***This form should be completed by Principal Investigators, Sponsors or CROs wishing to conduct research at Hollywood Private Hospital. Please complete this form and submit to*** [***research.hph@ramsayhealth.com.au***](mailto:research.hph@ramsayhealth.com.au) ***to obtain initial Site support for your research Project. Once support is confirmed you will be able to finalise your research application with the Ramsay National Research Unit Research Governance Office via*** [***REGGS***](https://ethicsandgovernance.ramsayhealth.com.au)***.***

# The Proposed Study

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Study Summary | | | | | |
| **Principal Investigator:** | |  | | | |
| **Third party coordinating trial on site *(if applicable)*:** | |  | | | |
| **Sponsor: *(if applicable)*** | |  | | | |
| **Ramsay Clinical Trials Unit** | | **YES  NO** | | | |
| **Research Project Title *(in full)*:** | |  | | | |
| Other Study team members:  *(provide: Name, email address, Role and Ramsay Affiliation for each team member)*  ***NOTE***: If the PI is a student, please provide details of Supervisor and University | |  | | | |
| Study Type | | | | | |
| Please select one of the following to best describe this research project: | | | | | |
|  | | Clinical Trial - Drug | |  | Clinical Trial - Other | Health Research |
|  | | Clinical Trial - Device | |  | Clinical Research | Data linkage |
|  | | Clinical Trial - Drug and Device | |  | Clinical Registry | Other: |
|  | | Clinical Trial - Biological Product | |  | Clinical Audit (requiring Ethical approval) | Specify: |
| Human Research Ethics Committee Review | | | | | |
| **Ethics review application status** | | Not yet Submitted to HREC  Submitted to HREC  HREC Approval Obtained  HREC Approval Obtained for Site | | | |
| **HREC Reference Number:** | |  | | | |
| Reviewing HREC Name:  (if approved) | |  | | | |

# Description of the Research Project

|  |  |
| --- | --- |
| Summary of Research Activities | |
| **Please provide a summary of the research project you wish to undertake.** | |
|  | |
| Project Duration | |
| **Please provide the estimated Start and Finish dates for the research project at the site(s)** | |
| **Proposed Start Date** |  |
| **Estimated Finish Date** |  |
| **Duration of Project** |  |

# Demand for Hospital Resources

**This section is crucial for the local review as to whether capacity & resources at the site can meet the research demand, and whether the proposed means to cover the cost is acceptable.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Facility Impact Summary | | | | | | | | | | | | | | |
| **Please summarise the impact of the proposed research project on the facility (e.g. administrative support, access to procedural rooms, access to staff to conduct research activities, etc.)** | | | | | | | | | | | | | | |
| 1. Access to Facility/ Space: | 1. Ramsay Staff Members\*: | | | | | | 1. Cooperation from Operation Units: | | | | | | | |
| Meeting Room  Procedure Room  Infusion Unit  Endoscopy Suite  Operating Theatre  Cath Lab  Others \_\_\_\_\_\_\_\_\_\_ | Medical staff  Nursing staff  Allied Health staff  Administrative staff  Others\_\_\_\_\_\_\_\_\_\_ | | | | | | admission  pharmacy #  pathology #  radiology #  Medical records Dept  Wards: \_\_\_\_\_\_\_\_\_  Others (e.g. day oncology centre): \_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| 1. Clinical Groups involved (e.g. Medical Oncology, Cardiology etc.) (please list): | | | | | | | | | | | | | | |
| \*If Ramsay staff members are involved, **please specify the specific research activities** they will be conducting and provide an estimate of the number of staff hours involved and type of instruction they will be given. | | | | | | | | | | | | | | |
| # If External Parties are involved, **please specify the specific research activities** they will be conducting. | | | | | | | | | | | | | | |
| **Have the relevant clinical groups and operational units consented to be involved in this research project?** | | | | | | | | | YES | | | | | NO |
| Training | | | | | | | | | | | | | | |
| **Will any staff members / VMOs / contractors at this facility require training in order to participate in this research project?** | | | | | | YES | | | | | | | NO | |
| If yes, what training is required: | | | | | | | | | | | | | | |
| Who will provide the training? | Who is to be trained? | | | | | | Who will bear the cost for training? | | | | | | | |
| Hospital Admissions | | | | | | | | | | | | | | |
| **Number of patients that will be recruited at this site:** | | | | |  | | | | | | | | | |
| **Will hospitalisation be required for this research project?** | | | | YES | | | | | | NO | | | | |
| **What type(s) of admissions/presentations will be required?** | | | Surgical Procedure  Day Admissions  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | Overnight Hospital Stay  Outpatient Visits | | | | | | |
| **Are these admissions/visits in addition to standard of care?** | | | | | YES | | | | | | | NO | | |
| **Will the additional admission/ presentations be funded by the research?** | | | | | YES | | | | | | NO | | | |
| Medical Records (if indicated at 3.1) | | | | | | | | | | | | | | |
| **Est. number of medical records to be reviewed** | | | | |  | | | | | | | | | |
| **Who will access the medical records?** | | | | HIS | | | | | | Investigator | | | | |
| Financial Considerations **This section is crucial for the local review as to whether capacity & resources at the site can meet the research demand, and whether the proposed means to cover the cost is acceptable.** | | | | | | | | | | | | | | |
| **Please provide details of any funding that will be given to the facility as a part of the participation in this study:**  *Note: Once initial support for the research at this Site has been provided, budgets for the planned research will need to be negotiated with the Site and included in any Research Agreements***.** | | per patient payment (as per the CTRA)  negotiated admission payment  negotiated lump sum payment  no payment  Other arrangements, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | |
| **If applicable, who will cover the cost of the investigational drug / device / procedure?** | | Medicare  Private Health Insurance  Sponsor  Other | | | | | | | | | | | | |
| **If funding for the research project is not provided to the facility, please provide justification:** | |  | | | | | | | | | | | | |

# Patient Safety

**This section is only required for research that involves treatments or procedures. If your planned project does not involve direct intervention on patients, you do not need to complete this section.**

|  |  |
| --- | --- |
| Research Treatment and Standard of Care | |
| **Please indicate which of the following treatments / procedures / interventions on participants this research project involves:** | Investigational Drug / Device / Procedure/ off-label use  Standard Comparator Drug / Device / Procedure  Tissue Samples  Blood Samples  Radiation/Imaging Procedures  Others:  None of the above/not applicable\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| For each treatment / procedure / intervention involved in the research project, please specify the following: | |
| **What is the Standard of Care for patients undergoing treatment for this disease if they were not participants in the research project?** | |
|  | |
| **How does the care in the research project differ from the routine Standard of Care?** | |
|  | |
| Impact on Patient Safety | |
| **Please outline any risks that may exist for the participant if they elect to participate in the research project:** | |
|  | |
| **Please indicate how likely it is that these risks will occur, and explain how these risks will be managed during and after the research related procedures** | |
|  | |
| Participant’s consent to research activities (*please tick all that apply*): | |
| **The study requires** (please tick all that apply)**:**  Written consent to participate in the specific research study  Consent for access to participants’ Ramsay medical records  Consent for access to data stored in Ramsay IT systems(other than patient’s medical records)  Consent for collection and use of patient’s tissue samples  Waiver of consent approval by HREC  Consent already in place (datasets collected with prospective consent will be used in this study)  Other, please specify | |

|  |  |  |
| --- | --- | --- |
| **Signature of Principal Investigator** | | |
| **I have attached:**  Study Protocol  Participant Information and Consent Form  Other (specify):    **Name of the Principal Investigator:**  **Signature:**  **Date:** | | |
|  |  |  |
| Office Use Only: |  |  |
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