Australian Society of Medical Imaging and Radiation Therapy
The national professional organisation representing medical radiation practitioners
ABN 26 924 779 836

22 March 2019

Consultation: The National Clinical Trial Governance Framework
21 January 2019

The Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) is the peak body representing medical radiation practitioners in Australia. Our aims are to promote, encourage, cultivate and maintain the highest principles of practice and proficiency of medical radiation science, always mindful that the welfare of the patient should be at the centre of everything we do.

ASMIRT would like to provide the following comments to the National Clinical Trial Governance Framework.

Overall, ASMIRT recognises this document as an extremely comprehensive document that has a clear purpose and is well articulated. However, we believe that the following feedback would further add to the high quality of the existing framework.

i. The Framework should be commended for its strong emphasis on patient safety. This should, and always will, remain the primary pillar of any clinical trial. ASMIRT is also of the strong belief that staff safety remains of paramount importance in the context of all clinical trial activities. The recognition of "Importance of organisational culture in clinical trial governance" (p.16) is highly commended. A strong workplace culture is not only pertinent to the safe, optimal delivery of clinical trials, but perhaps more importantly, day-to-day clinical operations. The further detail articulated on page 17 further clarifies the framework's commitment to this component.

ii. To further build on this, ASMIRT would support additional recognition of the role of clinical staff in the safe delivery of clinical trials. Our membership, purely through their designated clinical roles at the very 'coal face' of the provision of patient care, are intricately involved in the delivery of care of patients enrolled on clinical trials. Whilst we recognise the draft framework stresses the importance of appropriately qualified staff to provide 'high-quality clinical trial services to patients' (Clinical performance and effectiveness, p.16), this should also be extended to recognise the safety of staff involved in the undertaking of clinical trials. Deviations from planned care can place a significant emotional burden on staff. Emphasis on appropriate staff training and qualifications, therefore, should recognise both the potential patient and staff considerations. Both patient and staff safety are implicit on each other. Patient safety will be compromised if the safety of the staff involved in their care provision is not deeply considered.

iii. Standard 1 (Governance, leadership and culture p.28) could be further strengthened by reinforcing the importance of hospital service management embracing clinical trials and providing support for ALL staff involved in clinical trials, and not just those in leadership

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roles. Such recognition would better reflect our membership's involvement in clinical trial activities (as detailed above).

iv. Management must also be involved in site feasibility, to justify the cost of credentialing and training, to ascertain the worth of these additional requirements if their site anticipates recruiting patients to a trial.

v. Under the premise of "Patient safety and quality improvement systems" (p.31), additional dialogue allowing clinical staff the opportunity to assess the protocol and ensure that they can complete requirements as specified and/or requirements for their own site to conduct the trial, would further strengthen this section. This should be undertaken in collaboration with management and multidisciplinary team members involved in the undertaking of ALL trial activities.

vi. Please consider changing the wording in the following statement on page 5 from:

"Clinical trials are undertaken to determine the safety and effectiveness of therapies and devices"

to

"Clinical trials are undertaken to determine the safety and effectiveness of therapies, devices and techniques"

to better reflect the contribution of ASMIRT members (and potentially, other allied health members) in the delivery of care in clinical trials

vii. Recognising a patient's right to opt out of any clinical trial activity, even following consent, could be better articulated. The 'Roles and functions' of 'Patients and consumers' (p.19) recognises "patients and consumers participate as partners to the extent that they choose". Additional detail regarding a patient's right to opt out of clinical trials, within the 'Partnering with consumers standard' (most notably 'Sharing decisions and planning care' (2.6, p.49)), should be included in this section of the framework.

viii. The cost of implementing such a framework, and the associated resource implications, must also be addressed. Any additional requirements placed on clinical departments to reach the required standards, will most likely be absorbed within a budget already stretched with current clinical trial activity. This may, in fact, exclude select hospital and smaller providers from offering given trials to their patients.

ix. The time and resource requirement for obtaining local site governance to undertake clinical trials is often extensive. Greater clarification of the additional requirements- if any- to attain site governance, should be addressed. This will enable participating sites to make an impact assessment of a pending trial and its associated costs.

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x. A significant amount of clinical research undertaken by the ASMIRT membership focuses on health services research and cohort studies. Whilst not implicit with the current National Clinical Trial Governance Framework, development of a similar framework for such work would be welcomed.

xi. The 'Safe environment for the delivery of care' (p.46) recognises the importance of the inclusion of ATSI participants in clinical trials. This should be expanded to also include CALD and minority groups to ensure equity in clinical trial access to all.

xii. Clinical trials involving the ASMIRT membership often incorporate a significant amount of data sharing, including large files such as diagnostic and radiotherapy planning images. Safe data sharing principles should be incorporated into the framework to emphasise the importance of ALL data sharing sensitivities.

We are of the strong belief that this framework further strengthens the ability of our membership to deliver optimal patient care in the setting of a clinical trial. ASMIRT look forward to working with the final version of this critically important framework when it is released in the very near future.

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