

## Model annex

### “Data protection declaration of consent”

(Last updated: 05/11/2018)

#### Disclaimer:

The translations of these materials into languages other than German are intended solely as a convenience and information to the non-German-reading public. These translations have not been checked by any lawyer with jurisdictional background in non-German jurisdictions. If any questions arise related to the accuracy of the information contained in these translations, please refer to the original German version of these documents which represent the official versions of these documents that were only discussed by the involved parties.

If you notice any inconsistency in this translation, please send your comments to [info@vfa.de](mailto:info@vfa.de)

#### *Instructions for use:*

This data protection declaration of consent should be submitted individually and in person by all members of the investigating team at the trial site. This declaration must be signed by these individuals before initial data relating to them is processed.

#### **Sample wording of data protection statement\*:**

I am aware and agree that the sponsor and/or companies affiliated with the sponsor as outlined in section 15 et seqq. of the German Stock Corporation Act and/or third parties authorised by the sponsor may collect, store, transmit or otherwise use (hereinafter collectively referred to as “process”) personal data pertaining to me, such as (i) contact details and details about my life, (ii) data about my participation in the trial, (iii) records of my training and (iv) results pertaining to me from audits performed in connection with the trial (hereinafter referred to collectively as “data”).

In accordance with the applicable data protection legislation, this data shall be processed (a) for the purposes of conducting the trial, (b) for regulatory purposes, and (c) for trial site management purposes (including the initiation of future clinical trial(s)), and will be erased or anonymised 25 years after the conclusion of the trial unless a longer period is required by law. The sponsor shall be permitted to publish this data in external public registers of clinical trials, such as [clinicaltrials.gov](http://clinicaltrials.gov), and may also disclose it to authorities to the extent required by the applicable legislation or make it available for publication. I am aware that as part of the aforementioned activities my data may be processed in non-EU member states, for which the European Commission has not established that an adequate level of data protection is in place. In such cases, the sponsor shall arrange standard EU contractual conditions.

I am aware that there are also legal bases for certain forms of processing my data for the aforementioned purposes, but that my consent forms the sole legal basis for other forms of processing, particularly any processing for trial site management purposes.

I am aware that my consent is voluntary and that I have the right to withdraw this consent at any time without affecting the legitimacy of the processing performed on the basis of this consent until its withdrawal. Furthermore, I am also aware that the data collected pertaining to me up until my withdrawal of consent may continue to be processed in the manner outlined above provided that another legal basis for such processing exists. If there is no other legal basis, however, I may also request the erasure of my data when withdrawing my consent as soon as no further data retention period applies.

I also have the right to inspect my data and, if it is incorrect, to demand rectification of the data, and I may also request that processing of my data be restricted for the duration of the inspection. Furthermore, I have the right to lodge a complaint with a data protection supervisory authority in the event of a possible data protection violation. In addition, I have the right to receive my data from the sponsor in a structured, conventional, machine-readable format on request and to transmit this data to a third party.

Should I wish to exercise the aforementioned rights, I can contact [\[contact details for the Controller in terms of data protection and its data protection officer where applicable\]](#) .

**By signing this document, I declare that I expressly consent to the processing of my data as outlined above.**

.....

Place, date

.....

Signature

\*Please note: This clause has been drafted with respect to the new provisions set forth in the EU General Data Protection Regulation [EU] 2016/679, which has been in effect since 25 May 2018. No official practice has yet been developed for dealing with these new provisions. In view of this, those using this declaration of consent after 25 May 2018 must – as far as possible – take into account the corresponding developments in official practice and case law.