Instructions for Implementation of ARPANSA Statement in Victoria

In line with the ARPANSA Statement on Ethical Review for Multi-centre Trials released in February 2020[1], the following revisions have been adopted for the ethical review and site authorisation (governance approval) processes of multi-centre trials under National Mutual Acceptance (NMA) [2]:

1. It is the responsibility of the sponsor[3] of the trial to survey the Participating Sites included in the initial application to the Reviewing HREC with respect to whether the ionising radiation required under the Protocol is considered standard of care or additional to standard of care at each site. If additional, a Medical Physicist's report must be submitted by the Co-ordinating Principal Investigator (CPI) to the Reviewing HREC. This process also applies when new Participating Sites are subsequently added via amendment applications to the Reviewing HREC.
2. The Medical Physicist's report for each site should clearly state the Risk Category as defined in the ARPANSA Code of Practice: *Exposure of Humans to Ionizing Radiation for Research Purposes*: Radiation Protection Series Publication No. 8 (May 2005)[4].
3. The Reviewing HREC will consider the Medical Physicist's report with the highest assessed dose available at the time of review with respect to the balance of risk and benefit.
4. The report should be accompanied by a justification from the CPI for these exposures that will be additional to normal clinical management for the trial participants. The justification should be included in Section M6.2.1.3.1 of the Human Research Ethics Application form (HREA) which asks, "What evidence will you be providing that you have complied with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) requirements regarding ionising radiation?"
5. The Ethics Approval Certificate should list the radiation risk category (in accordance with the Code[4]) considered by the Reviewing HREC in giving its approval.
6. Each Participating Site's Research Governance Officer (RGO) should review their local Site's radiation safety risk assessment (either the Notification to the Reviewing HREC form or Medical Physicist's report as per Site requirements) and the Ethics Approval Certificate.
7. If the radiation risk category assessed by the Site is the same as or lower than the risk category listed on the approval certificate, the radiation risk can be accepted as part of the Site Authorisation (or Governance Approval) review process, without the need for further HREC review.
8. In cases where the radiation risk category assessed by the Site is deemed higher than that specified on the Ethics Approval Certificate, then the Site's Principal Investigator should seek additional approval from the Reviewing HREC via the CPI through an amendment application.
9. If an amendment to the Protocol involves a change in the frequency, number or modality of ionizing radiation procedures that are in addition to standard care, a revised Medical Physicist's report will be required for each Participating Site.
10. If the Protocol amendment results in an increase in the radiation dose which moves it to a higher radiation risk category (in accordance with the Code[4]), the report with the highest assessed dose available, along with a justification from the CPI, are to be submitted to the Reviewing HREC for consideration via an amendment application.
11. The revised radiation risk category should be listed on the Amendment Approval Certificate.
12. Each Participating Site is to assess their local Site's radiation safety risk assessment. If it is the same as or lower than the risk category listed on the Amendment Approval Certificate, no further HREC review is required.

13. If the Site's radiation risk category is deemed higher than that specified on the Amendment Approval Certificate, then the Site's Principal Investigator should seek additional approval from the Reviewing HREC via the CPI through an amendment application.

1 ARPANSA Statement on Ethical Review for Multi-centre Trials (February 2020) https://www.arpansa.gov.au/about-us/advisory-council-and-committees/radiation-health-committee/trials-statement

2 NHMRC Ethical review process for each Australian state and territory: National Mutual Acceptance of ethics review for multi-centre clinical trials https://www.australianclinicaltrials.gov.au/ethical-review-process-each-australian-state-and-territory

3 Sponsor is defined as "An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial." INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH): ICH HARMONISED GUIDELINE - INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2*)* Current Step 4 version dated: 9 November 2016 https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf In Australia the sponsor is usually an Australian legal entity.

4 ARPANSA Code of Practice: Exposure of Humans to Ionizing Radiation for Research Purposes: Radiation Protection Series Publication No. 8 (May 2005) https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rps8