30th June 2022

National One Stop Shop Consultation on National SSA minimum requirements

Thank you for the opportunity to submit feedback to the consultation on the minimum core elements of the national Site-Specific Assessment.

About Australian Genomics

Australian Genomics is an Australian Government initiative supporting genomic research and its translation into clinical practice. Through broad engagement and a national collaborative approach, it achieves two key objectives: to improve efficiency, reach and timeliness of genomic research projects, and to support Commonwealth State and Territory health departments in the implementation of genomics research outcomes by refining and communicating evidence to inform policy development.

Australian Genomics engages with current and emerging government policy and priorities to identify gaps and opportunities, to support policy and action for integrating genomic technologies into the health system. By interfacing with consumers, governments, industry and global genomics initiatives, Australian Genomics drives change and growth in the sector.

Since 2016, Australian Genomics has employed research coordinators across Australia to facilitate its national, multi-site research program, and support of other genomic research in Australia. The coordinators have managed the research ethics and governance approval processes through 5 HRECs and 32 Governance Office's at study recruitment sites nationally. Through their experience with such systems in all Australian jurisdictions, the research coordinators have provided combined feedback on the consultation document, outlined in the following sections.

Feedback on National Site-Specific Assessment Core Elements

Overall, the National Site-Specific Assessment core elements documents captures all the requirements of such processes currently in place nationally. Specific questions and comments include:

- In the document preamble, the definitions of 'above' and 'below' the line were not clear.
- The template form is missing the ability to provide a short summary of the project.
- Please consider including an option to select more than one type of "Research Type" which may be important for multi-disciplinary research.
- Please clarify whether pathology laboratories, such as genetics/genomics sequencing laboratories, would be considered a research site or a facility.

- Please clarify whether there should be a distinction between a clinical site (e.g. hospital) and a research site (e.g. research institute).
- Proposed duration of study at site – it would be good to have the ability to have different dates for different sites.
- Study Personnel – should include a field to capture 'role in study' to ensure it fits within their scope of practice and credentialing. This will require additional fields to meet South Australian requirements for studies involving minors, allowing applicants to upload a working with children check and confidentiality agreement.
- WA Health HRECs and RGOs require all AIs, PIs and CPIs to have Good Clinical Practice certification for all research, not just clinical trials. Will this requirement be adapted in the SSA for certain jurisdictions, or will there be a national consensus on this requirement that jurisdictions need to follow?
- WA Health SSAs through the Research Governance Service (RGS) has a "Recruitment" process section where details are added about how participants are identified and how initial contact with participants is made. This is valuable to application reviewers, to understand the time and resources required to recruit participants, and factors like whether the site is introducing the study and referring patients to the lead site or recruiting/consenting the patients themselves. This could be partially or completely pre-filled from the HREC application.
- Will there be a site-specific budget form? In WA, the budget form is part of RGS and the SSA form which need to have been signed off before the SSA form.
- Budget form templates and standard minimum requirements for budget forms would also be useful.

Feedback on the design and functionality of the platform

- Pre-filling/auto-population of fields would be useful functionality, but how this will work and the extent to which it will be used is unclear.
- The ability to change or update pre-filled sections in the form would be useful.

Current SSA pain points that should be addressed in the new system:

- Automated/pre-filled fields that cannot be overridden can be burdensome. For example, within the South Australian research governance and ethics management system (GEMS), if the Site PI is also the department head, then they cannot approve the research to take place due to a conflict of interest. As the department heads are pre-filled, this creates a frustrating error. It requires a work around to that it auto pre-fills their next line in charge.
- Obtaining the head of department (HoD) and hospital administrator sign-off/authorisation of the SSA and budget form in WA is the biggest hold-up with application progression. The new

system should be built in such a way that the new SSA process streamlines sign-off. Potentially the RGOs could add the relevant HoD/Hospital Administrators for the department to the system (and update that when there's a replacement) that can then pre-populate the form, with the ability to change the nominated HoD/Hospital Administrator when required (e.g. when HoD is a project member and therefore cannot authorise themselves).
- A PI delegate is highly desirable or the ability for project members to complete tasks on behalf of the PI.

Feedback of Australian Genomics personnel from the recent One-Stop-Shop workshops

- The platform is a proof-of-concept at this stage. There will be further consultation on user experience at the later date, which Australian Genomics personnel would be willing to willing to participate in.
- While not mandatory for jurisdictions to use the new platform, we strongly support its uptake across all jurisdictions, as there has been considerable effort in addressing current pain points.
- One of the key messages arising from the demonstration of the proof-of-concept platform was that the system is being designed to facilitate / accommodate processes, not to dictate them. While we agree with this, many of the barriers to a proper functioning HREC/RGO system arise not from the submission platforms but from individual HRECs/RGOs dictating their own, individual requirements. This serves to overcomplicate the system.
- We applaud the Commission's parallel initiative seeking to address variability in HREC review and develop accreditation and quality standards for the review of research.
- Australian Genomics looks forward to following the progress of this work, particularly how HREA and SSA will be combined into a single national workflow.

Sincerely,

Tessa Mattiske

Dr Tessa Mattiske
National Coordination Manager
Australian Genomics