KRALOVSKE VINOHRADY UNIVERSITY HOSPITAL
Šrobárova 1150/50, 100 34 Prague 10, Phone: +420 267 161 111, CIN: 00064173
VATIN: CZ00064173, Bank: Czech National Bank, Account No.: 16334101/0710

RULES FOR CONDUCTING CLINICAL STUDIES AT KVUH

Effective April 1, 2025

AGREEMENT
Option 1) Tripartite Agreement with Separate Compensation for the Principal Investigator and Study Team Members - The Tripartite Agreement will include an appendix with a budget for the Principal Investigator and Study Team members. The compensation will be paid separately by the Sponsor to the individual bank accounts of the Principal Investigator and the Members of the Study Team.
Option 2) Tripartite Agreement and Separate Written Agreement on Compensation of the Principal Investigator and Study Team Member(s) - The Principal Investigator and, if applicable, Study Team Member(s) will conclude a Separate Agreement with the Sponsor regarding compensation for the clinical study concurrently with the Tripartite Agreement. All separate agreements concluded with the Principal Investigator and/or Study Team Member(s) for the clinical study in question shall be provided to the Department of Clinical Trials of the KVUH.
Option 3) Tripartite Agreement - The compensation for the Principal Investigator and Study Team Members will be paid through the KVUH in accordance with internal regulations of the KVUH.
The preference of agreement type is at the discretion of the Principal Investigator, and the selected type will apply to all Study Team Members, except for Team Members from the Institutional Pharmacy and the Department of Pathology, whose compensation will be disbursed by the KVUH. A preference is anticipated in the above order.
REQUIREMENTS FOR PROVIDED CONTRACTUAL DOCUMENTS
Contractual Document (Agreements/Amendments) – The Sponsor/CRO shall provide the draft contractual document in an unlocked format (editable) to allow version comparisons. – The KVUH prefers to sign contractual documents with a qualified electronic lock.
Budget – A draft itemized budget per procedures in MS Excel shall be provided by the Sponsor/CRO.
FINANCIAL DISTRIBUTION
The financial split between the KVUH and the Principal Investigator with the Study Team is in **30** (KVUH) to **70** (Principal Investigator + Study Team) ratio. The division will occur after deduction of fees and the costs of requested examinations.

KVUH ADMINISTRATIVE FEES
Start-up Fee – Department of Clinical Trials of the KVUH – A fee for administrative agreement processing, in the amount of **CZK 35,000**/EUR 1,400 + VAT (at the statutory rate), is payable after the agreement is signed. The KVUH is entitled to payment of the fee even if the contract is not concluded due to an obstacle on the part of the Sponsor/CRO.
Amendment Processing Fee – Department of Clinical Trials of the KVUH – A fee for administrative processing of agreement amendments, set at **CZK 10,000**/EUR 400 + VAT (at the statutory rate), is payable after the signing of an agreement amendment.
Start-up Fee – Clinic Conducting the Clinical Study – An administrative fee for the preparation process of the clinical study, set at **CZK 15,000**/EUR 600 + VAT (at the statutory rate), or **CZK 5,000**/EUR 200 + VAT (at the statutory rate) for non-interventional studies, is payable after the agreement is signed. The KVUH is entitled to payment of the fee even if the contract is not concluded due to an obstacle on the part of the Sponsor/CRO.
Start-up Fee – Institutional Pharmacy – An administrative fee for the preparation process of the clinical study at the Institutional Pharmacy, set at **CZK 5,000**/EUR 200 + VAT (at the statutory rate), is payable after the agreement is signed. The KVUH is entitled to payment of the fee even if the contract is not concluded due to an obstacle on the part of the Sponsor/CRO.
Start-up Fee – KVUH Central Laboratory – An administrative fee for the preparation process of the clinical study at the KVUH Central Laboratory, set at **CZK 1,000**/EUR 40 + VAT (at the statutory rate), is payable after the agreement is signed. The KVUH is entitled to payment of the fee even if the contract is not concluded due to an obstacle on the part of the Sponsor/CRO.
Start-up Fee – Department of Radiology and Nuclear Medicine – Primary Department of Radiology – An administrative fee for the preparation process of the clinical study at the Department of Radiology and Nuclear Medicine – Primary Department of Radiology, set at **CZK 1,000**/EUR 40 + VAT (at the statutory rate), is payable after the agreement is signed. The KVUH is entitled to payment of the fee even if the contract is not concluded due to an obstacle on the part of the Sponsor/CRO.
Start-up Fee – Department of Radiology and Nuclear Medicine – Primary Department of Nuclear Medicine – An administrative fee for the preparation process of the clinical study at the Department of Radiology and Nuclear Medicine – Primary Department of Nuclear Medicine, set at **CZK 1,000**/EUR 40 + VAT (at the statutory rate), is payable after the agreement is signed. The KVUH is entitled to payment of the fee even if the contract is not concluded due to an obstacle on the part of the Sponsor/CRO.
Start-up Fee – Department of Pathology – An administrative fee for the preparation process of the clinical study at the Department of Pathology, set at **CZK 5,000**/EUR 200 + VAT (at the statutory rate), is payable after the agreement is

signed. The KVUH is entitled to payment of the fee even if the contract is not concluded due to an obstacle on the part of the Sponsor/CRO.

Start-up Fee – Cooperating Clinic – An administrative fee for the preparation process of the clinical study at the cooperating clinic, set at **CZK 1,000**/EUR 40 + VAT (at the statutory rate), is payable after the agreement is signed. The KVUH is entitled to payment of the fee even if the contract is not concluded due to an obstacle on the part of the Sponsor/CRO.

Close-out Fee – Clinic Conducting the Clinical Study – An administrative fee for the process of closing the clinical study at the clinic conducting the clinical study in the amount of **CZK 20,000**/EUR 800 + VAT (at the statutory rate), or **CZK 5,000**/EUR 200 + VAT (at the statutory rate) for non-interventional studies. The KVUH is entitled to payment of the fee even if no participant was enrolled in the clinical study.

ISF Administrative Fee – paper version of ISF – a one-time fee for administration related to the creation of the ISF in the amount of **CZK 10,000**/EUR 400 + VAT (at the statutory rate), is payable after the agreement is signed + **an annual fee** for administration related to the management of the ISF, including printing of documentation (including, but not limited to, the ICF), in the amount of **CZK 10,000**/EUR 400 + VAT (at the statutory rate), is payable for each commenced 12-month period from the initiation of the clinical study

– electronic version of ISF – an annual fee for administration related to the management of the ISF, including printing of documentation (including, but not limited to, the ICF), in the amount of **CZK 10,000**/EUR 400 + VAT (at the statutory rate), is payable for each commenced 12-month period from the initiation of the clinical study

The fee is payable only if the Sponsor/CRO does not provide, or will not provide, complete clinical study documentation in paper form. If this situation occurs during the course of the clinical study, the fee will be charged retrospectively.

The KVUH is entitled to payment of the fee even if no participant was enrolled in the clinical study.

Archiving Costs – medicinal products are set at **CZK 30,000**/EUR 1,200 + VAT (at the statutory rate) per study, or **CZK 5,000**/EUR 200 + VAT (at the statutory rate) per study for a non-interventional study. The KVUH is entitled to payment of the fee even if no participant was enrolled in the clinical study.

Archiving Costs – medical devices are set at **CZK 20,000**/EUR 800 + VAT (at the statutory rate) per study, or **CZK 5,000**/EUR 200 + VAT (at the statutory rate) per study for a non-interventional study. The KVUH is entitled to payment of the fee even if no participant was enrolled in the clinical study.

REQUESTED EXAMINATIONS
The costs for the requested examinations will be determined based on the study protocol and the questionnaires completed by the Sponsor/CRO for the cooperating clinic(s)/department(s), which will be provided by the Department of Clinical Trials of the KVUH after initial contact by the Sponsor/CRO. Sponsors/CROs are requested to pay due attention to the completion of the questionnaires, as they are crucial for the preparation of the clinical study budget.