Australian Clinical Trials Alliance

ACTA Submission to the NHMRC Public Consultation

Section 3 (Chapters 3.1 & 3.5), Glossary and Revisions to Section 5
National Statement on Ethical Conduct in Human Research, 2007

December 2016

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1. Introduction to Section 3

The proposed changes to Section 3 are aimed at providing more clear guidance to those writing proposals for all types of research involving humans rather than singling out specific methodological approaches as was the case before. This is a better approach and is welcomed by ACTA as it recognises that many studies employ more than one methodology such as clinical trials that include psychosocial studies, health economic analyses and biomarker sub-studies to name just a few that will accompany the main investigation.

ACTA recognises that the use of human biospecimens and human genetic studies does raise some additional issues related to biobanks and registries and also for related persons not directly included in the research. Equally xenotransplantation appears to warrant its own section.

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2. Chapter 3.1

ACTA notes that the flow of this section now mirrors that of the recently released HREA. We welcome the opening statement that ethical considerations should be made at the earliest point of a research project's planning. The section is written to be read by both researchers and HREC members which is welcome as it will contribute to a greater understanding and appreciation of each other's role and responsibilities.
The use of Elements 1 to 7 is helpful and the topics appropriate.

3.1.2. It is not clear what the purpose of identifying a), b) or c) contributes to the ethical reflection specifically as written. As written they do not appear to make any link to an ethical issue as for instance d) does (or indeed e) and f).

3.1.3. ACTA endorses this becoming a 'must' rather than a 'should'.

3.1.5. Whilst this is a fair requirement to place on reviewers, applicants should also articulate their case for not having to use statistical significance in their outcome measures.

3.1.7. A comment about a possible staged submission/approval process based upon the identified steps could be included.

3.1.8. This should be deleted as it is suggesting that the HREC should play a role in determining whether or not researchers or their facilities are adequate. The HREA does not provide a space for this to be done as it is clearly a part of the site-specific assessment and not an ethical issue. It is not clear how the researchers can articulate this other than to make simple statement that they will do it or else provide a comprehensive business case with full costings which the HREC members will not be in a position to evaluate.

3.1.18. “innovative” does not appear to be the appropriate word here. The ethical issue arises from testing an intervention within or outside of its current indication. If it is being used for the first time and is not approved in that indication, then that needs to be disclosed. So perhaps “…whether it is an entirely novel intervention that has not yet been approved in any indication or for the circumstance in which it proposed to be trialed, or whether it is an approved intervention that is being tested in a new or modified setting”.

3.1.19. It is not clear from the statement why the seriousness is important. Some form of explanatory sentence is required or it should be deleted.

3.1.20. It is not clear what this adds that is not covered subsequently by 3.1.21 and 3.1.22. As written it is too vague to be useful.

3.1.23. It is not clear why the level of detail should be correlated with risks as stated. It would be clearer if it simply stated that they should describe and justify their approach.

3.1.24. We disagree. The HREC purpose is to approve the intended final documents and so technically they are not drafts, or at the very least are intended to be the final draft. It implies an initial review process, which comes from nowhere. If it is intended that someone in the HREC office make a first pass review then it should say so explicitly, or else be deleted.

3.1.27. It is not clear what is intended here. Why do potential participants need to know about who else has been approached and who has been selected or agreed to participate?
3.1.29. This should also refer to other benefits that arise that are not monetary, such as making sufficient numbers to allow the study to close and be published.

3.1.30c. Appears to need a few words to close the sentence at the end.

3.1.31. This needs to be clarified as it implies that participants may have a choice not to receive information, including information that they may actually be interested in if they knew in advance what it meant to them. Making a decision not to receive any information is not informed consent. It also appears to be out of place considering it appears to be covered in Element 5.

3.1.37. It would be preferable to say simply that they are not required by these guidelines. The second clause will create ambiguity and even license some HRECs to continue the practice, which is entirely unnecessary.

Under Element 4 introduction, line 3 of paragraph 3: Delete the word “complex” before privacy. Not all the issues are complex and this is an unnecessary adjective here.

The clarification around identifiability provided in **3.1.38-3.1.44** is excellent.

3.1.55. Is problematic as it implies a responsibility exists that may outlive the biobanks itself. It should be deleted. It also appears to give a license to therapeutic misconception which should not be embedded in an ethical guideline.

3.1.68c. needs to be clarified to ensure that the decision at the time of consent is not about whether to be told about potentially relevant results but whether or not this will occur in the future. The decision to receive them or not is then at that latter time point. If they do not wish to receive results at all from the outset then they should not participate in the study at all. Making a decision not to know results at the start of a study is not an informed decision and may have to be over-ridden in their best interests, making it an entirely redundant exercise in the first place.

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3. Chapter 3.5

Whilst Genomics is an important area of research in which a number of ACTA's member groups are active, we acknowledge that other organisations have a much greater depth of specialist understanding of the ethical issues related to genomics research. ACTA was grateful for the opportunity to review the submission put together by colleagues at the Kinghorn Cancer Centre/Garvan Institute for Medical Research and we support the considered feedback they have provided on proposed revisions to Chapter 3.5.

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4. Section 5

The flow on changes to Section 5 make sense in the light of the changes proposed in Section 3 and reflect a clear distinction between those proposing the studies, those running them and those responsible for ensuring they are conducted appropriately.