WHAT'S NEW IN THE NSW SSA

The REGIS SSA form

There are several changes to the NSW Site Specific Assessment (SSA) form in REGIS that reflect reform- and system-related improvements. Here is an overview of what's new in the REGIS NSW SSA, compared to the NSW SSA form that is in Online Forms.

<table>
<thead>
<tr>
<th>NEW SSA</th>
<th>OLD SSA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NAVIGATION</strong></td>
<td>Navigable by page number only.</td>
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<tr>
<td>7 sections always visible on left-hand side.</td>
<td>Section overview not visible when working inside the form.</td>
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<tr>
<td>Sections labelled by section title, and show what's complete or requires more information.</td>
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</tbody>
</table>

**PART A: PROJECT-WIDE INFORMATION**

All completed at Project Registration, and pre-populated into each related SSA, including site names.

**PART B: PROJECT TEAM**

Applicant completes remaining information about the Principal Investigator (PI) entered at Project Registration, and completes remaining information about - and adds any additional - site team members.

- Allows for entry of Associate Investigators (AI), other research personnel requiring physical access to the site who are not NSW Health staff at that site, and administrative contact.
- Collects student information, and requires supervisor declarations.
- Does not collect training information; has fields for project role and expertise.

Required re-entry of PI's information.

- Allowed for entry of AI's and a contact person.
- Did not collect student information at the SSA level.
- Collected a list of researcher-required training; had four fields for qualifications, experience, expertise and role.
### WHAT'S NEW ON THE NSW SSA

#### NEW SSA

**PART C: DEPARTMENTS/SERVICES**

Department, and Head of Department (HoD) name and email address, prepopulated from pre-set, updateable list provided by Research Office and uploaded into system.

Each HoD must have a REGIS account before SSA form can be submitted.

New field provided for each PI to state support required from HoD (e.g. personnel, services, facilities, equipment) which is populated onto each relevant declaration.

**PART D: RECRUITMENT, RECORDS, TISSUE AND DATA**

- **Non-clinical trials:** free text field for proposed number of participants.
- **Clinical trials:** minimum and maximum enrolment numbers collected for NSW metrics program.
- Categories of people recruited not asked, as available elsewhere.
- Two new fields for, if applicable, number of medical records proposed for review, and number of tissue samples proposed to access.

**PART E: SITE COSTING AND FUNDING**

- Both funding and cost information collected, with real-time in-system calculation of difference between the two.
- Six funding types available (commercial, donations/bequests, grants, non-commercial, other external and internal department).
- Non-financial costs and estimated dollar value collected, and included in calculations.

#### OLD SSA

**PART C: DEPARTMENTS/SERVICES**

Department information entered into separate "time and resources" table and "departments and services involved" table.

HoDs did not require system account for SSA form to be completed in system; declarations of support often collected external to system.

**PART D: RECRUITMENT, RECORDS, TISSUE AND DATA**

- One free-text field for proposed number of participants.
- Asked about categories of people to be recruited.
- For NSW clinical trial recruitment metrics, enrolment numbers entered by the research office.
- No fields about medical records or tissue samples.

**PART E: SITE COSTING AND FUNDING**

- Only funding information collected; no costing information collected.
- Four funding types available (commercial, sponsored other, external and internal/department).
- No in-system calculations provided.
- Amount units varied (e.g. per year or per participant).
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<td><strong>PART F: ATTACHMENTS</strong>&lt;br&gt;<strong>SITE-SPECIFIC DOCUMENTS</strong>&lt;br&gt;Site-specific attachments uploaded as part of SSA.&lt;br&gt;No duplicative checklist provided. PIs encouraged to refer to required lists per policy and site requirements.&lt;br&gt;Fields provided for document type and title, wherein investigator may enter date and version.</td>
<td><strong>Although SSA provided a yes/no checklist that recommended required attachments, documents were uploaded under a separate tab and were not linked to the checklist.</strong>&lt;br&gt;Fields provided for document type, version, date and description.</td>
</tr>
<tr>
<td><strong>PART G: DECLARATIONS</strong>&lt;br&gt;Only the PI completes a declaration, on electronic submission of the application.&lt;br&gt;HoDs, including Authority for Data Provision, receive email notification upon SSA completion, and confirm or qualify their support by logging into the system.&lt;br&gt;HoD information pre-populated from Part C.</td>
<td><strong>Declarations generated inside SSA form for PI, all AIs, and HoDs.</strong>&lt;br&gt;Declarations could be made electronically within system or collected via email or web signature and included as attachments.&lt;br&gt;No pre-population from Department tables to declarations.</td>
</tr>
<tr>
<td><strong>OTHER DIFFERENCES</strong>&lt;br&gt;Anticipated start and finish dates requested.&lt;br&gt;For clinical trials, requires identification of an AI who will act as substitute for the PI when available.&lt;br&gt;The &quot;complete SSA&quot; button automatically sends application to HoDs for their review.</td>
<td><strong>Start and finish dates not asked.</strong>&lt;br&gt;Generation of a submission code did not electronically submit the form; PIs needed to send a PDF of the form via email or post.</td>
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**FOR MORE INFORMATION**

You may contact the OHMR Research Ethics and Governance unit at researchethics@doh.health.nsw.gov.au