**STRESS-L trial: STudy into the REversal of Septic Shock with Landiolol (Beta Blockade)**

**Chief Investigator: Dr Tony Whitehouse**

**LEGAL REPRESENTATIVE CONSENT FORM**

Centre ID: Participant ID:

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Please **initial** box | |
| 1. | I confirm that I have read and understood the Legal Representative information sheet **……………………………………….**for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | |  |
| 2. | I understand that my relative, partner or close friend (or the person I represent) does not have to take part, they can stop/I can withdraw them at any time by telling the researchers, without giving any reason and without their medical care or legal rights being affected. I understand that should they/I withdraw them then the information collected so far cannot be erased and that this information may still be used in the study analysis. | |  |
| 3. | I understand that relevant sections of any of my relative, partner or close friend (or the person I represent) medical notes and data collected during the study may be looked at by authorised individuals from the University Hospitals Birmingham NHS Foundation Trust, Warwick Clinical Trials Unit, the research group, the local NHS R&D department and regulatory authorities where it is relevant to their taking part in this study. I give permission for these individuals to have access to these records. I understand that my relative, partner or close friend (or the person I represent) personal details will be kept confidential. | |  |
| 4. | I understand that my relative, partner or close friend (or the person I represent) medical records may be used to keep in touch with my relative, partner or close friend (or the person I represent) and to check their health status. I give my permission for nominated members of the direct research team to access them for these purposes. | |  |
| 5. | I agree to the GP of my relative, partner or close friend (or the person I represent) being informed of their participation in the study. | |  |
| 6. | I believe that………………………………………………………………..  (The participant) would have no objections to taking part in the above study. | |  |
| 7. | Blood samples for the study to help us to define the mechanisms involved in treating sepsis with beta blockade  I understand and agree that any blood samples collected during the study can be sent to other researchers in the University of Birmingham for study related analysis. I understand that the samples will have any details that could identify my relative, partner or close friend (or the person I represent) removed before sending. | |  |
| 8. | Optional: Consent for storage and use in future research  I agree to donate the additional blood samples my relative, partner or close friend (or the person I represent) has provided to the Human Biomaterials Resource Centre at the University of Birmingham where they will be stored, linked to his/her medical records, for use in future ethically approved research (including genetic studies).  I understand that his/her samples may be used by local researchers, research groups elsewhere in the UK or overseas, and possibly for research involving private or commercial companies.  I also understand that any samples or data released by the Human Biomaterials Resource Centre will be anonymised so that researchers will not be able to identify my relative, partner or close friend (or the person I am representing).  (*I understand that my relative, partner or close friend (or the person I represent) can still take part in the Trial if I do not initial this*)  **Yes**  **No** | | Please **initial** box |

­­­­ Name of Participant Relationship of legal representative to participant

Name of Legal Representative Signature Date (dd/mmm/yyyy)

Name of Person taking consent Signature Date (dd/mmm/yyyy)

3 copies: 1 for legal representative, 1 for the medical notes and 1 for the STRESS-L Investigator Site File

**If consent has been obtained over the telephone or teleconference facilities because the personal legal representative is not able to be present physically to sign for themselves**

I witnessed the accurate reading of the consent form to the participant’s personal legal representative, who could ask any questions and got satisfactory replies.

I confirm that they gave their consent freely.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | |  |  | | |  | |
| **Name of Legal Representative** | | |  | **Relationship to participant** | | |  | |
|  |  |  | | |  |  | |
| **Name of Witness** |  | **Signature** | | |  | **Date (dd/mm/yy)** | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Person Taking Consent** |  | **Signature** |  | **Date (dd/mm/yy)** |