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**Submission to the Scientific Management Panel**

**NeuRA Imaging**

BEFORE filling out this form:

**Have you discussed this study with staff at NeuRA Imaging?**

We would advise you to do this in order to ensure that you have the most appropriate study design, acquisitions and analysis methods for your research as well as appropriate information for your ethics submissions.

**Have you obtained human ethics clearance?**

You must obtain human ethics approval for your project before it can be considered by the Scientific Management Panel. UNSW HREC is the primary site recommended by us unless you are undertaking significant work or recruitment at sites covered by other ethics committees. This SMP application form also incorporates the information needed for your site specific approval with NeuRA.

**Site Specific Approval (SSA)**

SSA is a component of research governance and involves assessment of the suitability of the site and the Investigators for the proposed research. Research governance is a framework for institutions to use to ensure research is conducted responsibly and safely and is scientifically and ethically sound. Research governance considers the legal compliance, financial management, accountability and risk management associated with a participating site.

**Have all investigators who will be using the facility registered for MRI safety training?**

It is a requirement that any investigator who is planning to enter the facility undergo and pass NeuRA Imaging MRI safety training and be familiar with all appropriate facility operating procedures. Only certified investigators will be allowed to enter the facility.

Please complete the following form and send signed copies to Bronwyn Chapman at NeuRA. An electronic version may be lodged by email. Send to smp-approvals@neura.edu.au.

Please attach copies of the application, all associated documents, and approval letters for any required human ethics clearances. Note that a site-specific approval must also be obtained from NeuRA before any study can commence; this process is incorporated into the Scientific Management Panel application form.

**Note:** The submission will not be considered formally unless complete copies with signatures of ALL chief investigators have been received. Please use a font like Times New Roman in 10-12 point size.

|  |
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| **SECTION A: PROJECT DESCRIPTION** |
| 1. **Title of project:**
 |
| 1. **Short title for the project (in lay terms):**
 |
| 1. **Lay description of the project (100 words):**
 |
| **SECTION B: INVESTIGATOR DETAILS** |
| **Chief Investigators for the Project***: list all Chief Investigators for the project including their primary university or other affiliation***Principal Investigator** |
| Name and title |   |
| Qualifications, expertise and experience relevant to this project(3-5 lines) |   |
| Position |  |
| Affiliation |   |
| Address |   |
| Phone and fax numbers |   |
| Email address |   |
| ORCID iD |  |
| **Associate Investigator 1** |  |
| Name and title  |   |
| Qualifications, expertise and experience relevant to this project |   |
| Position |  |
| Role in this project |  |
| Affiliation |   |
| Address |   |
| Phone and fax numbers |   |
| Email address |   |
| ORCID iD |  |
| **Associate Investigator 2** |  |
| Name and title  |  |
| Qualifications, expertise and experience relevant to this project |  |
| Position |  |
| Role in this project |  |
| Affiliation |  |
| Address |  |
| Phone and fax numbers |  |
| Email address |  |
| ORCID iD |  |

**Associate Investigator 3**

|  |  |
| --- | --- |
| Name and title  |  |
| Qualifications, expertise and experience relevant to this project |  |
| Position |  |
| Role in this project |  |
| Affiliation |  |
| Address |  |
| Phone and fax numbers |  |
| Email address |  |
| ORCID iD |  |

If this project has more than three associate investigators, please add details of the other investigators by copying/pasting the section above.

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| **Name, Position, Phone, email address, and postal address for the contact investigator**:  |
| **Billing details**:Company/Institution Name: ABN: (Ignore if NeuRA)Contact Person: Telephone:Email Address:Billing Address:  |
| **Suitably qualified and responsible person to receive “duty of care” radiology reports, including phone, fax, email address, and postal address.** |
| **SECTION C: PROJECT DETAILS**  |
| 1. **Proposed start and completion date for the project, and for the scanning**:

**Approximate duration (months):**  |
| 1. **List any Doctoral or Masters students involved in the project**:
 |
| 1. Please describe the project in less than two pages. Please indicate the novelty of the proposal and the need for scanning at 3T. **Make sure you include details of the scanning sequences you would like to use.** A list of references may be appended.
 |
|  |
| 1. **List any specific requirements for the project: (include the need for ‘development’ of protocols/procedures with an estimate of required time for this)**
 |
| 1. **Participant details – what categories of people will be recruited?** (*eg children and young people, people with an intellectual or mental incapacity, people highly dependent on medical care, people in dependent or unequal relationships, Aboriginal and Torres Strait Islander people, persons in custody, etc*):

**Proposed number of participants:**(please provide rationale for this number of participants) **If recruiting children, do all those in contact with children have the relevant Working with Children Check clearance?** YES ☐ NO ☐ N/A ☐ **Attach a copy of the Working with Children Check to this application.***Under law, no work with children can commence at NeuRA until it has been cleared by NeuRA (as a worksite) through the Office of the Children’s Guardian database* |
| 1. **Project Code (see Appendix A for naming structure):**
 |
| **Does your project require use of any equipment inside the scanner room in addition to that supplied by NeuRA Imaging?** YES ☐ NO ☐ N/A ☐ If yes, please list the equipment and its manufacturer.Has the equipment been approved by the radiographer? YES ☐ NO ☐ N/A ☐ If the equipment is portable and electric, has it been tested and tagged? YES ☐ NO ☐ N/A ☐ Please confirm that the equipment meets the required regulatory standards (e.g. medical device registration for clinical trials (CTN/CTX #) etc.). YES ☐ NO ☐ N/A ☐  |
| **SECTION D: PROJECT BUDGET** |
| 1. **Study Budget – how is this research project funded at this site?** *To assess the full financial impact of the research and any costs incurred by the organisation should be provided.*

**Please provide details covering the conduct of the trial:****Source of Funding/Scheme:** Click here to enter text.**Amount – $/yr or $/participant** Click here to enter text.**Will this funding cover the full conduct of the proposed research or clinical trial?**  Yes ☐ No ☐ If No please explain how this will be achieved: Click here to enter text. |
| 1. **Other financial, material and capital support** *(eg infrastructure charge, supply of drug(s), loan of equipment etc):*
 |
| 1. **Administering Organisation of the funding**Organisation Name:

Contact Person: Position: Email: Phone: **Insert the account number(s)/cost centre details into which funds will be deposited:**  |
| **SECTION E: DATA** |
| 1. All data will be archived on the NeuRA Imaging storage node. Please indicate whether you intend applying to NeuRA IT for access to this server and whether you would also like to use it for data processing.
 |
| 1. NeuRA has a database of images acquired using a number of standard, optimized sequences. Would you like to use archived data for your study? YES ☐ NO ☐

Please give details:* 1. Which data would you like to use?
	2. Will you need raw or processed data?
	3. How will use of the data enhance your study?
 |
| 1. Are you willing to contribute data to this database? YES ☐ NO ☐

Please give details:* 1. Which data would you be willing to contribute?
	2. Will you be providing any metadata to accompany it?
 |
| **SECTION F: GRANTS & PUBLICATIONS** |

If you are a current user of the facility please provide an updated list of publications and/or successful grants which have used the facility for our records. It is also a condition of use that copies of publications arising out of this current proposal be lodged with the Bronwyn Chapman b.chapman@neura.edu.au.

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| **Details of grants/publications (not including those already reported):**  |
| **SECTION G ETHICS** |
| **Does the project involve human or animal subjects?** YES ☐ NO ☐ |
| **If yes, has the project received ethical committee approval?** YES ☐ NO ☐**Provide the name of the committee(s) and details of the approval (including the duration and any conditions applied).** **Please note the information on the NeuRA Imaging website concerning human research ethics issues and ensure that your project complies. If you already have a NeuRA site specific approval please attach a copy of the approval letter.** |
| **Human or Animal Ethics Application Reference Number/Approval Number:** **HREC Approval Dates (start and end dates):** |
| **SECTION H: SITE SPECIFIC APPROVAL (SSA)** |
| 1. **Who is sponsoring this study?***The sponsor of a study is the company, institution or organisation which takes responsibility for the initiation, management, and/or financing of a study. All projects hosted by NeuRA involving NeuRA staff or external staff must have appropriate insurance and indemnity arrangements in place prior to commencement.* ***NeuRA employees conducting a research project in the capacity of their employment with NeuRA are covered by NeuRA insurance where approval from HREC has been obtained and NeuRA Research Governance approval has been granted****.*

Click here to enter text. |
| 1. **Please attach CVs for each investigator (all investigators, staff and students who will be undertaking tasks on site at NeuRA Imaging).**

 *Note: Individuals holding a current appointment at NeuRA do not need to provide a CV* |
| 1. **Will any researchers require extra training to enable participation in this research?**  Yes ☐ No ☐

If yes – provide details: Click here to enter text. |
| 1. **What additional time and resources, above normal routine duties, will be required of NeuRA staff throughout the research project?**
 |
| 1. **Does the research comply with Site Specific Policies and requirements?** Yes ☐ No ☐

*Details are available on the NeuRA Imaging website* |
| 1. **Does the research team have dedicated available time to undertake the project?**

**Indicate proportion of staff time and funding source allocated to the project**. *eg Investigator B 0.2FTE or X h/week funded by NHMRC Investigator Granteg Investigator J 1.0FTE Research Assistant funded by MRFF grant.eg Investigator K 1.0FTE PhD student funded by RTP scholarship.*

|  |  |  |
| --- | --- | --- |
|  | **Time commitment/position** | **Funding** |
| Investigator 1 | Click here to enter text. | Click here to enter text. |
| Investigator 2 | Click here to enter text. | Click here to enter text. |
| Investigator 3 | Click here to enter text. | Click here to enter text. |
| Investigator 4 | Click here to enter text. | Click here to enter text. |
| Investigator 5 | Click here to enter text. | Click here to enter text. |
| Investigator 6 | Click here to enter text. | Click here to enter text. |

 |
| **7. Anticipated start and finish dates for the research project:**State date (dd/mm/yyyy): Click here to enter text.Finish date (dd/mm/yyyy): Click here to enter text.Duration (months): Click here to enter text. |
| **Clinical Trial Information**1. **Is the research being conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Schemes?** Yes ☐ *complete details below* No ☐ *go to Q9*

**8a. Is this a:** Clinical drug trial ☐ Device trial ☐ **8b. Is the Medicines Australia Standard Indemnity Form(s) signed by the sponsor attached?** Yes ☐ No ☐ N/A ☐ If No or N/A please provide an explanation: Click here to enter text.**8c. Is evidence of adequate Insurance cover attached?** Yes ☐ No ☐ N/A ☐ If No or N/A please provide an explanation: Click here to enter text.**8d. Is the Medicines Australia Standard Clinical Trial Agreement(s) signed by the sponsor attached?** Yes ☐ No ☐ N/A ☐ If No or N/A please provide an explanation: Click here to enter text. |
| 1. **Good Clinical Practice (GCP) training**

*NeuRA requires all research staff to undertake this training to be aware of their responsibilities in conducting human research or clinical trials. A simple and free online course is available at:* <https://genesisresearchservices.com/education/> *or through UNSW RECS.*

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| Have all study staff personnel completed ICH GCP training? | Yes ☐ | No ☐ |
| Record/s of GCP Certificate/s Attached | Yes ☐ | No ☐ |

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1. **Biosafety, chemical and radiation safety**

|  |  |  |
| --- | --- | --- |
| Is Institutional Biosafety Committee (IBC) notification and/or licence application to the office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisation required? | Yes ☐ | No ☐ |
| Will the project require NHMRC Gene and Related Therapies Research Advisory Panel (GRAP) assessment?  | Yes ☐ | No ☐ |
| For projects where Australian Radiation Protection & Nuclear Safety Agency (ARPANSA) Code compliance is required, is additional State specific radiation safety approval and registration required? | Yes ☐  | No ☐ |
| 1. Approved relevant Risk Assessments (RA) and Safe Work Procedures (SWP) for the conduct of this study are in place? Yes ☐ To be completed ☐ Please indicate RA&SWP Name/Number and approval date: Click here to enter text.☐ Not previously supplied, please attach.
 |
| 1. ☐ I acknowledge that the conduct of this research must comply with NeuRA Policies and requirements. Details can be found at <https://intranet.neura.edu.au/display/POL>. In particular Compliance, WHS and HR.
 |
| 1. **Reporting of adverse events**

☐ I acknowledge the requirement for all accidents, incidents and near misses to be reported in line with [WHS31 Incident Report and Investigation Procedure](https://intranet.neura.edu.au/download/attachments/6848643/WHS31%20Incident%20Report%20%26%20Investigation%20Procedure%20v2.1.pdf?api=v2) and recorded in the NeuRA Online Incident and Accident Reporting Tool at <https://forms.neura.edu.au/login>. Incidents are to be logged by the radiographer if investigators are non-NeuRA MRI users. |

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| ***Name, signature and date must be given below for ALL listed investigators. In signing this form you indicate that you have read the terms and conditions in the accompanying document and agree to abide by them.***  |
| **Name** | **Signature** | **Date** |
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**Scientific Management Panel**

*Professor S Gandevia*

*Professor C Rae*

*Doctor R Shnier*

Appendix A: Project Code Structure

Appendix B: Checklist

Appendix C: Site Specific Approval Declaration
(If the project already has NeuRA SSA this is **NOT REQUIRED)**.

**-APPENDIX A-**

 *Project code structure
The “project name” can only contain upper-case alphabetical characters. It cannot contain:*

* *Numerical characters [0-9]*
* *Lower case characters*
* *Wildcard, symbol characters e.g. ! @ # $ % ^ & \* ( ) \_ - = + ~ ` ? [ ] { }*
* *Delimiter or escape characters e.g. / \ | , . ; : ‘ “*
* *Spaces*
* *Patient name(s) or initials*

*Try and keep the “project name” reasonably short (3 ≤ characters ≤ 5). Only one “project name” will be assigned to your project. Once set it cannot be changed so choose wisely.*

 *Refrain from burdening the “project name” with anything but a simple description of the project. For example don’t put words like: control, affected, trial, pilot*

*Good examples of project codes: CPDTI, MTA*

*Bad examples of project codes: TEST000, HIV#TE, PILOTSCANS*

**-APPENDIX B-**

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| --- | --- | --- |
| Checklist | **Investigator Completing Form** | **Office Use only** |
| Has a CV been attached for each investigator? | Yes ☐ | No ☐ | NeuRA staff ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Has a contact person for this research project been nominated? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Have you completed all financial/budget details in Section D? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Has a copy of the ethics approval letter been provided? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Has a copy of the ethics application form been provided? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Has a copy of the protocol been provided? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Has a copy of the Investigator's Brochure/drug information / device information been provided? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Are all Participant Information and Consent Form(s) attached and show the name of the Institution and contact details of the Principal Site Investigator? The version number, and date should be in the footer. | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Has a copy of advertising been provided? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Has a copy of any questionnaires been provided? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Has a copy of any other document, which will be given to research participants been provided? Eg: patient diary | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| If a clinical trial, are CTN/CTX forms attached? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Is the Medicines Australia Standard Indemnity Form, signed by the sponsor, attached? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Is evidence of adequate insurance cover attached? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Is the Medicines Australia Standard Clinical Trial Agreement(s), signed by the sponsor, attached? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Is Evidence of GCP training for all study personnel attached? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Has evidence of Biosafety approval been provided? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Has evidence of an application for NHMRC Gene Related Therapies assessment been provided? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Has evidence of Radiation Safety approval been provided? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Is a "Declaration by Principal Investigator" signed and attached? | Yes ☐ | No☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |
| Are all pages (including attachments) numbered and dated in the footer? | Yes ☐ | No ☐ | N/A ☐ | Yes ☐ | No ☐ | N/A ☐ |

**-APPENDIX C-**

(only required if project **DOES NOT** already have a NeuRA SSA)

**Site Specific Approval Declaration**

**Declarations**

1. **Declaration by the Principal investigator and Associate Investigator(s)**
* I declare that the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility for this site
* I will only start this research after obtaining authorisation from the site and approval from the responsible HREC
* I accept responsibility for the conduct of this research project according to the Principles of the *NHMRC National Statement on Ethical Conduct in Research*
* 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.
* I undertake to conduct this research in accordance with relevant legislation and regulations.
* I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC
* I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
* I will inform the HREC and the research governance officer if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.
* I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Principal Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site where I am Principal Investigator.
* I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, research governance officer, the sponsor or an independent body for audit and monitoring purposes.
* I understand that information relating to this research, and about me as an investigator, will be held by the HREC, research governance officer, and on Research Ethics Database. 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.

Principal Investigator

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Associate Investigator 1

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Associate Investigator 2

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Associate Investigator 3

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Associate Investigator 4

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

1. **Recommendation by the Research Governance Office**

The Site Specific Approval (SSA) form has been completed (with all attachments).

SSA authorisation is:

Recommended ☐

Not recommended ☐

Requires Chief Executive/delegate consideration ☐

If not recommended or requires Chief Executive/delegate consideration, give reasons:

**Research Governance Officer**

Site Name: NeuRA

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

1. **Authorisation by Chief Executive (or delegate)**

This research is:

Authorised ☐

Not authorised ☐

Specify whether there are any conditions applying to authorisation or reasons for not authorising:

**Executive Director/CEO (or delegate):**

Site Name: NeuRA

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_