Informed consent form

Participation in "patient journey"

☐ I am a patient

☐ I am the authorized representative of a patient

☐ Yes, I would like to participate in a patient journey

If you agree to participate in a patient journey, Work Package 4 under Endo-ERN will process certain personal data, as described below, and need to obtain consent as further described below. Work Package 4 (WP4) consisting of two health care providers (dr. Susan Webb of xxxxx and dr. Anna Nordenstrøm of xxxxx and two patient representatives, Diana Vitali of xxxxx and Jette Kristensen of xxxxwill will act as the controller for the processing of those personal data.

Your data, your rights

All personal data which is collected in the context of the patient journey is processed by and on behalf of WP4 as data controller.

WP4 aims to conduct patient journey surveys in order to enhance the knowledge and available data about the patients' needs in relation to the provision of healthcare and social services.

The following personal data may be collected and processed on the basis of this informed consent form:

- Contact details (name, e-mail address) of the person(s) signing this informed consent form ("Contact Data");
- Personal data of the patient, including name, contact details, nationality, data concerning health (including but not limited to disease, symptoms, diagnosis, physical condition, treatments, disease history, quality of life, [other]) ("Patient Data").

The Contact Data and Patient Data will be stored in a secured database which is only accessible for members of WP4 and representatives of Endo-ERN on a strict need-to-know basis.

The Contact Data provided via this informed consent form will be used for the following purposes: registering the informed consent and contacting the relevant person in the context of the patient journey.

The Patient Data collected in the context of the patient journey by the patient or by its authorized representative, will be entered into standard forms, which do not contain identification data of the patient or its authorized representative, such as name, e-mail address and phone number ("worksheets").

Commented [AA1]: NOTE TO PATIENT ORGANIZATION: This form should be signed before the start of any data collection.

Commented [AA2]: NOTE TO PATIENT ORGANIZATION: Please note that the collected data should be proportionate and strictly limited to the purpose at stake.

WP4 will use the pseudonymized data included in the worksheets for the following purposes: analysis, scientific and statistical research in connection with the provision of health and social services. The aggregated results thereof may be shared with third parties through conferences, publications, websites, interviews and [other].

The personal data, including both Contact Data and Patient Data, which is collected in the context of the patient journey is processed on the basis of consent, as expressed in this consent form. The patient or its authorized representative are free to decide whether or not to sign this consent form; if not, then WP4 will not process any personal data that may already have been provided and will immediately delete those personal data.

Any person signing this consent form, is at any time thereafter free to withdraw its consent for the processing of the personal data, without giving any reason, by notifying it to WP4. Upon the withdrawal of your consent, the processing of your personal data will stop.

If you want to provide Patient Data to WP4 and you are not the patient or the patient's authorized representative, then you need to ensure that the patient or its authorized representative also sign this informed consent form.

The personal data collected in the context of the patient journey will not be disclosed outside of the European Economic Area. However, the aggregated results of the research which do not include any personal data may be shared with third parties outside of the European Economic Area through conferences, publications, websites, interviews as described above.

The informed consent forms and the Contact Data contained therein will be stored by WP4 for as long as WP4 needs to be able to prove that it has obtained informed consent for the processing of personal data as described in this form and in accordance with the retention periods required or permitted by law

The worksheets are kept as long as necessary to achieve the abovementioned purposes.

Within the limits provided by the General Data Protection Regulation, as a data subject, you have a right to:

- receive a copy of your personal data or to have your personal data rectified, deleted or restricted.
- request to receive the personal data concerning you, which you have provided to us, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller.
- to object to the processing of your personal data.

Any questions or concerns about the processing of your personal data by WP4 as described in this informed consent form, can be sent by e-mail to WP4 (mail address).

You also have the right to file a complaint with the competent supervisory authority of your country.

Commented [AA3]: NOTE TO PATIENT ORGANIZATION: It is recommended to detail this as much as possible.

Commented [AA4]: NOTE TO PATIENT ORGANIZATION: We recommend including information on third parties (if any) to which the data may be disclosed. When the third parties cannot be identified, information on the category of the recipients/purposes for which the data will be transferred should be included. On top of this, we recommend including the information on how the data will be protected when it is being transferred (e.g. coded information, encryption, etc.).

Commented [AA5]: NOTE TO PATIENT ORGANIZATION: preferably we put a specific retention term. If this is not possible, then we should give criteria that will be used to determine the retention period.