**NUHS PDPA Declaration Form for Waiver of Informed Consent**

Please complete all sections below if the study team is requesting for a waiver of informed consent to,

1. use the personal data of the research subjects within NUHS/NUH for the purposes of the study; and/or, to disclose the personal data of the research subjects outside of NUHS/NUH for the purposes of the study;

AND

1. the study team will be in contact with patient identifiers during data collection (i.e. viewing medical records from CPSS); and/or, the study data contains identifiers.

The study must fulfil ALL elements in the Personal Data Protection Act 2012 of Singapore (“PDPA”) criteria (in additional to the DSRB criteria) in order to obtain the waiver of informed consent.

**Study Title:** Click here to enter text.

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| **PDPA Criteria Elements** | | |
| 1 | The research purpose cannot reasonably be accomplished unless the personal data is provided in an individually identifiable form. Please explain why patient identifiers are necessary to conduct the study. | |
|  | Click here to enter text. | |
| 2 | The Principal Investigator (PI) confirms that the results of the research will not be used to make any decision that affects the individual. | Choose an item. |
| 3 | There is a clear public benefit to using the personal data for research purpose. | |
|  | Click here to enter text. | |
| 4 **This Criterion is applicable only if personal data of the research subjects will be disclosed outside of NUHS/NUH to an external Organisation for the purposes of the study.**  It is impracticable for the study team to seek the consent of the individuals for the use because, *(please select the statement(s) applicable to the study)* | | Choose an item. |
| 1. NUHS/NUH does not have current contact information of the potential research subjects nor sufficient information to seek up-to-date contact information. NUHS/NUH should be able to demonstrate that the potential research subjects cannot be reached using the contact information, such as by attempting to contact the potential research subjects; and/or | |  |
| 1. The target population involves personal data of deceased individuals; and/or | |  |
| 1. Given the target population required for meaningful conclusions to be drawn from the research, the quantum of the research grant and the period allotted for the research as a condition of the research grant, the financial, organisational costs of attempting to seek consent from each potential research subject would impose such disproportionate resource demands and burden on NUHS/NUH or take up so much time (assuming the organization has made every reasonable effort to provide for the required time and resources) that carrying out the research is no longer viable. In this regard, there is no fixed number of potential research subjects that would be determined as “impracticable” to seek consent from. Such an assessment would be based on all relevant circumstances of the case, which may include the required number of potential research subjects, whether or not there is an existing relationship with the individuals, and other factors affecting the difficulty of contacting the required potential research subjects; and/or | |  |
| 1. Exceptional circumstance where seeking the research subject’s consent would affect the validity or defeat the purposes of the research, in particular, where seeking consent would skew the research or introduce bias into the research such that no meaningful conclusions can be drawn. NUHS/NUH should nevertheless consider whether it is possible to seek consent in a manner that would not introduce such bias.   **Note**: To be clear, factors like mere inconvenience (to NUHS/NUH or the potential research subject), additional costs or time delays resulting from having to contact individuals for consent, on their own, are insufficient to demonstrate **“impracticability”**. These, however, may be relevant considerations if the added financial or organisational costs (of having to seek consent from the individuals) is so onerous that the research is no longer viable. NUHS/NUH may wish to consider convenient and practical means for individuals to provide consent, for instance by replying to a letter, email, text message or recording of voice call, instead of requiring the individual to make a trip to NUHS/NUH’s physical location for the purpose of giving consent. | |  |
| If any of the statements were selected, please explain. | | |
| Click here to enter text. | | |

**Declaration by PI**

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| I confirm that I have reviewed all the conditions in Part 2, Division 3 of the Second Schedule of the PDPA, and having clarified the key considerations above, I am satisfied that the said requirements of the PDPA are fulfilled such that the personal data of the research subjects can be used within NUHS/NUH without their consent for the purposes of the study. |  |
| I confirm that any research results published would not be in a form that identifies the individual. |  |
| **Only applicable if personal data will be disclosed outside of NUHS/NUH to an external Organisation**  NUHS/NUH will be disclosing the personal data of the research subjects to Click here to enter text. (Organisation name) (“**Organisation**”) for the purposes of the study.  I confirm that I have reviewed all the conditions in Part 3, Division 2 of the Second Schedule of the PDPA., and having clarified the key considerations above, I am satisfied that the said requirements of the PDPA are fulfilled such that the personal data of the research subjects can be disclosed outside of NUHS/NUH without their consent to the Organisation for the purposes of the study. |  |



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Name: Click here to enter text.

Department: Click here to enter text.