



Value for Money, Due Process, and a Proposal

MEMO from David Naylor, Cate Hankins, and Tim Evans

The COVID-19 Immunity Task Force [ITF] was announced two months ago. Thanks to all members volunteering countless hours advancing the ITF agenda on multiple fronts we are entering a new phase of increased investment flow. Partnerships with national and provincial agencies have thus far led to procurement of 140,000 serology tests that will be run through the summer. Additional provincial and territorial [P/T] testing partnerships are anticipated – a by-product of the strong representation of P/T partners at the ITF. Similarly, we anticipate increased investments through academic research teams, not least those generated through our partnership with CIHR. It therefore is timely to review and revise our modus operandi with two issues in mind. The first is value for money. The second is due process and conflict of interest.

Value for Money

The ITF has been mandated to ensure that, across Canada, 1,000,000 serology tests are performed carefully and analyzed rigorously over the 2-year lifespan of the project. Benchmarks suggest that an average cost for those tests would be on the order of \$200 each, driven not by the price of testing kits *per se*, but by the many costs associated with obtaining specimens to be tested, acquiring data about the people from whom they come, transporting samples, and analyzing both samples and data. That average masks substantial variation in per-capita costs, from little more than the cost of the test kits themselves for work done with various partners using existing laboratory capacity and left-over sera, to much higher costs for prospective studies that involve recruiting participants after obtaining their consent in diverse populations and settings or in remote areas where data and sample acquisition will be challenging.

Recognizing this cost/test benchmark and embracing our Canada-wide mandate imply that some very large contracts will be written. For example, a group planning to do 30,000 tests over 12 months could advance a request for \$6,000,000. While time is of the essence, these sums cannot be allocated without due diligence and careful consideration of alternative and more cost-efficient ways of acquiring comparable data.

Health Canada/PHAC will conduct in-depth budgetary diligence starting with the process whereby an Invitation to Submit a Funding Request [ISFR] is generated. However, the ITF itself also has important fiduciary duties. Among others, these include ensuring that the tests to be done reach a high performance standard, that sampling and sample sizes are efficient, and that repeated waves of testing are not done without careful review of earlier results and without a clear rationale.

The co-chairs are accordingly taking a general position that funding commitments will often need to be made on a staged basis, with subsequent funds released based on factors such as achievement of milestones, proof of feasibility, and interim analyses of results. This position has been strongly supported by senior officials in Health Canada and PHAC.

Due Process and Conflict of Interest

The Leadership Group immediately saw challenges and began modifying its governance processes as soon as approval of big-budget field studies came onto the agenda. In that regard, we hit reset 2 weeks ago after one trial run at a review and decision process involving the wider Leadership Group. Today's meeting has seen major enhancements to the process to review three internally-led proposals coming forward.



However, in our view – one that we are confident many ITF members share -- the procedures still lack certain elements that are best practices to deal with open and fair process in terms of who develops projects and how perceived and actual conflicts-of-interest are handled.

We have full confidence that all ITF members have conducted themselves with integrity. We appreciate greatly that, in the national interest, you have also been giving up your scarcest non-renewable resource: waking hours. It is that last point, however, that leads us to be concerned. Colleagues who are doing volunteer service on top of other onerous responsibilities should not be put at reputational risk because we have not made adjustments to deal with this new phase of our work.

A Proposal

When the ITF was being created, consideration was given to setting it up as a single “arm’s-length panel” of senior scientists and professionals who would not be seeking any funding from the ITF. It would draw on advice from professionals and researchers with deep content expertise, with Task Force work to be done largely on a Request For Expressions of Interest (RFEOI) basis. There would be occasional direct contracts where there was one dominantly plausible contractor. The overwhelming challenge with this model was that it was precisely those individuals who were ‘in the fray’ who best could get the ITF moving and help frame key tasks efficiently, address testing technology issues, analyze priorities, and locate or build the relevant collaborative networks. The current group of outstanding colleagues was accordingly assembled.

Thanks to all your efforts, that choice has paid clear dividends in the last 2 months. Now, to enhance both value-for-money and the management of due process and conflict of interest, a hybrid approach seems best. We are therefore proposing modifications to the functions of the ITF Leadership Group that would delegate decisions related to investment to an Executive Committee [EC].

The EC’s primary functions would be to oversee the due process for development of investments including peer review and RFEOIs, approve all Task Force investments, and set the terms by which they will be implemented with a view to optimizing value-for-money. To better manage conflict of interest, all members of the EC would affirm that they have no intent to seek funding from the ITF for any field study or translational immunity research project during the life of the ITF. Members would be chosen based on a mix of expertise, considerations of the Canadian mosaic, and, their willingness to devote the extra time involved. As well, membership would rotate at yet to be determined intervals.

The ITF Leadership Group would continue its existing functions – broad strategic oversight, peer review of investments as requested, assessment of study results, and analysis of policy implications. Likewise Working Parties in the areas of testing, field studies and immune science would continue to focus on strategic priority setting and addressing measurement and methodological issues relevant to their domains. The process of advancing an identified area of priority research requiring substantial ITF funding would be firewalled, however, and stewarded by the EC in collaboration with the secretariat.

We believe this is a timely and prudent step that addresses a structural challenge in advancing academically-led projects, while strengthening governance engagement with overall expenditures. It also provides a more explicit consideration of the link between spending and strategy --- an essential part of public accountability for the tax dollars provided to the ITF. We welcome your feedback on this proposal.

We are sensitive to the fact that investments pending decision today are likely to incur some delay due to this proposed change. However, absent the equivalent of an EC and stronger processes, these projects and their proponents will be wide open to criticism, however unreasonable. Simple modifications to our



structures now can help minimize it. Recognizing the urgency to keep things moving forward, we aim to finalize the functions and membership of the EC in the next 3 days and convene its first meeting within a week.