Instructions for the Patient Information Sheet and Informed Consent Form in the "SCI-POEM" study (v1.1)

Summary

- Inform the patient about the study **prior to any study-specific intervention** (e.g. study-specific pregnancy test, preoperative patient questionnaire, surgery, conservative treatment etc.)
- Ask the patient to **personally date and personally sign** the informed consent form.
- Provide the patient with one signed duplicate of the informed consent form (**blue version**)
- Keep one signed duplicate in the patient file (**white version**)!
- Document the process of informing and consenting patients **in the medical chart** (including name of the study, patient trial number and date of informed consent).
- This study includes vulnerable patients due to the psychological burden of the injury. Therefore, please note the specific guidelines below.

Patients who are unable to read or write

- If the patient is unable to write (e.g. physically impaired patients), an **independent witness** is present during the patient information process.
- By signing the informed consent form, the witness confirms that the consenting process was performed correctly and the patient agreed orally to participate in the study.

Patients who lack capacity to provide informed consent

Patients suffering from tSCI may be mentally incompetent as a result of the trauma and/or medication. For example, patients with a GCS of 14 points are eligible for study participation. However, this may imply that the patient is only able to perform a "confused conversation" (see Appendix 3 for details of the GCS). Such patients may be unable to give neither oral nor written informed consent at the time of admission due to their medical condition. When the patient lacks capacity to give informed consent prior to surgery, the patient may still be enrolled according to the following process:

How to appoint a consultee?

- The researcher must **take reasonable steps to identify someone** who is willing to be consulted about the participation in the approved project of the person who lacks capacity.
- Ideally, the consultee will be someone who **knows the person** who lacks capacity well but is not acting in a professional or paid capacity (a personal consultee). If this is not possible, the researcher must nominate a third party unconnected with the research who is willing to act as a **nominated consultee**.
- The researcher's proposals to identify a consultee must respect the principles of confidentiality.

Personal consultee

- A personal consultee could be:
  - a **family member**, **carer** or **friend**
  - an **attorney** acting under a Lasting Power of Attorney
  - a **court appointed deputy**, provided that they had a relationship with, or personal knowledge of, the person lacking capacity before their appointment as deputy (for example, a deputy could be a family member).
- The personal consultee **must not be someone who is caring for the person** who lacks capacity or is interested in their welfare in a professional capacity or for remuneration
- In accordance with the general principles of the Act, the researcher must make every effort to **take into account the wishes of the person** who lacks capacity about whom to consult (e.g. their partner, or a particular friend or carer) and to act **in accordance with any relevant previous statement or wishes**

What must the personal consultee do?

- The personal consultee must themselves have capacity at the material time and be prepared to be consulted by the researcher about the possible involvement in the project of the person who lacks capacity (they must be **willing to do it and able to understand the information** provided about the project).
- In addition to the normal participant information leaflet it will also be necessary to explain to the personal consultee that they are being asked to **advise** on whether the person who lacks capacity should take part in the project.
- The consultee is bound by the normal duty of care to **act responsibly and in good faith** when advising on the **past and present wishes and feelings**.
- Please remind the consultee that they are not being asked for advice on their personal views on participation in the specific project, or research in general. The consultee is **not being asked to consent on behalf of the person** who lacks capacity. The consultee must set aside any views they may have about the research and consider only the views and interests of the person who lacks capacity. A consultee should be asked to **consider the broad aims of the research, the risks and benefits and the practicalities of what taking part will mean for the person** who lacks capacity.

Nominated consultee

- Where no personal consultee is available, the researcher must nominate, according to the procedure required in their hospital/institution, a person who has **no connection with the project** and who is willing to be consulted about the participation of a person who lacks capacity in an approved research project.
- The nominated consultee may be a **member of the care team**, provided that they had **no connection with the research project** (For example, the consultee should not be someone who is involved or has a financial or professional interest in the progress of the research. They should not be under the influence of the research team, either professionally or personally.)

What must the nominated consultee do?

- The nominated consultee is required to perform the same role as a personal consultee (see above)

- The nominated consultee may not know the person who lacks capacity. In determining what the person's wishes and feelings about the research would be if they had capacity, the nominated consultee should attempt to seek views from any family, friends or carers who may not be willing or able to act as a consultee.
- The nominated consultee will have to consider any possible potential or perceived conflict of interest in the outcome of the research when weighing up the views of family, friends or carers

When will the patient be approached?

- Arrangements are made to inform the patient (or legally authorized representative) as soon as possible about the patient's study participation and all aspects of the study.
- The patient is asked to provide informed consent for participation as soon as his/her medical condition allows.
- If the patient disagrees to participate in the clinical investigation, the PI makes sure that no data of this patient is collected. No more study-specific interventions will be performed unless treatments necessary to assure the patient's safety.