# 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.

| NEW SSA | OLD SSA |
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| **NAVIGATION** | |
| 7 sections always visible on left-hand side. | Navigable by page number only. |
| Sections labelled by section title, and show what's complete or requires more information. | Section overview not visible when working inside the form. |
| **PART A: PROJECT-WIDE INFORMATION** | |
| All completed at Project Registration, and pre-populated into each related SSA, including site names. | Only Project title, summary and HREC name pre-populated from the NEAF. |
| **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. | Required re-entry of PI's information. |
| 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. | Allowed for entry of AI's and a contact person. |
| Collects student information, and requires supervisor declarations. | Did not collect student information at the SSA level. |
| Does not collect training information; has fields for project role and expertise. | Collected a list of researcher-required training; had four fields for qualifications, experience, expertise and role. |

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| **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. | Department information entered into separate "time and resources" table and "departments and services involved" table. |
| Each HoD must have a REGIS account before SSA form can be submitted. | HoDs did not require system account for SSA form to be completed in system; declarations of support often collected external to system. |
| 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. | One free-text field for proposed number of participants. |
| **Clinical trials:** minimum and maximum enrolment numbers collected for NSW metrics program. | Asked about categories of people to be recruited. |
| Categories of people recruited not asked, as available elsewhere. | For NSW clinical trial recruitment metrics, enrolment numbers entered by the research office. |
| Two new fields for, if applicable, number of medical records proposed for review, and number of tissue samples proposed to access. | No fields about medical records or tissue samples. |
| **PART E: SITE COSTING AND FUNDING** | |
| Both funding and cost information collected, with real-time in-system calculation of difference between the two. | Only funding information collected; no costing information collected. |
| Six funding types available (commercial, donations/ bequests, grants, non-commercial, other external and internal department). | Four funding types available (commercial, sponsored other, external and internal/department). |
| Non-financial costs and estimated dollar value collected, and included in calculations. | No in-system calculations provided. |
| | Amount units varied (e.g. per year or per participant). |

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| **PART F: ATTACHMENTS SITE-SPECIFIC DOCUMENTS** | |
| Site-specific attachments uploaded as part of SSA. | 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. |
| No duplicative checklist provided. PIs encouraged to refer to required lists per policy and site requirements. | |
| Fields provided for document type and title, wherein investigator may enter date and version. | Fields provided for document type, version, date and description. |
| **PART G: DECLARATIONS** | |
| Only the PI completes a declaration, on electronic submission of the application. | Declarations generated inside SSA form for PI, all AIs, and HoDs. |
| HoDs, including Authority for Data Provision, receive email notification upon SSA completion, and confirm or qualify their support by logging into the system. | Declarations could be made electronically within system or collected via email or web signature and included as attachments. |
| HoD information pre-populated from Part C. | No pre-population from Department tables to declarations. |
| **OTHER DIFFERENCES** | |
| Anticipated start and finish dates requested. | Start and finish dates not asked. |
| For clinical trials, requires identification of an AI who will act as substitute for the PI when available. | Generation of a submission code did not electronically submit the form; PIs needed to send a PDF of the form via email or post. |
| The "complete SSA" button automatically sends application to HoDs for their review. | |

## FOR MORE INFORMATION

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