### Section A: To be completed by Principal Investigator/Project Coordinator

|  |  |  |  |
| --- | --- | --- | --- |
| Service Department: | New Technology Clinical Practice  | Principal Investigator |       |
| ERM Number (5-digits): | RMH-      | RMH Local Project No: |       |
| Short Project Title: |       |
| Is this a commercially sponsored clinical trial? | [ ]  Yes [ ]  No | Estimated number of participants: |        |
| Provide a brief description of service requested or reference the page/section in the protocol |       |
| Does the study involve using a genetically modified organism (GMO)? [ ]  Yes [ ]  No |
| If Yes, has the service department been provided information and procedures for all GMO specific study requirements? [ ]  Yes [ ]  No |
| Protocol No.: |       | Version: |       | Date: |       |
| ***[ ]  I confirm that I have supplied the NTCP with the most recent version of the protocol*** |

####  Conflict of Interest Declaration

|  |
| --- |
| In accordance with MH36.01 [Identifying and Responding to Conflicts of Interest Procedure](https://app.prompt.org.au/download/199905?code=a0399284-d231-4fba-a62b-4a5394a6e79f), I declare that:[ ]  I have no interests to declare which may relate to the proposed NTCP.[ ]  I have listed below all interests which I have that may relate to the proposed NTCP. Describe the nature of the conflict of interest and how this will be managed. |
|       |

#### Staffing

|  |  |  |
| --- | --- | --- |
| Will this procedure / intervention / practice impact upon current staffing? | [ ]  Yes. Please describe:       | [ ]  No |
| Are there any implications for other Royal Melbourne Hospital craft groups? | [ ]  Yes. Please describe:       | [ ]  No |

#### Training and Credentialling

|  |
| --- |
| Will this procedure / intervention / practice impact upon current staffing? Are there any training requirements for the proposed procedure? [ ]  Yes [ ]  No If there are training requirements, list the names, qualifications and evidence of relevant training and courses attended of those individuals who wish to be credentialed for this procedure below: |
|       |
| Are there any implications for other Royal Melbourne Hospital craft groups? Does this new technology or clinical practice involve a change to scope of practice? [ ]  Yes [ ]  No |

#### Resources

|  |  |
| --- | --- |
| Does this procedure / intervention/ practice require any changes to clinical or physical infrastructure or facilities? [ ]  Yes. à comment and attach supporting documentation as relevant. [ ]  No |       |

#### Costs

|  |  |
| --- | --- |
| Have direct and indirect costs been considered? (Consider establishment and recurrent costs)[ ]  Yes. à comment and attach supporting documentation as relevant[ ]  No |       |
| What is the estimated total cost of each procedure/treatment? |       |
| How many procedures/treatments are predicted in the first and second year? | Year 1:      Year 2:       |
| Are there any cost benefits? [ ]  Yes. à comment and attach supporting documentation as relevant[ ]  No |       |

#### Consultation

|  |  |  |
| --- | --- | --- |
| Who will this impact?  | Position | Date Consulted |
|       |       |
|       |       |
|       |       |
|       |       |
| Are there Occupational Health and Safety considerations?[ ]  Yes [ ]  No [ ]  NA | If Yes à consult Occupational Health and Wellbeing Service and attach correspondence  |
| Are there Infection Control Considerations?[ ]  Yes [ ]  No [ ]  NA | If Yes à consult Infection Prevention and Control and attach correspondence. |
| Are there any Information Technology considerations to support the practice?[ ]  Yes [ ]  No [ ]  NA | If Yes à consult Information Technology and attach correspondence |
| Are there any Biomedical Engineering considerations to support the practice?[ ]  Yes [ ]  No [ ]  NA | Yes à consult Biomedical Engineering and attach correspondence. |

#### Contact details of principal investigator / project coordinator submitting the form

|  |  |  |  |
| --- | --- | --- | --- |
| Name: |       | Date: |       |
| Email: |       | Phone: |       |

### Section B: To be completed by the Head of Service Department Head or Nominee, and signed by Service’s General Manager and Medical Director

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| --- | --- | --- |
| C:\Users\kresoa\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\73C6BP9J\attention-307030_640[1].png |       | Enter the date that this SOA was received by your Service Department*\*\*\*\*SOAs KPI to be completed within* ***7 days for commercially sponsored clinical trials*** *and within 14 days for all other projects\*\*\*\*\** |

|  |
| --- |
| I have reviewed and discussed the study protocol and applicable project documentation *with the principal researcher or their delegate* and confirm that this department (select one option only): |
| [ ]  Can undertake the investigations indicated with the present resources of the Department |
| [ ]  Is unable to undertake the investigations within the present resources of the Department but would be willing to with financial assistance as specified here: |
|        |
| [ ]  Is unable to undertake the investigations on the following grounds: |
|        |

#### Declarations by Head of Service Department

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| **[ ]**  | In signing this form, I declare that I am aware of the principles and obligations imposed by the *Australian Code for the Responsible Conduct of Research (2018)* and its associated guide documents. In particular, I acknowledge the importance of the responsible management of research data. |
| ***[ ]***  | I confirm that the information provided by the Principal Investigator/Project Coordinator is correct |

#### Signature – Head of Service Department or Delegate

|  |  |  |  |
| --- | --- | --- | --- |
| Name (Please print) |        | Position |       |
| Signature |       | Date |       |

#### Signature – Service General Manager

|  |  |  |  |
| --- | --- | --- | --- |
| Name (Please print) |        | Position |       |
| Signature |       | Date |       |

#### Signature – Service Medical Director

|  |  |  |  |
| --- | --- | --- | --- |
| Name (Please print) |        | Position |       |
| Signature |       | Date |       |

### Section C: New Technology & Clinical Practice Committee (NTCPC) Endorsement *(if required)*

#### Signature – New Technology & Clinical Practice Committee Chair

|  |  |  |  |
| --- | --- | --- | --- |
| Name (Please print) |        | Position | NCTCP Chair  |
| Signature |       | Date |       |