### 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

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| --- |
| 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

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| 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

|  |  |
| --- | --- |
|  | 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

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| --- | --- | --- | --- |
| 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 |  |