Waiver of Informed Consent

1. Does the study pose no more than minimal risk to the Participants?

Yes. The collection of data poses no risk at all to study participants. All patients' identifiers will be removed from the dataset to safeguard the patients' privacy and confidentiality.

2. Does the waiver of informed consent adversely affect the rights and welfare of the Participants?

No. Patients will not be coerced to participate in the study. They are free to withdraw or decline consent to the study.

3. Can the study be practically conducted without the waiver of informed consent?

No.

4. Whenever appropriate, will the Participants be provided with additional pertinent information after participation?

Not applicable because no patient follow up is required.

5. Do you have any additional comments supporting the waiver of informed consent?

The waiver of informed consent will be applied to all out of hospital cardiac arrest cases enrolled for this observational epidemiology study.

However, we will obtain informed consent from patients who survived to hospital discharge to assess their quality of life using EQ-5D. Only patients with Glasgow-Pittsburg Outcome: cerebral and overall performance scoring of 2 and below will be selected for the assessment. No patient's identifiers will be recorded during the EQ-5D assessment to protect their privacy and confidentiality.

Research Involving Children

(Persons under the age of 21 years)

1. Describe whether appropriate studies have been conducted on animals and adults first and the data available from such studies is available to assess risks to children participating in the research.

Not applicable.

2. Why does the research need to involve children? Can the research question be answered through alternative means?

As stated in the inclusion criteria, all out of hospital cardiac arrest patients presented at the emergency departments will be eligible. This may involve children too.

No, because this is an observational epidemiology study which only involves data collection of all out of hospital cardiac arrest cases. We are applying for waiver of consent as we will be only reviewing documents for all the enrolled cardiac arrest cases. There will be no patient or family interaction or intervention involved.

3. Describe how the relation of potential benefits to risks is at least as favorable to the children as that presented by alternative approaches.

As this is an observational epidemiology study which only involves data collection of all out of hospital cardiac arrest cases, it poses no risk at all to any study participants. There will be no patient or family interaction or intervention involved. All patients' identifiers will be removed from the dataset to protect patients' privacy and confidentiality.

4. Provisions for assent and parental permission?

Neither the children's assent nor parental permission will be obtained.

5. Describe the additional safeguards that will be provided to protect rights and welfare of the vulnerable participants.

Data will be stored in network server located at the data co-ordination center and only authorized research members are allowed to access the data.

Research Involving Prisoners

1. How does your research purpose justify enrolling prisoners?

As stated in the inclusion criteria, all out of hospital cardiac arrest patients presented at the emergency departments will be eligible. This may involve prisoners too.

2. Is there any evidence of duress, coercion, or undue influence in the particular prison(s) from which subjects will be recruited?

No.

3. Do potential research related risks commensurate with risks that would be accepted by non-prisoner volunteers?

As this is an observational epidemiology study which only involves data collection of all out of hospital cardiac arrest cases, it poses no risk at all to any study participants. There will be no interventions involved in this study.

4. Are there adequate systems in place to ensure confidentiality of participation and of data?

Yes, all patients' identifiers will be removed from the dataset to protect patients' privacy and confidentiality. Their legal status will not be recorded in the dataset, and there will be no patient interaction involved.

5. Describe the additional safeguards that will be provided to protect rights and welfare of the vulnerable participants.

Data will be stored in network server located at the data co-ordination center and only authorized research members are allowed to access the data.