

**CABRINI RESEARCH GOVERNANCE**

LOW RISK & GOVERNANCE REVIEW APPLICATION FORM

**Prior to completing this form, please read the** [**CRGO Handbook**](http://cabrini.com.au/research-and-education/research-ethics/) **and complete a level of risk checklist (**[**Attachment 4**](http://cabrini.com.au/research-and-education/research-ethics/)**).**

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| **1.** | **ADMINISTRATIVE INFORMATION** | | | | | |
|  | **1.1** | **Project Title:** |  | | | |
|  | **1.2** | **Principal Investigator:** | |  | | |
|  | | | | | **Yes** | **No** |
| **Is the Principal Investigator a Cabrini accredited Medical Practitioner?** | | | | |  |  |
|  | | | | | **Yes** | **No** |
| **Is the Principal Investigator a Cabrini staff member?** | | | | |  |  |
|  | | | | |  |  |
| **Note: If** NO**, please provide insurance/indemnity certificate which covers research** | | | | | **Yes** | **No** |
| **Is current certification of GCP training provided?** | | | | |  |  |
| **Note**: ***All Investigators need to provide evidence of current Good Clinical Practice (GCP) training.***  ***Visit the*** [***Australian Clinical Trials Education Centre***](https://actec.myopenlms.net/course/search.php?search=good+clinical) ***(A-CTEC) to complete ‘Good Clinical Practice (GCP) = Good Research Practice' course.*** | | | | | | |

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| **Qualifications:** |  |
| **Project tasks:** |  |
| **Address:** |  |
| **Email:** |  |
| **Telephone:** |  |

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|  | **1.3** | **Student Researcher (if applicable):**  (A student researcher must list a Cabrini supervisor as Principal Investigator above.) |

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| **Name:** |  |
| **Qualifications:** |  |
| **Project tasks:** |  |
| **Address:** |  |
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|  | **1.4** | **Associate Investigator/s** | |
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| **Name:** |  |
| **Qualifications:** |  |
| **Project tasks:** |  |
| **Address:** |  |
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***Repeat table for each additional investigator and provide a CV of all investigators. Please ensure that you provide an email address with a professional affiliation for both PI and AIs.)***

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|  | **1.5** | **Study Co-ordinator / Contact for correspondence** | |
| **Name:** | | |  |
| **Project tasks:** | | |  |
| **Qualifications:** | | |  |
| **Address:** | | |  |
| **Email:** | | |  |
| **Telephone:** | | |  |

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|  | **1.6** | **Payment Details** | | | | | | | | | |
|  |  |  | | |  | | | | | | |
|  |  | **If your project is billable, please provide details of the person responsible for payments. An invoice for submission fee will be sent during the review process.** | | | | | | | | | |
| Person responsible for payments: | |  | | | | | | | |
|  |  | **Name:** | |  | | | | | | | |
|  |  | **Position/Title:** | |  | | | | | | | |
|  |  | **Company/organisation:** | |  | | | | | | | |
|  |  | **Address:** | |  | | | | | | | |
|  |  | **Contact phone number:** | |  | | | | | | | |
|  |  | **Contact email:** | |  | | | | | | | |
|  |  |  | | | | | | **Yes** | | **No** | |
|  | **1.7** | **Will the research be conducted at Cabrini?** | | | | | |  | |  | |
|  |  | ***If yes, which site(s)? If no, where will the research be conducted?*** | | | | | | | | | |
|  |  |  | | |  | | | | | | |
|  | **1.8** | **Proposed commencement date** | | | |  | | |  |  | |
|  |  |  | | | | **( dd / mm / yyyy )** | | | | | |
|  | **1.9** | **Expected completion date** | | | |  | | |  |  | |
|  |  |  | | | | **( dd / mm / yyyy )** | | | | | |
|  | **1.10** | **Other information** | | | |  |  | | | |  |
|  |  |  |  | | | | | **Yes** | | **No** | |
|  |  | **1.10.1** | **Is there anything in this project that may conflict with Cabrini Health’s Mission Statement?** | | | | |  | |  | |
|  |  |  |  | | | | | **Yes** | | **No** | |
|  |  | **1.10.2** | **Is there anything in this project which is contrary to the NHMRC *National Statement on Ethical Conduct in Human Research*?** | | | | |  | |  | |
|  |  |  | | | | | | **Yes** | | **No** | |
|  |  | **1.10.3** | **Is there anything in the project that may contravene Catholic Health**  **Australia’s Code of Ethical Standards for research?** | | | | |  | |  | |
|  |  | ***Ensure that your wording regarding prevention of conception complies with our guidelines -***  ***Refer to the CRGO Handbook and the Informed Consent In Research Policy.***  ***If the answer to any of the above questions is yes, the application will be considered only when the researcher clarifies why this is necessary.*** | | | | | |  | |  | |

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|  |  |  |  | | | | **Yes** | **No** |
|  |  | **1.10.4** | **Have you sought approval to conduct this research from the relevant**   1. **Cabrini Research Academic Head of Department; and** | | | |  |  |
|  |  |  | 1. **Cabrini Clinical Craft Group Head?** | | | |  |  |
|  |  | ***If YES, provide evidence of their support. If NO, indicate why.*** | | | | |  |  |
|  |  |  | | | | | **Yes** | **No** |
|  |  | **1.10.5** | **Has this project been peer reviewed?** | | | |  |  |
|  |  | ***If YES, indicate who conducted the peer review, advise if recommendations were adopted, and provide evidence. If NO, indicate why. Retrospective data audits do not require peer review.*** | | | | |  |  |
|  |  |  | | | | | **Yes** | **No** |
|  |  | **1.10.6** | **If this is a clinical trial, have you registered?** | | | |  |  |
|  |  | ***All drug or device clinical trials must be registered with the*** [***Therapeutic Goods Administration***](http://www.tga.gov.au/)***. Clinical trials must also be published on a WHO Registry Network public platform e.g.*** [***https://clinicaltrials.gov/***](https://clinicaltrials.gov/) ***or*** [***www.anzctr.org.au***](http://www.anzctr.org.au)***. Attach evidence of registration for both, ensuring Cabrini is listed as a recruitment site. A CTN acknowledgement must be provided once issued by the TGA.***  **CTN / CTX Number**   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   **Date (dd/mm/yy)**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |   **Clinical Trials Registration Number (clinical trial public registry)**   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   **Date (dd/mm/yy)**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | | | | | | |
|  |  |  |  | | | | **Yes** | **No** |
|  | **1.11** | **Have other HRECs considered this project?** | | | | |  |  |
|  |  | ***Provide details of the progress of each approval and attach approval letter(s).*** | | | | |  |  |
|  |  | **Single Site Study** | | 🞏 **Yes** 🞏 **No** | **Multi site study** | 🞏 **Yes** 🞏 **No** | | |
|  |  | **Lead Site** | |  | **Coordinating Principal Investigator** |  | | |
|  |  |  | | | | |  |  |
|  |  | **HREC** | | | **Status of Approval (e.g. ‘Approved [date]’ or ‘Pending’)** | | | |
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|  |  | ***Add or delete rows as needed*** | | |  | | | |

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| **2.** | **RESOURCES** | | | | |
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|  | **2.1** | **How is the project being financed? *If funded by an internal or external grant, provide a copy of the offer letter or funding agreement and a Cabrini finance reference code if already assigned, otherwise a finance reference code will be arranged.*** | | |  |
|  |  | | | | |
|  | **2.2** | **If the project is sponsored, please provide Sponsor or CRG name, ABN/ACN number, address, contact person, contact phone and email. *Please refer to ICH GCP sponsor section 5, Section 5 of the National Statement and Australian Clinical Trials – Sponsoring a clinical trial in Australia for more information*** | | |  |
|  |  |  | | |  |
|  |  |  | | **Yes** | **No** |
|  | **2.3** | **Is there any conflict of interest, including financial or other interest or affiliation that bears on this project? Please explain.** | |  |  |
|  |  |  | |  |  |
|  |  |  | | **Yes** | **No** |
|  | **2.4** | **Is Cabrini Health expected to provide any funding for this project?** | |  |  |
|  |  | | | **Yes** | **No** |
|  | **2.5** | **Is Cabrini Health expected to provide any staff time for this project?** | |  |  |
|  |  | | | **Yes** | **No** |
|  | **2.6** | **Is Cabrini Health expected to provide any facilities for this project?** | |  |  |
|  | ***If the answer to any of these questions is yes, attach a completed project resourcing and costing template (Attachment 3) from the authorised person indicating their willingness to make the necessary resources available.*** | | | | |
|  | **2.7** | | **Please attach a project budget. *Include any anticipated costs and income such as per partieipant payments, if applicable.*** | | |

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| **3.** | **PROJECT** | | | | | | | |
|  |  |  | | | **Yes** | | **No** |
|  | **3.1** | | **Have you included/attached your Study Protocol with this application?** | | |  |  |
|  |  | | ***If No, please explain why?*** | | |  |  |
|  |  | |  | | |  |  |
|  | **3.2** | | **Project Summary** | | | | |
|  |  | | **Give a brief plain language summary of the project including aim/hypothesis and rationale relating to current literature. If there is more than one arm or multiples phases, provide a flow chart to illustrate project progression.**  ***The summary should be in plain (grade 8 level) language suitable to be read and understood by laypersons. Applications will not be considered by the Committee if the language is complex.*** | | | | | |
|  |  | | | | | | | |
| **4.** | **PROJECT DETAILS** | | | |
|  | **4.1** | **Recruitment** | | | | | | |
|  |  |  | | | **Yes** | | **No** | |
|  |  | **4.1.1** | | **Can this study be undertaken without using human participants?** Refer to the National Statement’s definition of ‘human participation in research’ which includes involvement in surveys / interviews / focus groups, psychological / physiological / medical testing, observation, researcher access to a participant’s personal documents and information, and collection / use of body organs / tissues / fluid. HREC approved waiver of consent still constitutes human participation. |  | |  | |
|  |  | ***If yes, please explain why this approach is not being adopted.*** | | | | | | |

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|  |  | **4.1.2** | **Please provide details of the participants in the table below:** | | | | | | | | | |
|  |  |  | | | | | | | | | |  |
|  |  | **Number at this site** | |  | **Number across all sites** |  | **Age**  **Range** |  | **Gender**  **(M/F)** | |  | |
|  |  | **Source of recruitment**  e.g. Researcher’s rooms, nursing staff, inpatient, other | | | | | | | | | | |
|  |  |  | | | | | | | | | | |
|  |  | **Inclusion Criteria** | | | | | **Exclusion Criteria** | | | | | |
|  |  |  | | | | |  | | | | | |
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|  |  | ***Add or delete rows as needed*** | | | | |  | | | | | |
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|  | **4.2** | **Informed consent** | | | | | | | |  | |  |
|  |  |  | | | | | | | | **Yes** | | **No** |
|  |  | **4.2.1** | **Does the study involve using identified or potentially identifiable information?** | | | | | | |  | |  |
|  |  | ***If yes, please explain why.*** | | | | | | | | | | |
|  |  |
|  |  | **4.2.2** | **How will the names of potential participants be obtained?** | | | | | | | | | |
|  |  | ***If through medical records, hospital or other databases, how will permission to review such records/databases be obtained?*** | | | | | | | | | | |
|  |  |  |  | | | | | | | **Yes** | | **No** |
|  |  | **4.2.3** | **Will you be seeking consent from all participants of the project**  **(including participants whose records are to be reviewed)?** | | | | | | |  | |  |
|  |  | ***If no, provide a justification for requesting a waiver of the requirement for consent by addressing each point under 2.3.10 of the National Statement. Only an HREC can approve a waiver of consent request for research involving personal information or personal health information.*** | | | | | | | | | | |

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|  |  |  |  | **Yes** | **No** |
|  |  | **4.2.4** | **Will each participant be capable of giving informed consent?** |  |  |
|  |  | ***Refer to National Statement Chapters 4.4 and 4.5 for the types of people who may be unable to provide informed consent. If no, the project is not low risk. For minors, refer to Chapter 4.2.*** | | | |
|  |  |  | | | |
|  |  | **4.2.5** | **Please attach a participant information and consent form** | | |
|  |  | ***Please note that the form should have a footer with the name of the document, version number, date, page number and number of pages on each page.*** | | | |
|  |  | **4.2.6** | **Describe the process for obtaining consent including when and how the explanation of the project will be given to potential participants, who will conduct the consenting process and how they will ensure that participants are able to make a free and informed decision to participate** | | |
|  |  |  | | | |
|  | | **Yes** | **No** |
|  |  | **4.2.7** | **Will you be using an opt-out approach for your research?** |  |  |
|  | | ***If yes, provide justification for using opt-out by addressing each point under 2.3.6 of the National Statement?*** | | | |
|  |  | **4.2.8** | **Will any special relationship exist between the recruiter and the participants?** e.g. doctor/patient, employer/employee, supervisor/worker/student |  |  |
|  | | ***If yes, how will this be managed?*** | | | |
|  | | | | **Yes** | **No** |
|  |  | **4.2.9** | **Is it clearly documented that participants may withdraw from the project at any time?** |  |  |
|  | | ***If not, why not?*** | | | |
|  |  | **4.2.10** | **How will this provision be drawn to the attention of participants?** | | |
|  | |  | | | |
|  | **4.3** | **Demands on participants** | | | |
|  |  | **4.3.1** | **Describe all the procedures to be conducted with participants which are specifically for this project (i.e. outside of standard of care)** | | |
|  |  |  | | | |
|  |  | **4.3.2** | **What demands, inconvenience or discomfort will be involved for the participants?** | | |
|  |  | ***Explain the number of visits, surveys etc., time commitment, possible dangers, risks, side effects of the procedures and compare this to standard of care*** | | | |
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| **5.** | **ETHICAL COMMITTEE ISSUES – data storage and protection** | | | | |
|  | **5.1** | **Storage of information about participants during and after completion of the project** | | | |
|  |  |  | | | |
|  |  | **5.1.1** | **In what formats and where will the information be stored during and after the research project and who will have access?** | | |
|  |  |  | | | |
|  |  |  | | **Yes** | **No** |
|  |  | **5.1.2** | **Will the information stored at the completion of the project be identifiable?** |  |  |
|  |  | ***If yes, explain why?***  ***If no, describe how it will be de-identified.*** | | | |
|  |  | **5.1.3** | **For how long will the information be stored after the completion of the project and why has this period been chosen?** | | |
|  |  |  | | | |
|  |  | **5.1.4** | **How do you intend to disseminate the results of the project?** | | |
|  |  | | | | |

**Please note: Sections 6 and 7 may not apply to your project.**

* **If the project involves any drug or therapeutic device or use of human tissue, complete the relevant section(s).**
* **If a section does not apply, select ‘No’ at the start, delete the rest of the section and go to the next section.**
* **If the project involves human genetic research or ionising radiation, the project is not low risk and full HREC review will be required by a registered ethics committee.**
* **Section 8 (Declaration) must be completed and submitted with all investigator signature(s).**

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| **6.** | **DRUGS AND THERAPEUTIC DEVICES** | | | | |
|  |  |  |  | **Yes** | **No** |
|  | **6.1** | **Does this project involve trial of a drug?** | |  |  |
|  |  | | | **Yes** | **No** |
|  | **6.2** | **Does this project involve trial of a therapeutic device?** | |  |  |
|  |  | | | | |
|  |  |  |  | **Yes** | **No** |
|  | **6.3** | **Does the research involve a practice or intervention that is not considered standard care?** | |  |  |
|  |  | | |  | |
|  | **6.4** | **What drug(s) or device(s) is/are involved in the project?** | | | |
|  |  | | | | |
|  | **6.5** | **What is the status of registration of the drug or device with the Therapeutic Drugs Administration?** | | | |
|  | ***If the drug(s)/device(s) is/are registered, indicate under what name*** | | | | |

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| **7.** | **HUMAN BIOSPECIMENS** | | | |
|  |  |  | **Yes** | **No** |
|  | **7.1** | **Does this project involve the collection and use of human biospecimens such as skin, saliva, hair, blood, bone, tissue and urine?** |  |  |
|  | ***If yes, complete Section 6***  ***If no, delete the rest of Section 6 and go to Section 7*** | |  | |
|  | **7.2** | **How will the collected biospecimens be labelled i.e. will any identifying information such as name or UR be included?** | | |
|  |  | | | |
|  | **7.3** | **Will any identifying information be recorded elsewhere?** | | |
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| **8.** | **DECLARATION** | | | |
| **Declaration by Principal Investigator:** | | | | |
| **I certify that:**   * 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. * I will only start this research project after obtaining authorisation from the Cabrini Research Governance Office and approval from the responsible Human Research Ethics Committee (HREC) if applicable. * I accept responsibility for the conduct of this research project according to the principles of the *National Statement on Ethical Conduct in Research* (NHMRC 2023). * 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/or Governance Office, and in accordance with *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC 2016), and Cabrini’s Safety Monitoring and Reporting in Research Policy. * I will adhere to the conditions of approval stipulated by the HREC and I will cooperate with the HREC monitoring requirements. * I will inform the HREC and Cabrini Research Governance Office 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 Cabrini Research Governance Office, and comply with their monitoring requirements. * I will discontinue the research if the Cabrini Research Governance Office withdraws authorisation. * I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, Cabrini Research Governance Office, sponsor or an independent body for audit and monitoring purposes. * I understand that information relating to this research and about me as a researcher will be held by the HREC and Cabrini Research Governance Office. I understand that 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. * I will also adhere to Cabrini Health’s Mission Statement, and the Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia. | | | | |
|  | | **NAME:** | **SIGNATURE:** | **DATE:** | |
| **Principal Investigator** | |  |  |  | |

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| **Declaration by Associate Investigator/Student:** | | | | | | |
| **I certify that:**   * The information in this form is truthful and accurate to the best of my knowledge and belief. * The research will be conducted in accordance with the *National Statement on Ethical Conduct in Research* (NHMRC, 2023). * I undertake to conduct this research in accordance with relevant legislation and regulations. * 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 Cabrini Research. * I will adhere to the conditions of approval stipulated by the HREC and will cooperate with the HREC monitoring requirements. * I will only start this research project after obtaining authorisation from the site and approval from the responsible HREC and/or Cabrinin Research Governance Office. * I will discontinue the research if the HREC withdraws ethical approval. * I will adhere to the conditions of authorisation stipulated by the Cabrini Research Governance Office, and will comply with their monitoring requirements. * I will discontinue the research if the Cabrini Research Governance Office withdraws authorisation. * I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, the Cabrini Research Governance Office, sponsor or an independent body for audit and monitoring purposes. * I understand that information relating to this research and about me as a researcher will be held by the HREC and the Cabrini Research Governance Office. I understand that 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. * I will also adhere to Cabrini Health’s Mission Statement, and the Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia. | | | | | | |
|  |  |  | | | |  |
|  | | | **NAME:** | **SIGNATURE:** | **DATE:** | |
| **Associate Investigator** | | |  |  |  | |
| **Student Investigator** | | |  |  |  | |
| ***Add or delete rows as needed*** | | |  |  |  | |
|  | | |  |  |  | |

**Declaration by Academic Head of Department:**

*• An investigator must* ***not*** *approve their own research on behalf of their department. If an investigator is also the Academic Head of Department, approval must be sought from the person to whom the Academic Head of Department is responsible.*

*• If an Academic Head of Department does not exist for your area of research, the study will be assessed by the multidisciplinary Cabrini Research Governance Committee.*

**I certify that:**

* I have read the research project application named above.
* The research aligns with Cabrini’s research strategy, does not duplicate existing research, and fosters collaborative rather than siloed research (where applicable).
* I have discussed this research project, and the resource implications for this department, with the Principal Investigator.
* All investigators/students from my department involved in the research project have the skills, training and experience necessary to undertake their role.
* There are suitable and adequate facilities and resources for the research project to be conducted at this site.

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| **Academic Head of Department Role** | **NAME:** | **SIGNATURE:** | **DATE:** |
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* I support this research project being carried out using such resources.

**Declaration by Craft Group Lead or Clinical Head of Department:**

*• A Head of Department may delegate responsibility to an appropriate staff member.*

*• An investigator must* ***not*** *approve their own research on behalf of their department. If an investigator is also Head of Department, approval must be sought from the person to whom the Head of Department is responsible.*

**I certify that:**

* I have read the research project application named above.
* I have discussed this research project, and the resource implications for this department, with the Principal Investigator.
* All investigators/students from my department involved in the research project have the skills, training and experience necessary to undertake their role.
* There are suitable and adequate facilities and resources for the research project to be conducted at this site.

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| **Craft Group Lead /**  **Clinical Head of Department Role** | **NAME:** | **SIGNATURE:** | **DATE:** |
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* I support this research project being carried out using such resources.