



NSW Health Consultation – Statewide Biobanking Consent

Submission from the Clinical Oncology Society of Australia and Cancer Council Australia

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The **Clinical Oncology Society of Australia (COSA)** is the peak national body representing health professionals from all disciplines whose work involves the care of cancer patients.

Cancer Council is Australia's peak national non-government cancer control organisation and advises the Australian Government and other bodies on evidence-based practices and policies to help prevent, detect and treat cancer.

COSA and Cancer Council welcome the opportunity to comment on the draft Policy Directive Consent for Research Biobanking. The draft policy is a significant improvement on the previous version and addresses many of the concerns with that earlier document. COSA and Cancer Council welcome the development of standard processes that will enable cancer researchers to streamline their work flows and ensure they are adopting best practices.

There are still some areas COSA and Cancer Council propose require some clarification or modification:

- 1) The policy applies to institutions in NSW but many research projects are national and international, especially where the disease types are rare. Indeed, as molecular profiling is adopted more widely many cancers will be deemed 'rare' in terms of incidence, and multicenter programs will be the only method by which they can be studied effectively. Section 2.3 of this draft policy directive appears to permit other jurisdictional practices to be used where there is an interjurisdictional project. However, from COSA and Cancer Council's perspective, working across oncology disciplines, issues at the practical working level may arise where there will be reluctance by NSW governance offices to permit a consent system that deviates in any way from this one to operate in NSW. A more effective approach would be to involve all states and territories in Australia. COSA and Cancer Council ask if there has been such discussion with other state health departments to achieve this. COSA would be willing to work with NSW Health and other State and Territory agencies to facilitate adoption of best practice in the policy to ensure that the ideals of the National Mutual Acceptance scheme for ethical review can be met.

- 2) Further clarification about who is qualified to obtain consent is needed. Section 3.2 is not sufficiently clear on how a person will be deemed qualified or how an organization will keep a record of their suitability. Who will monitor and check this? It is a standard ethical requirement detailed in the National Statement that those obtaining consent should be suitably qualified to do so. The additional detail here appears redundant for ethically approved studies without details about the precise mechanism by which it should be delivered.
- 3) In section 3.3 the draft policy states that a verbal discussion must take place. However, in practice if a person reads the documentation and is satisfied that this is sufficient to make a decision then they can exercise their autonomy without the need for a verbal conversation. COSA and Cancer Council recommend that the “must” should be changed to a “should where possible” to allow individual autonomy to be respected. The fourth bullet point allows for no verbal communication for large scale projects but the scale is not the only reason why this should not be required.
- 4) COSA and Cancer Council do not envisage the requirement of giving a person an option to NOT receive a Serious and Significant Finding (SaSFs) is practical, ethical or logical, as outlined in Section 4.2. Since this option can be over-ridden it appears to give a false option to a person, i.e. in reality there is no option. COSA and Cancer Council recommend deleting this entirely; instead it should state that participation involves the possibility that SaSFs may be given back through appropriate channels and if a person is not comfortable with this then they should not participate at all. All elements related to this need to be amended throughout the document. COSA and Cancer Council stress that whilst this may give comfort to legal concerns it is entirely impractical and unnecessary.