Site-Specific Assessment (SSA) national minimum core elements

The purpose of the SSA

The purpose of the SSA is to clearly document the basis of the arrangements between parties and to assure the institutional delegate that all relevant risks related to the research project have been identified and appropriately managed.

National SSA principles

- Aims to streamline the SSA process, minimising duplication and unnecessary requirements, and maximising consistency
- Includes common national (above the line) requirements
- Includes jurisdictional specific, legislated (below the line) requirements
- Is consistent with minimum requirements specified in the National Clinical Trials Governance Framework and all relevant legal or regulatory requirements, as well as being sufficient to provide decision-makers with confidence that patient safety and clinical standards are being maintained
- Collects sufficient quality data to strengthen the oversight provided by governing bodies
- Is adaptable, and enable periodic planned updates and modifications, to accommodate evolving requirements over time.

The SSA process

The site-specific assessment process ensures the arrangements between parties, for the conduct of research in health service organisations, are in place. The SSA process considers the following:

- The capacity for the site to support the project, including the availability of participants at the site
- Financial arrangements for the project
- Insurance and indemnity arrangements
- The availability of appropriately certified and trained staff to meet the requirements of the project
- Data access
- Local approvals relevant to the conduct of the project.

Pre-authorisation activities:

- Liaising with the research investigators, their teams and sponsors regarding the preparation of applications for site authorisation
- Managing the process of site authorisation, reviewing the SSA and recommending authorisation of the project to the Chief Executive Officer or their delegate
- Ensuring a copy of the HREC approval, indemnity and insurance documents have been received, agreements applicable to the project have been signed
- Ensuring collection of the appropriate fees for site authorisation
- Documenting all site-specific assessment decisions and maintaining a current record on the appropriate database
- Reviewing and managing amendment documentation related to projects
- Collecting and providing data on operational metrics to the governing body.

Post-authorisation activities activities:

- Managing and reviewing amendments of authorised research projects
- Having visibility of authorised projects through review of annual and final site progress reports submitted by the Principal Investigator
- Receiving project related safety reports
- Receiving complaints related to the conduct of a project and escalating these to the appropriate officer within the health service organisation.

Site-Specific Assessment (SSA) – final national SSA core elements

Please consider the following when reviewing the core elements:

- This SSA workflow should be considered within the context of the proposal for an **intuitive, single national approvals and research management and workflow system enabled through digital smart technology** with skip logic and auto-population of fields that will align with existing NAS data fields as required. At a minimum it is proposed that the One Stop Shop would:
    - provide cross-jurisdictional ethics approval and site-specific authorisation platform that incorporates key application, notification and approval systems
    - incorporate the Clinical Trials Notification and Clinical Trials Approval schemes administered by the Therapeutic Goods Administration and processes required by the Gene Technology Regulator
    - include an embedded and automated next-generation national registry
    - provide a research management system with sophisticated monitoring and reporting functionality for different users (including but not limited to, safety and adverse event reporting, annual HREC reports)
    - embed the National Clinical Trials Governance Framework accreditation obligations and automate data/reports/processes to support the accreditation process
    - assist all governments to respond to areas of need in a rapid, coordinated and strategic manner based on real-time, accurate information regarding research activity and site capability.

- Implementation of the SSA through the proposed national One Stop Shop platform would be supported by built-in training, explanatory notes and guidance for all users (including the applicant and the person undertaking the SSA review) as well as:
    - help text accessible by all users as they navigate through the smart form through active selection options. It would be provided in several ways (bubble notes, drop down notes, hover information fields and video's etc). It would include field definitions.
    - document management capability including to enable documents to be uploaded and stored with security settings based on user authorised access capability
    - a knowledge sharing system that provides a forum between different professionals to help answer questions and discuss common problems
    - system enabled notifications (internal and external) and communications
    - digital signatures and configurable site/jurisdictional delegations ad processes.

SSA Registration		**Help text** will be accessible by all users as they navigate through the smart-form through active selection options. It will be provided in several ways (bubble notes, drop down notes, hover information fields and video's etc). It will include field definitions.
0	**The SSA submission applies to the following jurisdiction(s):** *Select all that apply* [*Australian Capital Territory, New South Wales, Northern Territory, Queensland, South Australia, Tasmania, Victoria, Western Australia]*	Note: Depending on what jurisdiction is selected additional questions may be generated at the end of the SSA workflow.
1	**Project Reference Number** *single unique identifier that is system generated, auto populated and links the project to all parts of the platform including the project management functions and the next generation registry.*	
2	**Full Project Title** *auto populated*	
3	**Short Title/acronym** *auto populated*	
4	**Research Type** *drop down list auto populated and matches the NAS data fields and system enabled links to NHMRC Fields of Research.*	• **Interventional/Clinical Trials research:** Interventional research is the use of one or more substances, devices, treatments, therapies, techniques or processes in a defined cohort of participants to determine the impact or effect on individuals. Interventions can be physical, behavioural, psychological or informational and can be used in clinical, educational or other contexts. Interventional research may or may not: - Be comparative, - Randomise the participants, - Include an experimental arm, and/or - Include a placebo arm. The World Health Organization defines a clinical trial as "any research study that prospectively assigns human participants or

		groups of humans to one or more health-related interventions to evaluate the effects on health outcomes". FTIH/FTIP clinical trial – drug FTIH/FTIP clinical trial – device FTIH/FTIP clinical trial – drug and device Clinical trial of a drug Clinical trial of a device Clinical trial of a drug and device **Clinical trial – other** (eg: clinical trial follow on study) **Action research:** Action research is often community - or organisation - based and is carried out in the field. This approach involves testing ideas in practice as a means of improving social, economic or environmental conditions and increasing knowledge. Action research proceeds in a spiral of steps consisting of planning, action, and evaluation. It provides a basis for further planning of critically informed action. This method includes design and implementation research and 'rapid appraisal' research. • **Biospecimen analysis research:** National Statement Chapter 3.2 describes biospecimens as, "any biological material obtained from a person including tissue, blood, urine, sputum; it also includes any derivative of these such as cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person." Biospecimen analysis includes potential genetic or genomic investigations. • **Data linkage research:** The International Population Data Linkage Network describes data linkage as, "Secondary use of linked administrative data… often referred to as 'data linkage,' 'record linkage,' or 'linked data.' This is typically population based longitudinal data that has originally been collected for another purpose. Linkage may take place across data sets in a single domain (i.e. health) or across domains (i.e. health, education, environment, early childhood, etc.)"

		Note: The character of and planned activities related to data will be addressed in Section 3 of the HREA for all projects, irrespective of the methods selected. • **Ethnographic research:** Ethnographic research is a qualitative, iterative research method used to engage with a group, community, population or society that is aimed at description of everyday life and practice and the interpretation of cultural meanings, patterns and systems emphasising an 'insider's point of view'. Ethnographic research is usually based on fieldwork using a model of participant-observation and the research questions are often developed in collaboration with research participants. The result is an account of the people, place or institution with whom or with which the researchers have interacted. • **Epidemiological research:** The World Health Organization describes epidemiology as "the study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems. Various methods can be used to carry out epidemiological investigations: surveillance and descriptive studies can be used to study distribution; analytical studies are used to study determinants". • **Observational research**: Observational research involves the researcher observing participant/s in their own environment, or in the environment being studied. Data collection through observation can be structured or unstructured, with the observer as a collaborative participant (participant observation) or external to the environment. Clinical registries monitor the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information. The information is used to identify benchmarks, significant outcome variance, and inform improvements in healthcare quality.

		• **Survey/Interview/Focus Group research:** Interviews involve researchers talking to one or more participants, where the categories of response are focused but not necessarily pre-determined. Interviews are usually recorded by audio- or video-tape, or notes. These records are research data in themselves, but also may be transcribed. Interviews are usually conducted in locations mutually acceptable to participants and interviewers. Focus groups of participants discuss a set of research questions or topics. This may entail the researcher acting as a moderator for the discussion. This method includes research using oral history. • **Textual analysis research:** This method may involve evaluation of texts including film, television, photographs, magazines, advertisements, clothes, graffiti and other media. This method may include the study of content or specific language and its frequency (e.g. hermeneutics or linguistic analysis). **Implementation research:** Scientific study of the processes used in the implementation of initiatives as well as the contextual factors that affect these processes.
5	**If, interventional/clinical trial research, then select study type:** *drop down list auto populated based on NHMRC definitions, and, data fields are aligned with NAS values.*	
6a **6b.**	**Is this a low/negligible risk research?** ☐ Yes ☐ No **Is this greater than low risk research?** ☐ Yes ☐ No	**Low and negligible risk research:** The expression 'low risk research' describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk. The expression 'negligible risk research' describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. (National Statement) **Greater than low risk research:** Research is 'low risk' where the only

		foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.
7	**Site(s)**	Organisation that conducts and manages research that come under one research authorisation's sign off. A facility, location or service where the research is being conducted. *Note: Allow for multiple selections of sites*
8	**Proposed duration of study at site**	
9a	**Is this a teletrial?** ☐ Yes ☐ No ☐ N/A **For teletrials, select one option relating to site type:** **9b. Teletrial primary site** ☐ **9c. Teletrial satellite site** ☐	**Primary site**: Under the Teletrials Model, the Primary Site coordinates the trial across a cluster to enhance participant reach, recruitment and management. The Principal Investigator located at the Primary Site has full responsibility for conducting the clinical trial at their site and any Satellite Site within their cluster under ICH GCP. **Satellite Site:** A Satellite Site is located in a geographically separate health facility and trial activities are delegated by the Primary Site (clinical trial site) to the Satellite Site, to enable performance of activities associated with the conduct of a clinical trial at the Satellite Site and to support trial accessibility of remote participants to a clinical trial. A Satellite Site can be located in metropolitan, regional or rural settings. Delegated activities to be performed by a Satellite Site are trial and Satellite Site specific. The Primary Site must consider a Satellite Site's personnel and facilities in developing a Delegation Log and Supervision Plan suitable for a trial. The proposed delegation of duties and Supervision Plan must be agreed at the time of site selection and must be documented before the study is initiated at each For each trial, infrastructure and training

				requirements are the same for both the Primary and Satellite Sites. A Satellite Site should have the following: • Appropriately contracted qualified and trained Investigator(s) and delegated staff to undertake delegated trial related activities including obtaining informed consent (if required). Study staff are trained in the Protocol, IB, study procedures and Adverse Event (AE)/Serious Adverse Event (SAE) reporting. A system for safety reporting duties is in place for all study staff. • Study related documentation including a Satellite Site Study File, procedures for managing the security of information and trial data and a process for managing data security or privacy breaches. • An understanding of the process for securely and suitably storing and ensuring accountability for the Investigational Medicinal Product (IMP).
10a	**Site Principal Investigator** *Attach function. Documents will be stored within the platform with notifications to the individual when their documents are due to be updated:* • *Upload CV (not mandatory)* • *Upload GCP (if clinical trials only)*			The Principal Investigator (PI) is the investigator responsible for the conduct of a research project at a particular site. For projects conducted at multiple sites, the Principal Investigator is the person with responsibility for managing the research project at each site. A person who does not have the above responsibilities is often referred to as an Associate /Assistant/Sub-/Co- Investigator or Investigator.
10b.	**Title:** *drop down list [Professor, A/Professor, Dr, Mr, Ms]*	**10c: First Name**	**10d: Surname**	
10e	**Organisation**	**10f: Department**	**10g: Email address** **10h: Phone**	

11a	**Site Associate Investigators) / Co-Investigator/Coordinating Principal Investigator** *Attach function:* • *Upload CV (not mandatory if collected by the site through another means)* • *Upload GCP (if clinical trials only)*			
11b.	**Title** *drop down list*	**11c: First Name**	**11d: Surname**	
11e.	**Organisation**	**11f: Department**	**11g: Email address** **11h: Phone**	
12a.	**Site Coordinator/Contact Person** *Attach function:* • *Upload CV (not mandatory)* • *Upload GCP (if clinical trials only)*			
12b.	**Title** *drop down list*	**12c: First Name**	**12d: Surname**	
12e	**Email** address	**12f: Phone**		Provide the preferred contact email address to contact the person on during business hours. Provide the preferred phone number to contact the person on during business hours.
13a. **13b.**	**Conflicts of interest (actual or perceived)** *Declare any Conflicts of Interest [Platform to enable link to the NHMRC Guide on COI]* **Where a conflict of interest has been identified, note the strategy in place to manage this conflict of interest** *(free text field).*			Consider conflicts of interest that may arise when the health service organisation undertaking the research is also the sponsor of the sponsor of the project. Under the Australian Code for the Responsible Conduct of Research, 2018: *"All researchers are expected to act in accordance with their obligations under the Australian Code for the Responsible Conduct of Research, 2018"* *The NHMRC Chapter 5.4: Conflicts of interest Introduction - Chapter 5.4 A conflict of interest in the context of research exists where: a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or an institution's interests or responsibilities*

		have the potential to influence the carrying out of its research obligations. While a conflict may relate to financial interests, it can also relate to other private, professional or institutional benefits or advantages that depend significantly on the research outcomes. A conflict of interest may compromise the research process itself and/or the institutional processes governing research and may lead researchers or institutions to base decisions about the research on factors outside the research requirements. *5.4.1 Institutions should establish transparent processes to identify and manage actual and potential conflicts of interest involving:* *(a) the institution itself;* *(b) researchers; or* *(c) ethical review bodies, their members or advisors.* *5.4.2 An institution with a conflict of interest bearing on research should inform relevant ethical review bodies about the conflict.* *5.4.3 Ethical review bodies should see that measures are adopted to manage conflicts of interest involving researchers (see paragraph 5.2.10). These measures* *may include requiring that:* *(a) the information be disclosed to research participants;* *(b) a person other than the researcher make the initial approach to participants;* *(c) the information be disclosed in any report of the research;* *(d) the research be conducted by another researcher; or* *(e) the research not be conducted.* *5.4.4 Where an ethical review body becomes aware that there may be a conflict of interest involving the institution, the review body should notify the institution.* *5.4.5 An ethical review body should require its members, and also any experts whose advice it seeks, to disclose any actual or potential conflict of interest in research to be reviewed, including any:* *(a) personal involvement or participation in the research;* *(b) financial or other interest or affiliation; or*

			(c) involvement in competing research. *The review body should adopt measures to manage such conflicts. In the case of members these measures may include exclusion from a meeting, or from some* *or all of the body's deliberations, or in the case of expert advisors, requesting only written advice from them.* *5.4.6 Sometimes a researcher who discloses the fact that he or she has a conflict of interest may have an ethically acceptable reason for not disclosing what the conflict is, for example, that this might breach another person's privacy. The researcher may then remain involved in the research only if the review body is satisfied that the conflict can be managed without its nature being disclosed*. Conflict of Interest applies to all (Site Principal Investigator, Site Associate Investigators) / Co-Investigator, Site Coordinator/Contact Person
HREC Approvals			
14a	**Reviewing HREC Name** *auto populated with HREC identifier*		Human Research Ethics Committees (HREC) play a central role and review research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines, including the National Statement on Ethical Conduct in Human Research (the National Statement 2007, updated, 2018). Must be **registered** with the NHMRC
14b	**Reviewing HREC Reference** *auto populated*		
14c	**Reviewing HREC Project Approval Letter** *(attach)*	☐ Yes ☐To be provided	
14d	**Reviewing HREC amendment Approval to add Site** *(attach)*	☐ Yes ☐To be provided	
14e	**Additional HREC review required by site**		Provide details for each ethics committee that has reviewed an application (this does not include amendments) for example, review by an Aboriginal and/or Torres Strait Islander HREC; Justice Health

			or Mental Health HREC; deontology studies or for HREC approval of coronial material or government-held data. This includes Clinical Trial Approval notifications from the TGA. • **Clinical Trial Approval Scheme:** The Clinical Trial Approval Scheme (CTA) is established under the Therapeutic Goods Act 1989 (Cth) and is administered by the TGA. Under the CTA scheme, therapeutic goods are permitted to be used for experimental purposes if the relevant clinical trial is approved by the TGA.
14f	**Other HREC Reference** *auto populated*		
14g	**Other HREC Project Approval Letter** *(attach)*	☐ Yes ☐ No ☐ N/A	
14e	**Other HREC Approval to add Site** *(attach)*	☐ Yes ☐ No ☐ N/A	
14f	**Include protocol** *(attach):* **Approved protocol and project description** *auto populated*	☐ Yes ☐ No ☐ N/A	A document that provides the background, rationale and objectives of the research and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.
14g	**HREC approved advertising material for the research** *auto populated and enables multiple document upload functionality*	☐ Yes ☐ No ☐ N/A	Approved advertising material include recruitment material any participant-facing material and communication material
14h	**Approved advertising material updated for site specific requirements** *auto populated and enables multiple document upload*	☐ Yes ☐ No ☐ N/A	
14i	**Participant Information and Consent Form updated for site**	☐ Yes ☐ No ☐ N/A	Informed consent is a process of communication between a patient and a clinician about options for treatment, care processes or potential outcomes. This communication results in the patient's

	(administration matters only) *(attach)*		authorisation or agreement to undergo a specific intervention or participate in planned care. The communication should ensure that the patient has an understanding of the care they will receive, all the available options and the expected outcomes, including success rates and side effects for each option.
15	**Civil & Administrative Tribunal approvals** *(attach)*	☐ Yes ☐ No ☐ N/A	Attach Civil & Administrative Tribunal approvals if required.
Recruitment and financial information			
16	**Participant recruitment target at site** ☐ N/A if a data linkage study		Anticipated number of participants at the site
17	**Sponsor Type** *Drop down list [commercially sponsored, collaborative group, investigator-initiated group, institution, university, other]* *Platform enabled auto-population from other workflows and data sources.*		• Values to align with the NAS data fields • An individual, organisation or group taking on responsibility for the research project • For a commercially sponsored research, this is usually the company funding the trial • For non-commercially sponsored research this could be the collaborative research group, or the employer of the co-ordinating principal investigator, or a higher education institution, a research institute, or the public health organisation where the research is to take place.
18a	**Type of Funding Source** *Dropdown list [Commercially sponsored, collaborative group, External (e.g. NHMRC grant), Internal/Departmental, Other] allows for multiple selection* **18b. Commercially sponsored source** *18c. $xxxx per patient or per year.* *18d. Estimated Funding for the Project at this site $xxxx -name* **18e. Sponsored, other (e.g. collaborative group) source** *18f. $xxxx per patient or per year.*		Include the funding body/bodies and estimated amount of funding

	18g. Estimated Funding for the Project at this site $xxxx -name **18h. External funding source(e.g. NHMRC grant)** *18i. $xxxx per patient or per year;* *18j. Estimated Funding for the Project at this site $xx8oxx -name* **18k Internal/Departmental source** *18l. $xxxx per patient or per year;* *18m. In kind contribution* *18n. Estimated Funding for the Project at this site $xxxx -name* **18o. Other source** *18p. $xxxx per patient or per year;* *18q. In kind contribution (time or other resources provided by the site)* *18r. Estimated Funding for the Project at this site $xxxx add name of 'other source if known* **18s. Unfunded project** ☐ N/A option for data linkage studies		
19.	**Signed Finance Summary** *(attach)*	☐ Yes ☐ No ☐ N/A	The financial Summary or budget may be a checklist verifying the following information: • Current financial balance • Has a detailed budget been developed by the clinical unit? • Are Standard Fees included in the Sponsor accepted budget? • Required Per Patient Payment • Are there procedures additional to Standard of Care? • If 'Yes', are the costs of additional procedures fully covered in the Per Patient Payments? • Does budget cover all known costs for the project?

20. Supporting Department Approvals *(attach signed Heads of Department approval as required)* ☐ include N/A option for Department approvals section			An investigator must not approve their own research on behalf of their department. If an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible
21	**Joint Department approval by a joint Committee** *(attach)*	☐ Yes ☐ No ☐ N/A	
22	**Pharmacy** *(attach approval)*	☐ Yes ☐ No *(provide explanation)* ☐ N/A	
23	**Pathology** *(attach approval)*	☐ Yes ☐ No *(provide explanation)* ☐ N/A	
24	**Other** *Drop-down list of all other clinical departments. This is will not be mandatory and will enable multiple selection and 'other'*	☐ Yes ☐ No ☐ N/A	Other department approvals include but are not limited to: paediatrics, cardiology, oncology, outpatient, mental health, emergency, private research institution or co-located organisation.
25	**Imaging and/or radiology and diagnostic imaging** *(attach Medical Physicist Report and/or approval and/or therapeutic radiation dose/s levels)*	☐Yes ☐ No *(provide explanation)* ☐ N/A	This requires a Site Radiation Physicist Report to comply with ARPANSA regulator • Attach radiation safety report/exposure statement and/or institutional radiation safety committee approval. • Radiation safety approval and registration is not the same as diagnostic imaging & radiotherapy service declaration. A Medical Physicist report is required for research involving ionising radiation. • Each participating site should review their local site's radiation safety risk assessment and the approval certificate. • If the radiation risk category assessed by the site is the same as or lower than the risk category listed on the approval certificate, the project can be accepted (i.e. authorised at the site) without the need for further HREC review.

26	**Biosafety and chemical safety requirements** *(attach approval)*	☐ Yes ☐ No *(provide explanation)* ☐ N/A	Attach bio safety report/exposure statement.
27	**Does the study require Institutional Biosafety Committee (IBC) notification and/or licence application to the Office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisms?** *(attach approval)*	☐ Yes ☐ No ☐ N/A	Attach Institutional Biosafety Committee notification and/or Attach licence application to the OGTR office for approval of genetically modified organisms.
28	**Does the research project require a license issued by the NHMRC Embryo Research Licensing Committee (ERLC)?** *(attach approval)*	☐ Yes ☐ No ☐ N/A	Research involving human embryos carries additional requirements under Commonwealth legislation (see *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning Act 2002*) and related State and Territory legislation. This legislation provides a regulatory framework to prohibit certain unacceptable practices including human cloning, and to regulate uses of excess human embryos created through assisted reproductive technology. For more information on the ERLC and these requirements, see https://www.nhmrc.gov.au/research-policy/embryo-research-licensing. If review and licensing by the ERLC is required, **attach** evidence of the outcome of that process, including any license issued.
29a. **29b.**	**Medical records** **Access to health information**	☐ Yes ☐ No (*provide explanation)* ☐ N/A ☐ Yes ☐ No (*provide explanation)* ☐ N/A	Attach data custodian (health service if patient medical records) and data linkage approvals as required by jurisdictional legislation.

	(attach data custodian approval to access health information)		
30a	**TGA Notification required?** *auto populated* **30b.CTN**	☐ Yes ☐ No ☐ N/A **30c: CTN TGA reference number** **30d: Reference Number Pending** ☐ *(attach TGA reference)*	If the research is not a clinical trial, select No or N/A (in an automated system, this question would only appear if clinical trials was selected at question 4a) **Clinical Trial Notification Scheme:** The Clinical Trial Notification Scheme (CTN) is established under the Therapeutic Goods Act 1989 (Cth) and is administered by the TGA. Under the CTN scheme, therapeutic goods are permitted to be used for experimental purposes if the relevant clinical trial is notified to the TGA.
31	**Insurance** *(attach Certificate of Currency)*	☐ Yes ☐ No *(provide explanation)* ☐ N/A	
32	**Indemnity** *(attach Medicines Australia form of Indemnity signed by sponsor)*	☐ Yes ☐ No *(provide explanation)* ☐ N/A	
33	**Research Agreements** *(attach Medicines Australia or other approved contract or agreements such as collaborative agreements and/or material / data sharing agreements signed by Principal Investigator)*	☐ Yes ☐ No *(provide explanation)* ☐ N/A	
34	**Does the project require a teletrial sub-agreement at this site?** *(attach approved contract)*	☐ Yes ☐ No ☐ N/A	
35a	**If the not covered in the agreement, how are IP arrangements documented?"**	☐ Yes, IP is covered in the agreement ☐ No ☐ N/A	Intellectual property (IP) ownership can be agreed upon through appropriate contractual arrangements. The agreement should include: • whether, and when, transfer of ownership will take place

			• who has the right to exploit it • who is to pay for it • whether improvements or modifications are allowed
	35b. If No/NA, please provide details on who will own the IP		
36	**Investigator(s) Declaration**		
	1. I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site. 2. I will only start this research project after obtaining authorisation from the site and approval from the responsible Human Research Ethics Committee (HREC); 3. I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (20018) and the Australian Code for the Responsible Conduct of Research (2018) and Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). 4. I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved. 5. I undertake to conduct this research in accordance with relevant legislation and regulations. 6.I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC, RO and NHMRC 7. I will adhere to the conditions of approval stipulated by the HREC and RO and will cooperate with RO and HREC monitoring requirements. 8. I will inform the HREC, the RO and the delegated department or Divisional Head if the research project ceases before the expected date. 9. I will discontinue the research if the HREC withdraws ethical approval or the authorising authority at the site withdraws authorisation 10. I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, the RGO, the sponsor or an independent body for audit and monitoring purposes. 11. This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.		
	PRINT NAME	ELECTRONIC SIGNATURE	DATE