*- POSE-*

Peri-interventional Outcome Study in the Elderly
EUROPEAN, MULTI-CENTRE, PROSPECTIVE OBSERVATIONAL COHORT STUDY

Dear Principle Investigator,

The new General Data Protection Regulation (GDPR) became applicable on 25 May 2018. Considering the updated data protection rights provided for patients in the GDPR, future patient information sheets and consent forms must be adapted to the requirements of the GDPR.

**The following refers to the actually recruiting (includes also the follow up period) POSE sites in the EU, who have already received an ethical approval:**

Patients who have already received such patient information and/ or additionally signed consent form to participate in a clinical trial should be informed about the new subsidiary legal data protection regulations with the attached information sheet for study subjects. Please individualize the information sheet according to your centre (i.e. please fill in and check all the yellow highlighted fields).

In order to ensure transparency with regard to data protection, please hand over this information sheet to the study subjects. This can be done personally, by e-mail or post.

Please confirm the delivery or dispatch of the information sheet to your study subjects or that you have included the information about the new GDPR in your patient information with the enclosed signature page and send a copy back to us.

In case that you have used our GDPR information sheet: Please place the original signature page and a copy of each letter addressed to the patient in the investigator site file. Also fill in the attached Log to document the issuing of the information sheet.

Sincerely,

Prof. Mark Coburn (Study Director)

Attachments:

Signature Page for the Principal Investigator

New Information About Data Privacy Rights for Study Subjects

Data Protection Information Sheet Issuing Log

**INFORMATION SHEET ON THE GDPR FOR STUDY SUBJECTS SIGNATURE PAGE FOR THE PRINCIPAL INVESTIGATOR**

Study: Peri-interventional Outcome Study in the Elderly

SITE: XXX-XXX

PRINCIPAL INVESTIGATOR (First name, Last name): XXXXXXXXXXXXX

Dear Sir or Madam,

☐ I hereby confirm that I have handed over the attached information letter on the General Data Protection Regulation (GDPR) to all study subjects.

OR

☐ I hereby confirm that our patient information already includes/ has already included the information about the new General Data Protection Regulation (GDPR)

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Name of the Principal Investigator Date

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Signature

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| --- |
| **Please place the original of this signature page** **in your investigator site file.** **Please send a copy to the following fax number:****+49-241-80-3335766****or** **E-mail: akowark@ukaachen.de****Please add as attachment one copy of the Information Sheet on the General Data Protection Regulation (GDPR) for patients, which you have handed over to the study subjects in your language.** |