Compliance with Member State applicable rules for the collection, storage and future use of (personal) data (article 7 (1 d) of EU Regulation 536/2014)

Full title of the clinical trial	**EU trial number**
Click or tap here to enter text.	Click or tap here to enter text.
Responsible entity for the data (legally controller (article 4 (7) GDPR): Click or tap here to enter text.	

Section 1 – Newly collected (personal) data

1.1 What of the following (personal) data[1] will be collected from the subject?

- ☐ Not applicable
- ☐ Racial or ethnic origin, if so please explain why Click or tap here to enter text.
- ☐ Social security number, if so please explain why Click or tap here to enter text.
- ☐ Other revealing personal data, i.e. political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning a natural person's sex life or sexual orientation, namely: Click or tap here to enter text.

Section 2 - Does the clinical trial involve the collection of already existing (personal) data (derived from e.g. treating physician, family doctor, or previous participation in a study).

☐ Yes, please fill in the requested information in section 2
☐ No, not applicable. Please continue with section 3

2.1 What existing (personal) data will be used?

- ☐ From treating physician/medical specialist
- ☐ From previous studies, please enter EudraCT or EU clinical trial number: Click or tap here to enter text.
- ☐ Other, please indicate: Click or tap here to enter text.

2.2 Will new consent be obtained for the use of these data in this clinical trial?

- ☐ Yes
- ☐ No, please explain: Click or tap here to enter text.

Section 3 – How will the (personal) data for the purpose of the clinical trial (i.e. for use described in the protocol) be handled?

[1] Only the collection and processing of special categories of personal data have to be included here. Collection and processing of health data, as a special category of personal data, is part of clinical trial as described in protocol and does not have to be repeated here.

3.1. Where will the data be analysed? *I.e. Within the clinical site, within/outside the Sponsor's organization, within/outside the member state where collected or within/outside EU/EEA.*
Click or tap here to enter text.

3.2 Where will the data be stored during the clinical trial? *I.e. within the clinical site, within/outside the Sponsor's organization, within/outside the member state where collected or within/outside EU/EEA.*
Click or tap here to enter text.

3.3 If the data is sent to countries outside the EU/EEA, on what basis is it transmitted?
☐ Not applicable, data is not transmitted to countries outside EU/EEA
☐ Subject to appropriate safeguards (article 46 through 48 GDPR)
And if so, what safeguards (e.g. binding corporate rules, standard contract clauses):
Click or tap here to enter text.
☐ On the basis of an adequacy decision (article 45 GDPR)
☐ On the basis of derogations (article 49, e.g. informed consent):
Click or tap here to enter text.

3.4 How long will the data be stored?
Click or tap here to enter text.

3.5 What type of connection is available between data and individual subjects?
☐ Direct connection *(data marked with e.g. initials, date of birth)*
☐ Pseudonymised connection *(data marked with code, e.g. 001-2022, 002-2022)*
☐ No connection, data are anonymized *(I.e. data can neither directly nor indirectly (with reasonably means according to recital 26, GDPR) be linked to the subject)*

3.6 Who will have access to the data?
Click or tap here to enter text.

3.7 Who will have access to the data code list?
Click or tap here to enter text.

3.8 Where will the data code list be stored?
Click or tap here to enter text.

Section 4 – Will the collected (personal) data be stored for future use?
(I.e. for use NOT described in the protocol)

☐ Yes, please fill in the requested information in this section
☐ No, please continue with section 5

4.1 What is the purpose of the future use?
Click or tap here to enter text.

4.2 Will the data for future use be stored for a longer period than described in 3.4 of this form?
☐ No
☐ Yes, how much longer?: **Click or tap here to enter text.**

4.3	Where will the data for future use be stored? **Click or tap here to enter text.**
4.4	If the data for future use is sent to countries outside the EU/EEA, on what basis is it transmitted? ☐ Not applicable, data is not transmitted to countries outside EU/EEA ☐ On the basis of an adequacy decision (article 45 GDPR) ☐ Subject to appropriate safeguards (article 46 through 48 GDPR). And if so, what safeguards (e.g. binding corporate rules, standard contract clauses): **Click or tap here to enter text.** ☐ On the basis of derogations (article 49 GDPR, e.g. informed consent): **Click or tap here to enter text.**
4.5	What type of connection is available between data and individual subjects? ☐ Direct connection *(samples marked with e.g. initials, date of birth)* ☐ Pseudonymised connection *(samples marked with code)* ☐ No connection, data are anonymized *(I.e. data can neither directly nor indirectly (with reasonably means according to recital 26, GDPR) be linked to the sample donor)*
4.6	Who will have access to the data for future use? **Click or tap here to enter text.**
4.7	Who will have access to the data code list? **Click or tap here to enter text.**
4.8	Will the subject be recontacted to give new consent to the use of the data in future research? **Click or tap here to enter text.**
Section 5 - Additional information on the collection, storage and future use of the (personal) data **Note: This section has only to be filled in if applicable**	
5.1	Provide any information (not described above) that is of relevance to the applicable rules on collection, storage, transport and future use of the data **Click or tap here to enter text.**