Informed Consent

Patient Identification Information

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Subject Notes

(Subject.GUPI) GUPI

(Subject.PatientNum) Patient Number

(Subject.DateInj) Date of injury
dd-mmm-yyyy

(Subject.EnrollDate) Date of Enrolment

(Subject.DateOfAdmission) Date Of Admission
(Ward OR ICU)

(Subject.ValidGUPI) ☐ Valid GUPI

(Subject.PatientType) Stratum
- ☐ ER
- ☐ Admission
- ☐ ICU

(Subject.Cohort) MRI Substudy
- ☐ No
- ☐ Yes

Informed Consent

(Subject.InfConsTyp) Type of initial consent
- ☐ Informed consent (by subject) oral
- ☐ Informed consent (by subject) written
- ☐ Proxy consent verbal
- ☐ Proxy consent written
- ☐ Deferred consent
- ☐ Waiver of consent

(Subject.InfConsInitialDate) Date of initial consent
dd-mmm-yyyy

(Subject.InfConsInitialTime) Time of initial consent
hh:mm

(Subject.InfConsWhen) Confirmation of consent
- ☐ Written proxy consent BEFORE enrolment
- ☐ Written proxy consent AFTER enrolment
- ☐ Written informed consent by patient

(Subject.InfConsDate) Date of written consent
dd-mmm-yyyy

(Subject.InfConsTime) Time of written consent
hh:mm

(Subject.InfConsBy) Consent obtained by
- ☐ Doctor (MD)
- ☐ Nurse
- ☐ Research assistant
- ☐ Other

Consented for
(check all that apply)

- (Subject.InfConsentData) ☐ Data
- (Subject.InfConsentBlood) ☐ Blood
- (Subject.InfConsentDNA) ☐ DNA
- (Subject.InfConsentMRI) ☐ MRI
- (Subject.InfConsentOutcomeAssmts) ☐ Outcome assessments

(Subject.EnrolledInOtherStudy) Enrolled in other study
- ☐ No
- ☐ Yes
- ☐ Unknown

(Subject.ObservStudyRegistry) Observational Study/Registry

- [ ] CREACTIVE
- [ ] TARN or EuroTARN registry
- [ ] German Trauma registry
- [ ] Net-QuRe
- [ ] Other Registry
- [ ] Other Observational Study

(Subject.ObservStudyOtherRegistry) Please specify other registry:

(Subject.ObservStudyOtherObservStudy) Please specify other observational study:

(Subject.RandomizedControlTrial) Randomized Controlled Trial

- [ ] CRASH-3
- [ ] EPO-TBI
- [ ] Eurotherm
- [ ] POLAR (Oxy-TC)
- [ ] NOSTRA
- [ ] Other Randomized Clinical Trial

(Subject.AssociatedStudy) Associated Study

- [ ] RESCUE-ASDH
- [ ] TAHITI
- [ ] PROLABI

(Subject.RandomizedControlTrialOther) Please specify other randomized clinical trial:

(Subject.ConsentWithdrawn) [ ] **Consent Withdrawn**

(Subject.ConsentWithdrawnDate) Date consent withdrawn
dd-mmm-yyyy

(Subject.ConsentWithdrawnTime) Time consent withdrawn
hh:mm

(Subject.ConsentWithdrawnReason) Reason for withdrawing consent

(Subject.WithdrawalOption) **Withdrawal Option**

- ○ **Complete Withdrawal** (no further contact, destruction of all data and samples collected up to that point)
- ○ No further study related activities, but consent to access of clinical notes and use of existing data