NHMRC PUBLIC CONSULTATION

Review of Chapter 2.3 of the National Statement: Qualifying or waiving conditions for consent

Clinical Oncology Society of Australia

July 2013

The **Clinical Oncology Society of Australia** (COSA) is Australia's peak multidisciplinary society for health professionals working in cancer research, treatment, rehabilitation and palliative care with over 1600 members. COSA is an advocacy organisation whose views are valued in all aspects of cancer care.

Contents

1 Responses to the consultation document

1.1 General comments.

COSA welcomes the opportunity to comment on this proactive approach to ensuring that important research can be carried out whilst maintaining ethical standards. The consultation document provides a clear argument for the rationale behind the proposal.

A combination of ways to secure consent is supported as a pragmatic and flexible approach. The option for opt-out consent would provide ethical review bodies with an additional tool to apply to types of low risk research such as epidemiological studies and clinical registries. For population based research, opt-out consent can assist in making the outcomes of a project more reliable due to near complete participation and less selection bias.

Whilst COSA agrees that there is a need to use alternative mechanisms to straightforward information sheets and written consent there are some concerns about the practicality of the proposed revisions.

The major issue will be that for opt-out to work there has to be confidence that sufficient information has been provided to those who may be included and yet there is no way to know that this has occurred. There is therefore a small risk that a person may be included who subsequently is not happy that this happened. It is not materially different to what would be achieved by a prospective waiver of consent. That is, under the current guidelines (National Statement 2.3.8) [1] institutions applying a waiver must make this publically known. In theory such disclosure could permit a person to complain if they understood that they were part of that cohort and possibly withdraw from further use of their data.

It is therefore incumbent upon researchers and HRECs to ensure that the use of opt-out consent is ethically defensible. The research should result in substantial public benefit and require near to complete participation. There must be a reasonable strategy to widely disseminate plain language but comprehensive information about the study and a mechanism for potential participants to obtain further information or to opt-out.

1.2 Please comment on the following definition of 'opt-out':

> ***A method used in the recruitment of participants into research where information has been provided to the potential participant regarding the activity and their involvement in which their participation is presumed unless they take action to decline to participate.***

The proposed definition of opt-out is satisfactory, although complex if used for the general public. A suggested plain language alternative could be: "A method in which data, tissue or blood is used for current and future research unless a participant specifically declines to participate or actively withdraws consent".

1.3 Please comment on the rationale provided for an opt-out approach (i.e. Section 3).

The rationale provided states that opt-out is appropriate in several domains of research such as epidemiological, public health and non-medical research. It is difficult to see how opt-out is preferable to a waiver of consent applied prospectively in these circumstances. If people can actively choose not to participate this may raise issues relating to bias. If it is acceptable to have people opt-out, then it would be better to go for a lighter (less onerous) version of consent. The NHMRC should clarify for HRECs that waiver of consent can be applied to prospective collection in certain circumstances. For example, population registries where the research is low risk and of significant benefit but it is impractical to obtain consent from the large numbers of people whose data will be included.

In both the public and private health sectors, the use of a series of bullet points that seek consent to use data for research, teaching and quality improvement activities are commonly used and adequately comply with the Privacy Act 2001. There is no evidence of widespread objection to this "unspecified consent" by patients. One could argue that patients would be reluctant to say no as they wish to be treated and might fear that this could compromise their relationship with the doctor. Again there is no evidence this is the case, particularly if the use is for bona fide research aimed at improving outcomes.

Importantly, the lack of a signature is not a substitute for consent because it is difficult to verify that a person received information upon which to base their decision. To overcome this issue a check box is used by companies for consent to software usage. There is no reason why a check box could not be used on medical documents as it already is in most private transactions (e.g. hotels, purchases, airlines). The NHMRC should clarify for HRECs that use of a check box or initials on standard consent to admission/treatment documents is robust and a perfectly acceptable way to safeguard individual's rights.

A sample brochure provided to patients as well as the consent label placed in the medical records is included as Appendix 1. This straightforward approach to dispersing information and documenting that the patient has read it is currently used at the St John of God Hospital in Perth to secure informed opt-in consent.

1.4 Please comment on the proposed limited application of an opt-out approach (i.e. Section 4).

The exclusion of research of more than low risk is obligatory because one cannot waive consent or presume consent where physical harm or harm greater than discomfort is likely. However, what is not satisfactorily addressed is how a balance can be assured between reduction in data bias for the greater good and protection of an individual's right to informed consent.

1.5 Please comment on the flow chart (i.e. Section 4).

The extent to which this helps clarify the complexity of the issue is not clear, as the key is the difference between waiver of consent for prospective use or the need to use an abbreviated consent rather than the average 12 page PICF (Participant Information and Consent Form).

1.6 Please comment on the appropriate mechanism for providing information to participants for the opt-out approach represented at box 6d of the flow chart.

The key to opt-out consent is how information will be provided to people in a way that permits confidence that they have actually seen the information that discloses the whole range of possibilities for which their data may be used. The information campaign also needs to be cost-effective given the current financial constraints on research.

Methods could include advertising through local newspaper, radio and social media. A quality improvement program in a hospital may be notified to patients in their admissions package. Information about what is collected in clinical registries may be communicated by a brochure and/or the internet. A good example of effective implementation of opt-out consent is the website for the Australian Stroke Clinical Registry [2].

At the same time however, failure in one instance could unravel the whole process. For example, where one person takes legal action because their data was used without their consent and who claims they never knew that it was to be used for a certain purpose. A tick or initial is evidence that they have at least been given some information (noting that the belief that people actually give 'informed' consent has been repeatedly proven, for the most part, to be erroneous).

1.7 Please comment on the proposed amendments to the National Statement (see Attachment A underlined and in red text).

The need to increase access to, and participation in research, is strongly acknowledged and endorsed by COSA. It is difficult however to see a functional utility for opt-out that a waiver of consent applied prospectively would not achieve.

- In instances where data must be collected from 100% of people then legislation should be introduced.
- Where 100% participation is not needed then a tick box (if low risk) or initial to indicate that information has been received is adequate, where practical.
- If impractical to obtain such consent then a prospective waiver could be applied, which is not philosophically different to a retrospective waiver.

1.8 Are there situations where an opt-out approach might be appropriate that have not been considered in the proposed amendments?

A concern with the proposed revisions is that the scope of opt-out consent is too narrow. It is referencing opt-out only in the context of existing biospecimens and routinely collected data. At present the majority of Australian HRECs rarely, if ever, approve opt-out consent for other research in the Australian health setting due to privacy concerns. This makes some forms of research impossible (e.g. healthcare communication research) and grossly changes the characteristics of the sample of participants, rendering them unrepresentative of the whole population.

1.9 Are there any situations you can think of where the draft amendments would allow an opt-out approach that may be inappropriate?

Strict procedures are necessary to ensure the privacy of individual data, particularly for patient groups likely to be more sensitive to the use of their health information (e.g. studies related to mental illness or sexual health).

The opt-out approach could lead to criticisms of inadequacy to inform. It is proposed that mandatory collection, opt-in using a very light format of consent or prospective waiver are more robust than the opt-out approach. These approaches cover the spectrum of research needs more appropriately, taking into account the rapidly changing environment within which research occurs and where people are sometimes asked to consider the potential for ongoing, long-term use of their data, tissue or blood.

1.10 Can you provide examples where an opt-out approach may be useful?

As described in the consultation document, opt-out may be appropriate in non-medical or public health research that is clearly of low risk.

Opt-out consent has a place in epidemiological studies and clinical registries where it is not practical or possible to obtain explicit consent. The accuracy of population based research also depends on the completeness of the sample. Research on explicit consent in such situations shows that it is generally associated with limited recruitment rates of between 30 to 50% [3]. With this level of recruitment, participants are unlikely to be representative of the whole population and potentially lead to bias.

In one study comparing recruitment procedures for a trial evaluating a decision aid for colorectal cancer screening, more people agreed to participate via an opt-out procedure (67%) than via an opt-in procedure (47%) [4]. Opt-in procedures resulted in fewer people from lower educational backgrounds and a significantly higher proportion of people who preferred an active role in health decision-making. The opt-in procedure was also more likely to recruit people willing to have the screening test and people with a known family history of bowel cancer. Thus the resulting cohort from the opt-in procedure was skewed on several important variables likely to affect study conclusions.

Whilst there is clearly a place for opt-out consent in the National Statement, in practice it should still be considered if a prospective waiver of consent might not be equally applicable in some circumstances.

1.11 General comments.

Table 1 – Comparison of Participant Recruitment Models

In regard to Table 1, the proposal to use opt-out for negligible risk research is not needed since in the National Statement this is clearly defined as secondary use of completely de-identified secondary data.

Privacy Considerations

Extensive changes to privacy laws have been made during the recent past, as part of an international response to increased community concern about privacy of personal information. Consequently, many HRECs have become more concerned about the practice of opt-out recruitment procedures for research studies.

The National Statement needs to address how opt-out consent should be managed by HRECs when they are required to comply with the privacy guidelines set out under section 95/95a [5]. The core issue is that use of data without explicit consent is a breach of IPP11 1a and NPP2.1 (b) (Privacy Act 1988, Cwth-s95 guidelines) and NPP2.1 (d) (Privacy Act 2001, private-s95a), unless a waiver of consent has been approved by the HREC as permitted in Sections 1.2 (and ensuing guidance) in s95 and A1.2-1.4 in s95a.

Lastly, it is also worth noting a survey conducted by Research Australia [6] which suggests that the broader community is more open to participating in research than might be expected from privacy laws. The study found that 76% of the Australian community is interested in health and medical research, with disease prevention programs being the area of greatest interest (43%). Further, 59% of people surveyed said they would be prepared to participate in a clinical trial. Only 8% indicated that concerns about security and confidentiality of personal health information was an important reason for them not to participate in research.

Conclusion

The major issue aligned to opt-out is whether the dissemination of information reaches those who are included. If this fails, then the principle of autonomy proposed by opt-out cannot be applied. As such, it would be no advance on a prospective waiver of consent or making certain data sets mandatory for collection and analysis.

2 Acknowledgements

COSA thank the review panel for the opportunity to make this submission to the National Health and Medical Research Council.

We would like to thank the members of the COSA Executive and Council for contributing their time and expertise to the development of this submission.

3 References

1. National Health and Medical Research Council (NHMRC), Australian Research Council and Australian Vice-Chancellors' Committee. National Statement on Ethical Conduct in Research Involving Humans Canberra; Australian Government: 2007.

2. http://www.auscr.com.au/patients-and-family-members/general-information/opt-out-consent-process-and-explanation/

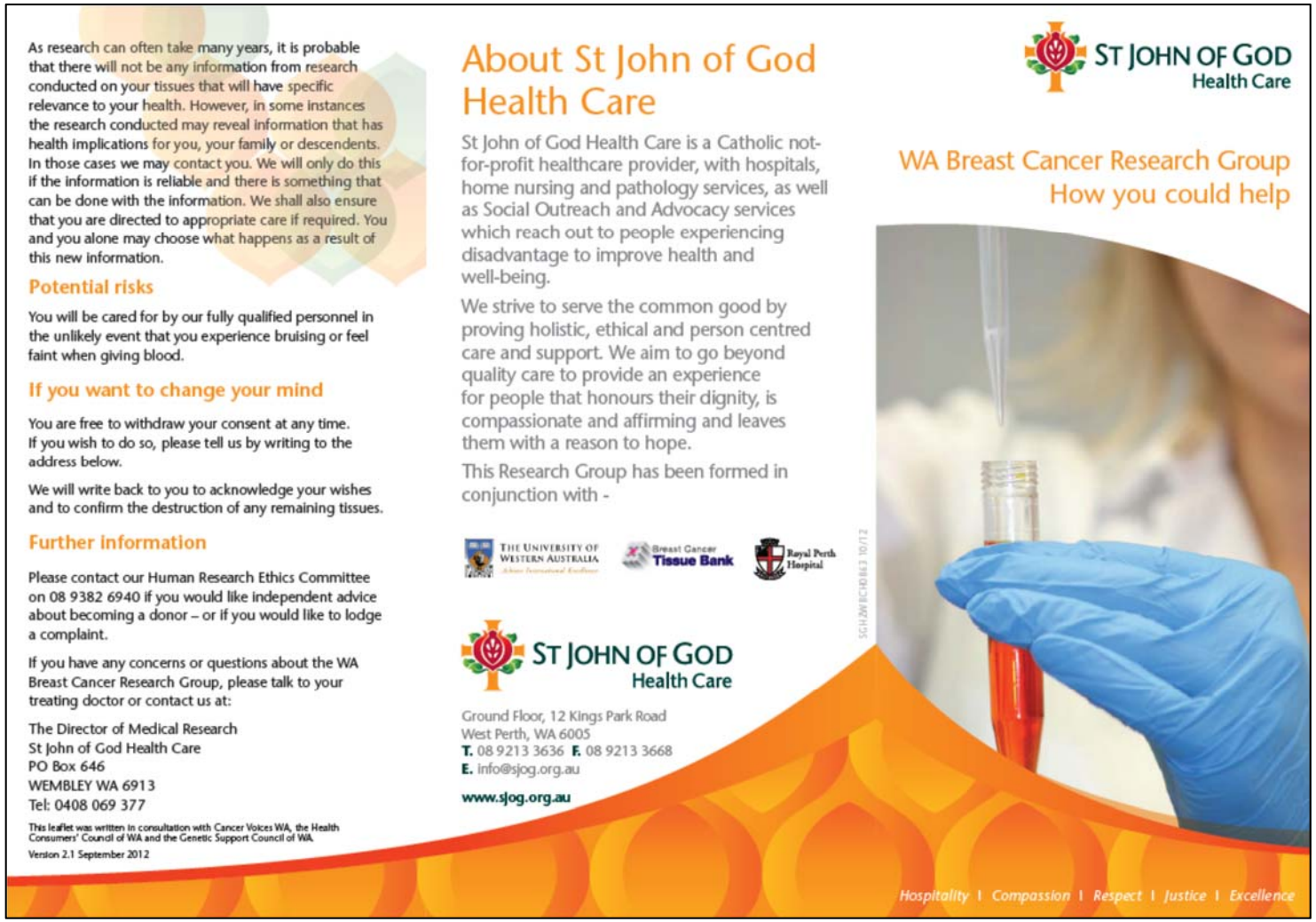
3. Gershon AS, Tu JV. The effect of privacy legislation on observational research. CMAJ 2008; 178:871-873.

4. Trevena L, Irwig L, Barratt A. The impact of privacy legislation on the number and characteristics of people who are recruited for research: a randomised controlled trial. Journal of Medical Ethics 2006; 32:473-477.

5. Guidelines approved under Section 95 (or 95a) of the Privacy Act. http://www.nhmrc.gov.au/guidelines/publications/e43

6. O'Grady K, Nolan T. Privacy: bad for your health? MJA 2004; 180(6):307.

4 Appendix 1 – Sample biobanking consent documents



As research can often take many years, it is probable that there will not be any information from research conducted on your tissues that will have specific relevance to your health. However, in some instances the research conducted may reveal information that has health implications for you, your family or descendents. In those cases we may contact you. We will only do this if the information is reliable and there is something that can be done with the information. We shall also ensure that you are directed to appropriate care if required. You and you alone may choose what happens as a result of this new information.

Potential risks

You will be cared for by our fully qualified personnel in the unlikely event that you experience bruising or feel faint when giving blood.

If you want to change your mind

You are free to withdraw your consent at any time. If you wish to do so, please tell us by writing to the address below.

We will write back to you to acknowledge your wishes and to confirm the destruction of any remaining tissues.

Further information

Please contact our Human Research Ethics Committee on 08 9382 6940 if you would like independent advice about becoming a donor – or if you would like to lodge a complaint.

If you have any concerns or questions about the WA Breast Cancer Research Group, please talk to your treating doctor or contact us at:

The Director of Medical Research
St John of God Health Care
PO Box 646
WEMBLEY WA 6913
Tel: 0408 069 377

This leaflet was written in consultation with Cancer Voices WA, the Health Consumers' Council of WA and the Genetic Support Council of WA.

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About St John of God Health Care

St John of God Health Care is a Catholic not-for-profit healthcare provider, with hospitals, home nursing and pathology services, as well as Social Outreach and Advocacy services which reach out to people experiencing disadvantage to improve health and well-being.

We strive to serve the common good by proving holistic, ethical and person centred care and support. We aim to go beyond quality care to provide an experience for people that honours their dignity, is compassionate and affirming and leaves them with a reason to hope.

This Research Group has been formed in conjunction with -

The University of Western Australia · Breast Cancer Tissue Bank · Royal Perth Hospital

ST JOHN OF GOD Health Care

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ST JOHN OF GOD Health Care

WA Breast Cancer Research Group
How you could help

Hospitality | Compassion | Respect | Justice | Excellence

Medical Research

The WA Breast Cancer Research Group conducts medical research to improve our understanding of diseases and find better ways to prevent or treat them. We do this by studying the biology of a disease using samples of blood and body tissue - and comparing the results with clinical information.

Tissue taken when you have a biopsy or surgery is processed in the pathology laboratory to diagnose your disease. Normally, part of your tissue is left over and, rather than waste it, we can use this material to conduct more research. This gives you the opportunity to make an important contribution to medical research.

To conduct research

- We require your permission for access to 'left over' tissue and health information
- Sometimes, we need to take an additional small blood sample (approximately 2-4 teaspoons)

The purpose of this brochure

a) Inform you about our ongoing need to do research into the prevention or treatment of disease,

b) Ask you to participate in research by giving us your consent to use your 'leftover' tissue, take additional blood if we need to and access your health records where required.

Please consider the following information carefully before making a decision. If you do decide to give us your consent, it is advisable that you tell your family of your decision and why you chose to support medical research in this way.

Please note;

- You are not obliged to be a donor or to give us your consent in regard to anything in item b) above.
- Your decision will not affect your care in any way.
- You may withdraw your consent at any time.

The following is important information that you need to know. Please read it carefully.

Confidentiality

The identification of your tissue and your health information will be kept in strict confidence for viewing and use by authorised people only.

We may on occasions be obliged by law to release relevant items of your medical information to a third party.

What will be done with your samples?

Your tissues will only be used for bona fide research studies. Some genetic information about you will be obtained and used with other data in your medical records to see how your genes relate to your diagnosis and general health.

In the longer term we may wish to continue to collect information on your health. This would involve contacting your local GP or other medical providers. If it is not possible to gather information from these sources, we may also wish to contact you directly by sending a card in the mail or with a follow up phone call.

What we will NOT do with your tissue

Your tissue will not be used for research involving reproductive technology, human embryos or cloning.

Keeping within acceptable community standards

All the research we do has to be approved by a Human Research Ethics Committee certified by the National Health & Medical Research Council. This Council is responsible to the Commonwealth Minister for Health & Ageing. This is to give you assurance that your tissue will only be used for genuine medical research with foreseeable community benefits.

Collaboration with other research bodies

Where appropriate, your tissue may be sent interstate or overseas for collaborative research purposes. This can only happen when we are sure that requisite approvals have been obtained and the necessary ethical and privacy safeguards are in place.

Commercial gain from use of your tissue

The law in Australia dictates that you may not be rewarded financially for donating tissue.

We are, however, allowed to profit from research outcomes that are ultimately successfully commercialised. Any money we receive from commercial ventures is always put back into medical research.

Results of Research

The research conducted using your tissues and health information may be published in medical journals or presented at scientific meetings in the future, but you will not be identifiable in any such publications.

The results of research performed on your tissues are intended to improve our understanding of disease and so provide general benefit to the community.

Medical Research
I have read the information brochure entitled

_____

and give my voluntary consent to the use of my biological specimens and health information for research purposes as described therein.

Signed _____

Name (printed) _____

Date _____