.

The meeting was adjourned at 4pm.