**CHECKLIST:** The following needs to be completed and submitted to the SALHN Office for Research before the Expedited Review Panel will assess your application for SALHN governance and/or SAC HREC approval:

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| **Low Risk Application Form** | | | | |
| PART A – All fields | | | | |
| PART B – All fields | | | | |
| PART C – All questions even if N/A. If C6 is answered YES, then Data Custodian authorisation is signed at PART H | | | | |
| PART D – All questions completed and SALHN Financial Authorisation is signed. | | | | |
| PART E – Principal Investigator Authorisation is signed. | | | | |
| PART F – Head/s of Site Department Approval is signed. | | | | |
| PART G – SALHN Site Divisional Director Approval is signed. | | | | |
| PART H – SALHN Data Custodian Approval is signed if question C6 is answered as YES. | | | | |
| **Document type uploaded with application** | | **Electronic File Name** | **Version No.** | **Date** |
| LNR Protocol Template | |  |  |  |
| Study Contract | |  |  |  |
| Participant Information Sheet/Consent Form | |  |  |  |
| Study Budget | |  |  |  |
| Study Tools | |  |  |  |
| Non-SALHN researcher Criminal History Screening | |  |  |  |
| Non-SALHN researcher Confidentiality Deed | |  |  |  |
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| PART A - Study-Wide Information | | | | | |
| 1. **Project Title** | | | | | |
| Click or tap here to enter text. | | | | | |
| 1. **Project Summary** | | | | | |
| Click or tap here to enter text. | | | | | |
| 1. **HREC Name** | | | | | |
| Choose an item.  Other HREC details not listed above Click or tap here to enter text.  The Southern Adelaide Clinical HREC can review this application concurrently with SALHN governance; for all other HREC nominations, an approval letter listing SALHN as a site must be attached to this LNR application form. | | | | | |
| 1. **Study Type** | | | | | |
| Choose an item. | | | | | |
| 1. ****SALHN Site Activity**** | | | | | |
| Activity: Click or tap here to enter text.  Outcome:Click or tap here to enter text. | | | | | |
| PART B - Study-Wide Information | | | | | | |
| 1. **Site Name** | | | | | | |
| Choose an item. | | | | | | |
| Click or tap here to enter text. | | | | | | |
| 1. **Principal Investigator** | | | | | | |
| Title/ First Name/ Surname: | | Click or tap here to enter text. | | | | |
| Position: | | Click or tap here to enter text. | | | | |
| SALHN Site: | | Click or tap here to enter text. | | | | |
| SALHN Department: | | Click or tap here to enter text. | | | | |
| Credentialing | | Is this person credentialed at SALHN?  Choose an item.  Expiry Date: Click or tap to enter a date. | | | | |
| Contact phone: | | Click or tap here to enter text. | | | | |
| SALHN Email: | | Click or tap here to enter text. | | | | |
| Describe the person’s expertise relevant to this research project below:  Click or tap here to enter text. | | | | | | |

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| 1. **Contact Person Details** | | | | |
| Title/ First Name/ Surname | | | Click or tap here to enter text. | |
| Position | | | Click or tap here to enter text. | |
| Employer/Organisation Name | | | Click or tap here to enter text. | |
| Department | | | Click or tap here to enter text. | |
| Email (Business) | | | Click or tap here to enter text. | |
| 1. **Additional Site Team Members** | | | | |
| **Student/s details** | | | | |
| **Tick if not applicable** | | | | |
| All Student Names | Click or tap here to enter text. | | | |
| Institution | Click or tap here to enter text. | | | |
| Study Program/Degree | Click or tap here to enter text. | | | |
| Supervisors | Click or tap here to enter text. | | | |
| Role (activity in the study) | Click or tap here to enter text. | | | |
| **SALHN Associate Researchers (add additional rows if required)** | | | | |
| **Name** | **Role (activity in the study)** | | **Credentialing body/EXP date** | |
| **Click or tap here to enter text.** | Click or tap here to enter text. | | Choose an item. / Click or tap to enter a date. | |
| **Click or tap here to enter text.** | Click or tap here to enter text. | | Choose an item. / Click or tap to enter a date. | |
| **Click or tap here to enter text.** | Click or tap here to enter text. | | Choose an item. / Click or tap to enter a date. | |
| \*Non-SALHN Associate researchers (add additional rows if required) | | | | |
| **Tick if not applicable** | | | | |
| **Name** | **Role (activity in the study)** | | **Organisation** | |
| **Click or tap here to enter text.** | **Click or tap here to enter text.** | | **Click or tap here to enter text.** | |
| **Click or tap here to enter text.** | **Click or tap here to enter text.** | | **Click or tap here to enter text.** | |
| **Click or tap here to enter text.** | **Click or tap here to enter text.** | | **Click or tap here to enter text.** | |
| \*non-SALHN researchers coming onsite and interacting with staff or patients need to be COVID-19 vaccinated, have a relevant criminal history screen (no more than 3 years old) and need to submit a SALHN Confidentiality Deed (available on [Low risk research at SALHN](https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/southern+adelaide+local+health+network/research/for+researchers/low+risk+research+at+salhn)) | | | | |

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| 1. **SALHN Departments** | | | |
| **Department/s Name** | **Head of Department** | **Resources you require this department to provide (e.g. staff, service/s, investigations etc)** | |
| **Click or tap here to enter text.** | Click or tap here to enter text. | Click or tap here to enter text. | |
| **Click or tap here to enter text.** | Click or tap here to enter text. | Click or tap here to enter text. | |

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| PART C - Recruitment, Records, Tissue and Data and Contracts |
| 1. Will participants be enrolled for the research at this site? |
| Choose an item. |
| |  | | --- | | Will consent be obtained? Choose an item. |   What population group is involved in your study? Choose an item.  **If your population group is identified in the above question as a “vulnerable population group”, you will need to submit a greater than low risk application via the GEMS platform to both ethics and governance**  Is there a numeric site enrolment target? Choose an item. |
| What is the maximum number of participants to be enrolled at this site? |
| Click or tap here to enter text. |
| 1. Are you planning on accessing SALHN patient records or information systems for this research? |
| Choose an item. |
| Who will access SALHN patient information systems to obtain the data?  Click or tap here to enter text.  Has this person obtained approval to obtain SALHN patient information systems?  Choose an item.   1. Are you planning on collecting/obtaining tissue samples from this site? |
| Choose an item. |
| Is this in addition to usual care? Choose an item.  How many tissue samples are you proposing to access from this site?  Click or tap here to enter text. |
| 1. Will any SALHN data or tissue be transferred to an entity external to this site?   Choose an item.If yes, a data or material transfer agreement is required and needs to be attached to your LNR application |
| 1. Please list all entities the tissue is being transferred to   Click or tap here to enter text. |
| 1. Will you be accessing any registries or data sets?Choose an item.   If yes, seek data custodian approval from all data custodians in Part G |
| 1. Do you have any agreements or contracts for this project?   Choose an item. |
| 1. Please record details for any agreements and contracts for this project that requires signing and is attached to your LNR application – add rows if more than one agreement | |
| |  |  | | --- | --- | | **Agreement Type**  **Select from dropdown** | **Reason for Agreement**  Click or tap here to enter text. | | |

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| PART D - Site Costing and Funding |
| 1. **Funding Type** Choose an item. 2. **Study Budget** - Please complete the below document and attach to your application      1. **Costs attributable to the research**   Please describe any non-financial costs (e.g. SALHN or external resource allocations) associated with the project?  Click or tap here to enter text.   1. **Funding support**   Please specify the nature of the funding to support this project, including the amount of funding and duration; funding source; and any ‘in kind’ or monetary support being provided by the Site.  Click or tap here to enter text.  What resources (e.g. staff, service/s, investigations etc) do you require SALHN departments to provide  Click or tap here to enter text.   |  |  |  | | --- | --- | --- | | **Type of Funding** | **Source of Funding** | **Amount ($/year or $/participant)** | | Grant Funding | Click or tap here to enter text. | Click or tap here to enter text. | | Other external funding (i.e. University support) | Click or tap here to enter text. | Click or tap here to enter text. | | Internal/Departmental funding | Click or tap here to enter text. | Click or tap here to enter text. | | ‘In kind’ support | Click or tap here to enter text. | Click or tap here to enter text. |   Overall responsibility for the Project funding: Choose an item.  **SALHN Operating/SPF Details (if indicated above)**: Click or tap here to enter text.  Send your application to Health.SALHNFinanceBusinessAdvisoryService@sa.gov.au for endorsement prior to submitting to the Office for Research.  **SALHN Financial Authorisation (Official Use Only)**  Cost allocations and sources at this site have been agreed:  Yes  No  **Director of Finance/Financial Delegate:**  Mark Williams  Corporate Finance Manager  **Signature**…………………………………………………………. **Date**: / / |

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| PART E - Principal Investigator Declaration | |
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| **A Declaration by the Principal Investigator responsible for the site** | |
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| **SALHN Principal Investigator** | |
| 1. The information provided is truthful and accurate to the best of my knowledge and belief and I take full responsibility for this project at this site. 2. all members of the research team at this site have the appropriate qualifications, training, experience and facilities to conduct the research as set out in this application and to deal with any emergencies and contingencies related to the research that may arise; 3. I will ensure all team members receive any additional relevant training as required. 4. I will not start this research project at this site until I have received confirmation of site authorisation in writing from the Research Office and, that this will not be before evidence is received by them (provided by me) of ethics approval by an appropriate Human Research Ethics Committee (HREC); 5. I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (as amended) and the Australian Code for the Responsible Conduct of Research (as amended) and, where applicable, Note for Guidance on Good Clinical Practice. 6. If authorised to undertake this project at (this site),    1. I will inform the Research Office if the research project ceases before the expected date.    2. I will discontinue the research at this site if the HREC withdraws ethical approval.    3. I will adhere to the conditions of authorisation stipulated by the authorising authority at this site including any monitoring/reporting requirements.    4. I will discontinue the research at this site if the authorising authority withdraws authorisation. 7. I understand and agree that project files and documents and research records and data may be subject to inspection by delegates of the authorising authority at this site (generally the Research Governance Officer) for audit and monitoring purposes, AND 8. I understand that information relating to this research, and about me as an investigator, will be held within SA Health information systems and other local data collections. This information may be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Commonwealth) and SA Health Care Act and relevant laws in the States and Territories of Australia. | |
| **Signature:** | Date: / / |
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| PART F – Head/s of Site Department Approval | |
| **This component needs to be signed by all departments listed in B5** | |
| **Site Department Name/s:** | |
| **Department/s:** | |
| I declare that:   1. I have read the relevant project documents to inform my knowledge of the proposed research and its potential impact for FMC: Data Custodian 2. I have discussed this research project and the resource implications for FMC: Data Custodian with the principal investigator | |
| **Signature:** | Date: / / |
| **Part G - SALHN Site Divisional Director Approval** | |
| **Director Name**: | |
| **Division Name:** | |
| I declare that:   1. I have read the relevant project documents to inform my knowledge of the proposed research and its potential impact for FMC: Data Custodian 2. I have discussed this research project and the resource implications for FMC: Data Custodian with the principal investigator | |
| **Signature:** | Date: / / |
| **Part H - SALHN Data Custodian Approval – include all data custodians** | |
|  | |
| **Name:** Data set Name: | |
| I declare that:   1. I have read the relevant project documents to inform my knowledge of the proposed research and its potential impact for FMC: Data Custodian 2. I have discussed this research project and the resource implications for FMC: Data Custodian with the principal investigator | |
| **Signature:** | Date: / / |