Research Project Registration

Feasibility & Checklist Form

# 1. Scope

# This form, to be used in lieu of a cover letter and along with the Site-Specific Application (SSA), are the first steps towards research governance authorisation by the NWHHS delegate, without which no research may commence until granted (QH-POL-013:2015)

Please upload this completed form to your application on Ethical Review Manager.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Registration** | | | | | |
| **1** | **Study acronym:** | | | | |
|  | **Full title of study:** | | | | |
|  | **HREC number:** | | | | |
|  | **HREC expiry date:** | | | | |
|  | **SSA number:** | | | | |
| **2** | **Local PI or NWHHS study contact (person responsible for conduct of study at NWHHS)** | | | | |
| **Name:** | | | | |
| **Position title:** | | | | |
| **Department:** | | | | |
| **Site:** | | | | |
| **Phone number:** | | | | |
| **Email:** | | | | |
| **3** | **Name of sponsor organisation:** | | | | |
| **4** | **Name of funding organisation for the study:** | | | | |
| **Study type**  Commercial  Commercial grant Funding amount (attach budget breakdown)  Grant  Unfunded (e.g., academic study)  Investigator / Department / HHS funded | | | | |
| **Does the funding for this study involve a grant application?**  Yes  No  **If yes, please select the funding status of this application:**  Pre-application  Applied  Successful  **If a grant application is involved is NWHHS a:**  Co-applicant  Lead applicant | | | | |
| **Will NWHHS receive any funding to conduct this study?**  Yes  No | | | | |
| **How will costs (e.g., release of staff to assist) to NWHHS be covered?**  Commercially sponsored Funding Provided to NWHHS  Grant  In kind | | | | |
| **5** | **NWHHS Participation**  Lead site, single study  Lead site, multicentre  Participating site, multicentre  Patient Identification Centre | | | | |
| **6** | **Project Type**  Basic science study involving procedures with human participants  Clinical investigation or other study of a medical device  Clinical trial of an investigational medicinal product  Study administering questionnaires/interview for quantitative analysis, or using mixed quantitative/qualitative methodology  Study involving qualitative methods only  Study limited to working with data | | | | |
| **7** | **Study population**  Recruitment target:  Study population (participant type)  Patient  Other (please specify): | | | | |
| **8** | **Registration contact details**  To assist in accurate accrual data, please include details of the study team member/s who will be responsible for reporting study recruitment.  **Name**:  **Email**:  **Name**:  **Email**:  **Name**: **Email**: | | | | |
| **9** | **Local collaborators** Please include details for any departments who will be involved in this study and who must be notified on authorisation of the application.  **Department**:  **Email**: **Phone:**  **Department: Email: Phone:**  **Department: Email: Phone:** | | | | |
| **10** | **Proposed study dates**  Start date:  End date (all study activity ceases at site):  End of recruitment date (recruitment of participants only): | | | | |
| **Feasibility** | | | **Feasible (agree)** | | **N / A** |
| **Alignment with HHS goals** | | | | | |
| **11** | This study aligns with NWHHS strategic priorities or contributes to specific populations. | |  | |  |
| **Personnel** | | | | | |
| **12a** | **All personnel who will engage in the study:**   * Have appropriate experience, credentials, and training. * Have sufficient time available to conduct the research. * Will perform study activities commensurate with their job description and scope of practice; and * Will be appropriately supervised and monitored. | |  | |  |
| **12b** | NWHHS staff carrying out research activity will be able to do this as part of rostered workload.  **\*Prospective PI’s with limited research time should have approval from managers to take on research responsibilities over and above their regular work load.** | |  | |  |
| **Recruitment** | | | | | |
| **13b** | There is a sufficient study population from which to recruit participants and the accrual goal is likely to be achieved. | |  | |  |
| **13c** | If there is recruitment of vulnerable populations, appropriate measures have/will be put in place to ensure that participants are supportive of the research (e.g., community consultation). | |  | |  |
| **Data security considerations** | | | | | |
| **14** | Safeguards and resources are present for the secure collection, transfer, storage and retention of protected health information, and the necessary data access agreement (i.e., data custodian approval; PHA approval) have/will be obtained. (see Section 280 of the *Public Health Act 2005*) | |  | |  |
| **NWHHS agreements** | | | | | |
| **15** | **The following conditions apply to approved research projects, please indicate if you can meet these conditions.** | | | | |
| Any research involving a conflict of interest must be declared at the time of application submission. | |  | |  |
| Authorised studies must be reported on a quarterly basis (template provided) to the Research Committee until recruitment of participants is closed. | |  | |  |
| Final publications i.e., journal articles acknowledge the assistance of the North West Hospital and Health Service with the project. | |  | |  |
| **Declaration of feasibility review** | | | | | |
| **The signatures below indicate the proposed research study has undergone a feasibility assessment by the Principal Investigator and appropriate local individuals in accordance with departmental policies. These signatures confirm the necessary resources are available to successfully implement and complete the study.** | | | | | |
| **16** | **NWHHS Study contact   Name (print):**  **Signature: Date:** | | | | |
| **Department Head or delegate**  **Name (print):**  **Signature: Date:** | | | | |
| **Coordinating Principal Investigator (if multicentre study)**  **Name (print):**  **Signature: Date:** | | | | |
| **Checklist** | | | | | |
| **Please indicate what documents have been provided in your SSA application.** | | **Yes** | | **No** | **N/A** |
| Approved study protocol | |  | |  |  |
| Participant Information Sheet and Consent Form | | | | | |
| Master | |  | |  |  |
| Site specific  **\*use template provided** | |  | |  |  |
| Participant Information Sheet and Consent Form for Family and Carers | | | | | |
| Master | |  | |  |  |
| Site specific **\*use template provided** | |  | |  |  |
| Letter of Support from Aboriginal and Torres Strait Islander Community | |  | |  |  |
| Local finance declaration form signed by PI | |  | |  |  |
| Public Health Act application and approval letter  (or for QH staff seeking permission under section 150 Hospital and Health Boards Act 2011, SSA form signed by Data Custodian and RGO cover letter must state how study meets section 150 requirements i.e. study is for the evaluating, managing, monitoring or planning of health services) | |  | |  |  |
| Research Agreement / CTA - Studies involving a Non-QH Collaborator or Sponsor  (includes Student or university projects and other collaborative projects) | |  | |  |  |
| QCAT approval for adults with impaired capacity to consent: For advice see: <https://www.qcat.qld.gov.au/__data/assets/pdf_file/0015/100905/form-16-app-to-conduct-clinical-research.pdf> | |  | |  |  |
| Any other HREC approved study documents applicable to our site.  If yes, please list: | |  | |  |  |