## Consent V10 Dated22mar24

| Section I: Consent Wavier  This only applies to patients who are unconscious or otherwise unable to provide consent and do not have a legally authorized representative. Patient participants who are included under the waiver of informed consent have to be approached and receive information about the study, the option to opt out, and consented for follow up when they regain consciousness or a legally authorized representative is present. |                                                                                                                                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                    |
| Reason for waiver of consent                                                                                                                                                                                                                                                                                                                                                                                                                            | <ul> <li>Whether the patient is unconscious or not able to provide consent</li> <li>Do not have a legally acceptable representative (LAR)</li> <li>Both</li> </ul> |
| Please fill LAR attempt form to contact LAR                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                    |
| Section II: Opt in consent for follow up data colle                                                                                                                                                                                                                                                                                                                                                                                                     | ection                                                                                                                                                             |
| Who gave opt-in consent for follow-up data collection?                                                                                                                                                                                                                                                                                                                                                                                                  | <ul><li>Patient participant</li><li>Legally authorised representative</li><li>Opt-in consent not given</li></ul>                                                   |
| Please fill opt-out form                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                    |
| Why was participant representative approached for consent instead of the participant?                                                                                                                                                                                                                                                                                                                                                                   | <ul><li>☐ The participant is incapacitated because of the trauma</li><li>☐ The participant is younger than 18 years</li></ul>                                      |
| When did the participant or participant representative consented for follow-up data collection?                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                    |
| How did the participant or participant representative consented for follow-up data collection?                                                                                                                                                                                                                                                                                                                                                          | <ul><li>○ In writing</li><li>○ Verbally</li></ul>                                                                                                                  |
| Section III: Assent form                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                    |
| Did the participant representative consented for follow-up data collection?                                                                                                                                                                                                                                                                                                                                                                             | <ul><li>Yes</li><li>No</li></ul>                                                                                                                                   |
| Did the participant gave assent for follow-up?                                                                                                                                                                                                                                                                                                                                                                                                          | <ul><li>○ Yes</li><li>○ No</li><li>○ The participant is incapacitated because of the</li></ul>                                                                     |

**₹EDCap**°

07-06-2024 6:52pm