

Model Annex to Obligations within the scope of a clinical trial involving medicinal products

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Disclaimer:

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If you notice any inconsistency in this translation, please send your comments to info@vfa.de

Instructions for use:

This declaration should be submitted individually and in person by all investigators involved at the trial site. This declaration must be signed by the investigators involved before they begin conducting the clinical trial. The model annex has been worded for the investigator or for other physicians of the investigating team. Additional declarations are usually also obtained from other members of the investigating team, particularly with regard to data protection requirements. The corresponding sections of this model annex may also be used as a guideline in this regard.

Note:

- *The model contract clauses and this model annex do not make any statements on the topic of "Inventions/rights to results". The matter of the negative right of publication must be regulated in this context – as such, only a placeholder is included in this model annex.*

Sample wording of the declaration submitted by the investigator:

To

[Sponsor's name and address] ("**Sponsor**")

Declaration on the acceptance of obligations as an investigator/medical member of the investigating team at [name of trial site] ("Trial Site**") in connection with the [trial title] clinical trial ("**Clinical Trial**")**

To whom it may concern,

I am an employee of the Trial Site and will participate in the conduct of the Clinical Trial at the Trial Site as an investigator/medical member of the investigating team.

I hereby declare that I am willing to collaborate on the aforementioned Clinical Trial. I confirm that I have taken note of the provisions set forth below and the obligations arising for me from these provisions. I also undertake to follow the clinical trial protocol, the German Medicinal Products Act and the Ordinance on Good Clinical Practice as well as the ICH guidelines in their currently valid versions.

1) Confidential information:

I am aware of the provisions on maintaining confidentiality of confidential information that have been agreed between the Trial Site and the client in the clinical trial agreement for the Clinical Trial. For as long as my employment relationship with the Trial Site continues, you/the client may only assert claims arising from breaches of the confidentiality provisions against the Trial Site and not directly against me. In the event that my employment relationship with the Trial Site ends before the expiry of the period for which the confidentiality provisions remain valid, all corresponding obligations, with the exception of the obligation to compensate damages arising as a result of breaches of confidentiality obligations, shall pass to me.

2) Publications:

I am aware of the provisions governing publications that have been agreed between the Trial Site and the client in the clinical trial agreement for the Clinical Trial. For as long as my employment relationship with the Trial Site continues, you/the client may only assert claims arising from breaches of the regulations governing publications against the Trial Site and not directly against me. In the event that my employment relationship with the Trial Site ends before the expiry of the period for which the regulations governing publications remain valid, all corresponding obligations, with the exception of the obligation to compensate damages arising as a result of breaches of confidentiality obligations, shall pass to me.

3) Negative publication right:

A provision concerning the negative publication right (in accordance with Section 42(2) of the German Employee Inventions Act (Arbeitnehmererfindungsgesetz, ArbNErfG)) should be added here.

4) "Debarment":

I warrant that I have not been excluded ("*debarred*") from any medicine control agency or supervisory authority, nor from any other regulatory authorities in the world and that, to the best of my knowledge, no proceedings for such restrictions are pending or have been announced against me. I shall inform the client promptly should any such proceedings against me be initiated or announced throughout the duration of the Clinical Trial.

5) Financial disclosure*:

I am aware of the provisions governing financial disclosure that have been agreed between the Trial Site and the client in the trial contract for the Clinical Trial. In the event that my employment relationship with the Trial Site ends before the expiry of the period for which the regulations governing financial disclosure remain valid, all corresponding obligations shall pass to me.

6) Notification of competent authorities:

I agree that the client may notify the competent authorities of my involvement in the Clinical Trial in accordance with Section 67(1) German Medicinal Products Act (AMG) and Section 12(1) and (2) of the Ordinance on Good Clinical Practice, and hereby entrust the client with providing such notifications. **

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Place, date

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Investigator signature

*Please note: Provisions governing financial disclosure may arise at various points during the implementation process – e.g. when applications are submitted to ethics committees. It is important that the contracting parties agree on provisions with regard to financial disclosure within the scope of the main contract, that such provisions are known to the investigator in particular and that these provisions pass to the investigator should their employment relationship with the contractor end before the expiry of the validity period for the provisions governing financial disclosure set forth in the trial contract.

** This passage may be omitted if EU Regulation No. 536/2014 is applied.