**PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM**

**Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial**

**Participant ID \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**



You are being invited to take part in a research trial. Before deciding whether to take part, you need to understand why this research is being done and what it involves. Please take time to read the following information carefully and talk to others about the trial if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether you wish to take part.

**Purpose of the trial and what will happen**

1. **What is the purpose of the trial?**

We are doing a study at this hospital to see if a special training provided to the doctor(s), namely Advanced Trauma Life Support (ATLS), improves the care and outcomes in the patients with trauma.

1. **What is the intervention?**

We would not be directly giving any intervention to you, especially as a part of this study. The study intervention is a two- and half-day specialized training given to the doctor(s) who will be treating you.

1. **Why have I been invited?**

We would like you to be a part of this study because you came to this hospital after having an injury. We plan to include more than 4000 participants in total from 30 hospitals across India.

1. **What will happen to me if I take part?**

During your hospitalisation, some of the information required for this study will be collected from your routine medical records. This includes your age, gender, medical history, injury details, and treatment received during the hospitalisation. During the follow-up phase of the study the hospital research team will:

* Call you or a relative one day after you arrived at this hospital to hear how you are. If you are still in hospital, we will visit you in the ward.
* Call you or a relative 30 days after you arrived at this hospital to hear how you are. If you are still in hospital, we will visit you in the ward.
* Call you or a relative three months (90 days) after you arrived at this hospital to hear how you are. If you are still in hospital, we will visit you in the ward. At this time, we will also conduct a short interview, lasting less than five minutes, to find out about your health status.

1. **Do I have to take part?**

Participating in this study is completely voluntary. For the follow-up phase of this study (after hospital discharge), we will request you/your relative to sign an Informed Consent Form, but you will be free to change your mind and ask us to stop collecting the follow up data at any time without giving a reason. If you choose to not be contacted telephonically for follow-up data collection, your future medical treatment and normal standard treatment will not be affected in any way. However, any data already collected about you from medical records will continue to be used in the analysis, unless you/your relative contact the site research team and ask them to not use the previously collected data by signing an ‘opt-out’ form, enclosed with this information sheet. The details of the site research team are provided in this document.

1. **What will I have to do?**

We are requested to provide responses to the questions about your health and recovery during the telephonic follow-ups or in-person follow-up visits.

1. **What are the side effects of the intervention?**

There are no foreseeable side-effects of this intervention as we would not be directly giving any intervention to you.

1. **What are the possible disadvantages and risks of taking part?**
2. **What are the possible benefits of taking part?**

Our research may help to find tools that better identify injured patients in need of immediate care. Although this research will not affect the care you are given in this hospital at this time, its results might help others that are injured. There is no assurance you will benefit from this study. However, your participation may contribute to the medical knowledge about the use of this intervention.

1. **Will I be paid for taking part?**

You will not receive any payment for participating in this study.

1. **What if I decide I know longer wish to participate in the study?**

You are free to stop participating in this study at any time. You do not need to provide a reason and your decision will not affect your future care or medical treatment.

1. **Will my taking part in this study be kept confidential?**

All information collected about you as a part of your participation in this study will be kept strictly confidential and will be used for purpose of research only. Your information will not contain any identifying factor and will be kept in a highly secured server. All de-identified information about you will be handled in accordance with the Indian data protection law(s) to ensure strictest confidence. At the end of the trial, your anonymized trial data may be shared with researchers outside the George Institute for Global Health, both in India and abroad to further advance knowledge on injury care.

1. **What will happen to the results of this study?**

The results of this research may be published as a scientific article; however, it will not be possible to identify you by reading any article that may result from this work. Further, data from this project will be shared with other researchers in India and abroad, but it will not be possible to identify you using only that data.

1. **Who is funding this study?**

The study management is being supported by Karolinska Institutet, Sweden through a grant received from Swedish Research Council.

**Further information and contact details**

If you have questions about this research study and your rights or in the case of any injuries during the course of this study, you may contact the Principal Investigator

Add name and contact details of local principal investigator and co-investigator here:

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Name/ Designation)
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Name/ Designation)

If you have any questions related to rights as a participant or complaint about this study, you can contact <Name>\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, Chairperson <site name> Institutional Ethics Committee. The contact number is <phone number> \_\_\_\_\_\_\_\_\_\_\_\_\_\_ or you may contact <Name> \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Member Secretary Institutional Ethics Committee. The contact number is <phone number> \_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**PART II: INFORMED CONSENT FORM**

|  |  |
| --- | --- |
| Date |  |
| Name of Signatory |  |
| Signature/Thumb Impression of Participant or Legally Acceptable Representative |  |
| Date |  |
| Name of Investigator |  |
| Signature of Investigator |  |
|  |
|  |
| Date |  |  |
| Name of Witness |  |  |
| Signature of Witness |  |  |
|  |
|  |

**A copy of this Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the participant or his/her attendant**

**INFORMED CONSENT FORM**

|  |  |
| --- | --- |
| Study Title | Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial |
| Short Title | The Trauma Audit Filters Trial |
| Protocol ID |  |
| Details of the Indian Researcher (Principal Investigator) | Dr. Vivekanand Jha  Executive Director  The George Institute for Global Health, India  T +91 11 4158 8091-93  E [vjha@georgeinstitute.org.in](mailto:vjha@georgeinstitute.org.in) |
| Details of the Global Research (Principal Investigator) | Dr. Martin Gerdin Wärnberg  Associate Professor  Karolinska Institutet, Sweden  T +46 708539598  E [martin.gerdin@ki.se](mailto:martin.gerdin@ki.se) |
| Details of the Hospital Investigator | Name  Designation  Department  Institution  Telephone  Email |

|  |  |
| --- | --- |
| **Please provide participant’s particulars** | |
| Name | |
| Hospital ID/MRD | |
| Address | Phone Number |
| Date of birth (dd/mm/yyyy) | |
| Phone number(s) to your relatives or friends that you agree that we may call if you do not answer your phone: | |

**Section 1: Participant Signature/Thumb Impression**

a) Please use this section only when the participant can provide consent by signing/placing thumb impression;

b) If the participant is unable to sign/place but can place thumb impression an impartial witness should be present during the entire informed consent discussion;

c) After the information written in the participant information sheet has been explained to the participant, the witness should sign and personally date the consent form;

d) Investigator’s signatures are mandatory.

**If you agree with each sentence below, please initial the box**

| S. No. | Terms | Initials/thumb impression of the participant |
| --- | --- | --- |
| 1 | I confirm that I have read and understood the ICD Version 0.1 dated 29 February\_ 2024 for the above trial and have had the opportunity to ask questions |  |
| 2 | I understand that my participation in this trial is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected. |  |
| 3 | I understand that the Sponsor of the clinical trial, others working on the Sponsor’s behalf, the Ethics Committee and the Regulatory Authorities will not need my permission to look at my health records both with respect to the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information published or released to third parties. |  |
| 4 | I agree not to restrict the use of any data or result(s) that arise from this study provided such a use is only for scientific purposes. |  |
| 5 | I agree to take part in the above study. |  |

|  |  |
| --- | --- |
| Date |  |
| Name of Participant |  |
| Signature/Thumb Impression of Participant |  |
| Date |  |
| Name of Witness |  |
| Signature of Witness |  |
| Date |  |
| Name of Investigator |  |
| Signature of Investigator |  |

**A copy of this Participant Information Sheet and duly filled Informed Consent Form shall be handed over to the participant or his/her attendant**

**Section 2: Participant’s Legally Acceptable Representative’s Signature/Thumb Impression**

a) Please use this section only when the participant is unable to sign because of the medical condition but their legally acceptable representative is available to provide consent by signing/placing thumb impression;

b) If the participant’s legally acceptable representative is unable to sign/place but can place thumb impression an impartial witness should be present during the entire informed consent discussion;

c) After the information written in the participant information sheet has been explained to the participant’s legally acceptable representative, the witness should sign and personally date the consent form;

d) Investigator’s signatures are mandatory.

| **S. No.** | **If you agree with each sentence below, please initial the box** | **Initials/thumb impression of the legally acceptable representative** |
| --- | --- | --- |
| 1 | I confirm that I have read and understood the ICD Version 0.1 dated 29 February\_ 2024 for the above trial and have had the opportunity to ask questions |  |
| 2 | I understand that my relative’s participation in this trial is voluntary and that I am free to withdraw my proxy consent at any time, without giving a reason and without my medical care or legal rights being affected. |  |
| 3 | I understand that the Sponsor of the clinical trial, others working on the Sponsor’s behalf, the Ethics Committee and the Regulatory Authorities will not need my permission to look at my relative’s health records both with respect to the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my relative’s identity will not be revealed in any information published or released to third parties. |  |
| 4 | I agree not to restrict the use of any data or result(s) that arise from this study provided such a use is only for scientific purposes. |  |
| 5 | I agree to take part in the above study. |  |

|  |  |
| --- | --- |
| Date |  |
| Name of the Legally Acceptable Representative |  |
| Signature/Thumb Impression of the Legally Acceptable Representative |  |
| Date |  |
| Name of Witness |  |
| Signature of Witness |  |
| Date |  |
| Name of Investigator |  |
| Signature of Investigator |  |

**Opt-Out Form**

Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial.

| S. No. | Terms | Select all that applies | Initials/thumb impression of the participant |
| --- | --- | --- | --- |
| 1 | I hereby request to delete the previously collected and, in the future, not collect my/my relative’s routine medical information for the purpose of this study |  |  |
| 2 | I am choosing not to be contacted telephonically/in-person for follow-up data collection |  |  |

|  |  |
| --- | --- |
| Date |  |
| Name of the Participant/ Legally Acceptable Representative |  |
| Signature/Thumb Impression of Participant/ Legally Acceptable Representative |  |
| Date |  |
| Name of Witness |  |
| Signature of Witness |  |
| Date |  |
| Name of Investigator |  |
| Signature of Investigator |  |

**A copy of this opt-out form shall be handed over to the participant or his/her attendant**