SRHMRA Submission 172 — Dr Oksana Holubowycz

This submission focuses in its entirety on the significant barriers to investigator-initiated multi-centre clinical research, posed by the process of gaining ethical and governance approval for the conduct of such research.

The NHMRC has in recent years introduced a supposedly streamlined system of review for multi-centre research. My experience with this system has been one of utter frustration at the multiplicity of documentation required and the lack of consensus between accredited centres about the level of review required.

For example, in my case, I am attempting to follow-up elderly patients seven years after enrollment in a multi-centre randomized trial of hip replacement. The follow-up consists of one CT scan, exposing the patients to a low risk of radiation, and the completion of one questionnaire asking whether the patient has experienced any of 6 symptoms of hip instability, and whether there have been any hospital admissions and the reasons for these, since last review. This is hardly a complex research agenda, but its findings are critically important, as evidenced by both the original and follow-up studies being in receipt of an NHMRC Project Grant. However, the process of gaining ethics approval has taken many months, constituted hundreds of pages of documentation in total and involved many hundreds of hours of work by countless individuals, both in the submission stage and review process.

Quite clearly the system MUST change if the objectives of research are to be attained, ie good clinical research, preferably multi-centre, being undertaken in a timely fashion.

The system requires a complete overhaul. The starting point for this should be the end-users of the system, namely those researchers trying to get ethical approval and those sitting on the ethics committees, who must be asked to define what the current problems are, how these could be overcome and what the key elements to a successful, EFFICIENT system should be.

It is possible to introduce such a system. It should be multi-tiered, with different pathways for different submissions. The key definers of the appropriate pathways should be, as a starting point:

- Has the submission received high level competitive funding (eg NHMRC, NHF, Cancer-Council etc)? If so, review of the research aspects should be cursory only. If not, more attention must be paid to the research design and statistical issues to discourage the conduct of research that is not going to produce answers to the questions posed, because of inappropriate research methodology or too small a sample size.

- What is the level of risk involved in participation (and a consideration of risk/benefit)? For example, involvement of radiation at low levels, particularly to patients who are not young or of a reproductive age, should be universally

considered low risk and subjected to a more streamlined radiation approval process.

Further down the line, the inclusion of every individual question or item in the ethics submission must be justified. What may appear acceptable with the involvement of one or two clinical investigators can quickly become a torturous, time-wasting and annoying exercise, of questionable justification, when multiple clinical investigators at multiple sites are involved, eg the accumulation of multiple Professional Medical Registrations and CVs, particularly for clinicians well known to the institution.

In summary, we do not currently have a viable system for human ethics review. Importantly, because of the overly bureaucratic requirements of the ethics review process, and therefore the length of time required to attain approval, the current system discourages the conduct of investigator-initiated multi-centre clinical research, funded by highly competitive and peer-reviewed project grants and undertaken by academically independent organizations, such as hospitals or universities. On the other hand, drug and device companies have the capacity to negotiate the current systems. The implications of this are serious. Is clinical research in Australia heading towards a system where the majority of the research will be led by bodies potentially with a vested financial interest in the outcomes of that research? Unless the system is changed, this may be the outcome.