**Fluid Optimisation in Emergency Laparotomy (FLO-ELA) trial**

PATIENT CONSENT FORM

**(For use in Northern Ireland only)**

Name of Principal Investigator: [Insert here]

Site Name: [Insert here]

IRAS number: 214459 Trial ID: |\_\_|\_\_|\_\_| -|\_\_|\_\_|\_\_|\_\_|\_\_|

**Please initial box**

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| --- | --- | --- | --- | --- |
| 1. | I confirm that I have read and understand the information sheet dated 01/07/2020 (version 2.0) for the FLO-ELA trial. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily. | | |  |
| 2. | I understand that my participation 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 sections of my medical notes and data collected during the trial may be looked at by the research team, the national co-ordinating centre, the sponsor (and its representatives), or the *NHS Trust/Health Board* where it is relevant to this research. I give permission for these individuals and bodies to have access to my records. | | |  |
| 4. | I agree for the research team to contact my primary care practitioner (GP) in order to inform them of my involvement in this study. | | |  |
| 5. | I understand that information collected about me including my name, gender, date of birth and H&C number will be sent to NHS organisations (the Healthcare Trust or Business Services Organisation within Health and Social Care Northern Ireland) to obtain information about my health status for the purpose of this research. | | |  |
| 6. | I understand that data collected about me for this trial will be used for study analysis. I agree for my data to be securely stored and archived by University Hospital Southampton NHS Foundation Trust and Queen Mary University of London. | | |  |
| 7. | I agree for my anonymised data to be shared with other researchers for further studies and publications on this topic, but only if they guarantee to preserve the confidentiality of the information requested. | | |  |
| 8. | I agree to take part in the FLO-ELA trial. | | |  |
| Print name of participant: | | Date: | Signature: | |
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| Print name of person receiving consent  (designated responsible person): | | Date: | Signature: | |
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***When completed, give one copy to the patient; file the original in the Investigator Site File; and place one copy in the medical notes***