

Working Together

Guideline for Sponsors to collaborate with UMC Utrecht as study site

University Medical Center Utrecht

Welcome to UMC Utrecht

Welcome to UMC Utrecht, where world-leading science is combined with exceptional patient care.
We appreciate your interest in establishing a research collaboration with us.

At UMC Utrecht, our purpose is clear: Together, we are shaping a future where better health is within reach for everyone. By advancing scientific discovery, translating innovation into clinical practice, and delivering outstanding patient care, we are helping to create the healthcare of tomorrow.

In every clinical research partnership, our ambition is to combine scientific excellence with operational efficiency. We are committed to delivering the highest standards of academic quality while ensuring competitive and predictable study start-up timelines.
To facilitate a successful collaboration, we would like to introduce UMC Utrecht's procedures for the initiation of clinical studies. By providing a clear, transparent, and standardised overview of our research processes, we aim to support an efficient study start-up and establish a strong foundation for our collaboration.

The procedures described in this document are fully standardised across UMC Utrecht and are conducted in accordance with applicable Dutch legislation, national and international guidance issued by the Central Committee on Research Involving Human Subjects (CCMO). Adherence to these procedures ensures a robust, compliant, and efficient approach to the initiation and conduct of clinical research.

Should you have any questions regarding the information contained in this document, please do not hesitate to contact us at ResearchQuality@umcutrecht.nl.
For study-specific enquiries regarding the start-up of your clinical trial, please contact the local Principal Investigator (PI) or the delegated UMC Utrecht study team.
We look forward to working with you in advancing innovative clinical research and improving the lives of patients worldwide.

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1. Start-up phase

1.1. Confidentiality Disclosure Agreement (CDA) and Master CDA

UMC Utrecht will sign the Confidentiality Disclosure Agreement (CDA) upon approval of UMC Utrecht's legal affairs. When using the UMC Utrecht template, the UMC Utrecht can sign quickly. In case of frequent collaboration, establishing a Master CDA with UMC Utrecht can be a valuable option to accelerate timelines and reduce administrative workload. Currently, UMC Utrecht has more than 14 Master CDAs in place with clinical research organizations (CRO's), and commercial partners. Please contact U-TRIAL@umcutrecht.nl if you would like to arrange a Master CDA.

1.2. From site suitability to site feasibility

1.2.1. Feasibility questionnaire

Any (pre-)feasibility questionnaires will be completed by the study team of the respective department at their earliest convenience. Please include the following information: study outline and study phase, main objective(s), key in- and exclusion criteria and an estimated timelines for study start and execution. And if applicable, special procedures and/or measurements required for conducting the study.

Prior to the Site Selection Visit, please send the study protocol (or synopsis), timelines with respect to sending the site suitability declaration (VGO) to UMC Utrecht, Independent Ethics Committee (IEC) submission timelines and study timelines for the Netherlands (first patient in, last patient in, last patient last visit).

1.2.2. Site Suitability Declaration (VGO)

- UMC Utrecht follows the Site Suitability Declaration (VGO) procedure as developed by the Dutch Clinical Research Foundation which is available on the CCMO website.
- Before the UMC Utrecht starts the VGO procedure, UMC Utrecht requests written confirmation that, should the study not proceed the site will be compensated based on the prevailing hourly rate for the hours already invested. This applies in the situations in which the study is withdrawn at the initiative of the sponsor. In these cases, the hours and activities will be documented in a worksheet specifying the tasks performed and time spent.
- After the internal suitability check has been concluded positively, the Sponsor receives a digitally signed VGO. This means that the department of the PI and all supporting departments of the UMC Utrecht have given their preliminary approval to participate in the respective study.

Note:

- Providing documents (Participant Information Sheet (PIS)-Informed Consent Form (ICF)) and manuals, for example for laboratory and/or imaging tests, and pharmacy, will accelerate the conclusion of the VGO procedure.
- When measurements and/or procedures are not part of UMC Utrecht's standard-of-care, or when large numbers of assessments or participants are involved, please discuss this at an early stage.

1.2.3. Clinical Trial Agreement (CTA) and ethical review process

- UMC Utrecht strongly encourages the use of the **national CTA template**, as published by the CCMO, to prevent extensive delays due to legal review(s), see Annex 1. **Please note:** it is important to follow the 'guidance to CTA template' of the CCMO. In case the Sponsor is located outside the EEA, Standard Contractual Clauses (SCCs) are in most cases also required as part of the CTA.
- The Sponsor will provide the local PI (or delegate) with the final documents (relevant for local feasibility) that will be sent to the IEC.
- During the ethical review process, UMC Utrecht personnel will arrange all internal agreements and approvals required, including agreements with collaborating internal departments and approval from the privacy officer and when applicable also the Information Security Officer and legal affairs. The local PI (or delegate) will notify the Sponsor about the conclusion of all internal agreements and approvals required.

- During the ethical review process by the IEC, the Sponsor will keep the local PI informed about any changes that (might) have impact on site set-up and/or logistics of the study at UMC Utrecht.
- **Note for commercially sponsored studies involving pharmaceutical products:** The Sponsor is permitted to make arrangements with the **pharmacy** themselves. See UMC Utrecht website for available services and contact details.
- **Note:** All scientific studies in which participants are **exposed to ionizing radiation** must be assessed by the Radiation Protection Department of the UMC Utrecht. This department also reviews the respective information in the PIS-ICF. A calculation of radiation exposure by a clinical physicist from another center is not sufficient. Please allow for an assessment time of approximately 6 weeks.

1.3. Budget and Overhead

The CTA should include the mutually agreed budget. In the CTA's financial annex, UMC Utrecht includes an annual indexation clause to mitigate future cost increases. This clause should apply a rate based on NZA (Nationale Zorg Autoriteit) national price index figures or a fixed rate and take effect on January 1st of each subsequent year. This approach ensures predictability and transparency of revenues for UMC Utrecht and provides clarity and cost predictability for the Sponsor/CRO/other party.

Note for commercially sponsored studies: Study budget will be calculated based on time spent per activity, and the CGR tariff. Also, overhead (OH) will be considered. The OH applies to all prices and fees, to cover the total study costs: this includes general expenses such as administration, infrastructure, and support services.

In short: direct costs plus overhead constitute the total revenue.
At UMC Utrecht, the 25% overhead is calculated on the basis of the total revenue. This therefore requires applying an overhead uplift equivalent to 1/3rd of the direct costs.

Example:
- An ICF-conversation costs directly €300 (activities of the PI/RN; these are the direct costs).
- To cover indirect costs related to studies, 1/3rd is added: €300 + €100 = €400 (total revenue).
- The additional €100 is considered the overhead, which is 25% of the total revenue (€400).

2. Other procedures / important information

Below, for your information is an overview of how we work at the UMC Utrecht, so that this can be taken into consideration during the start-up phase of the study.

2.1. Standard Operating Procedures (SOPs)

The study team follows the specific UMC Utrecht or departmental Standard Operating Procedures (SOPs). UMC Utrecht SOPs take precedence over SOPs from external parties. However, procedures from external parties can be followed if they are not in conflict with UMC Utrecht SOPs and legal regulations. It should be agreed in the CTA when and which SOPs from the Sponsor are used.
The UMC Utrecht's SOPs can be viewed by the Sponsor (or delegate) on-site during a site visit.

2.2. E- Signatures

UMC Utrecht uses ValidSign for electronic signatures (E-signatures). For every signed document, UMC Utrecht includes the Evidence Summary. ValidSign is NEN 7510 certified, ensuring that it meets high standards for information security with regards to identity verification, document authentication, and audit trail. More information on ValidSign can be found here. UMC Utrecht does not require the Sponsor/CRO to sign in Validsign, UMC Utrecht accepts the use of a combination of tools (UMC Utrecht signs in Validsign and the Sponsor/CRO signs with their tool if applicable).

2.3. Site staff, delegation and training

2.3.1. Healthcare professionals who are indirectly involved in the study

Physicians and other healthcare professionals who only perform standard clinical assessment, i.e. no study-specific assessments, are **not** recorded on the delegation log, unless they act as sub-investigator (in accordance with 2.3.3 GCP R3)

2.3.2. Study team

All members of the local study team are trained in International Council for Harmonisation Good Clinical Practice (ICH-GCP).
Investigators are BROK® certified. BROK® is a mandatory basic course on Regulations and Organization for clinical investigators working in academic centers of the Netherlands. The BROK® is accepted by the Dutch Health and Youth Care Inspectorate and has also been recognized by TransCelerate Biopharma Inc. as a "GCP training meeting the minimal criteria".
The ICH-GCP and BROK® certificates are mentioned in the CV and do not need to be printed separately. BROK® certification is also registered at the BROK® register. The information in the BROK® register is a valid proof of being BROK® certified.

2.3.3. Role of Nurse practitioner/ Physician assistants

The Dutch Healthcare Professions Act (Wet BIG) recognizes nurse practitioners (NP) and physician assistants (PA) as a distinct and regulated academic profession within the Dutch healthcare system. More information in Dutch: physician assistant / nurse practitioner.

Both NP and PA are allowed to conduct routine study related activities when they have sufficient scientific knowledge and experience in patient care. The local PI motivates, based on a risk analysis, which assessments can be performed by a PA or NP. This motivation is in line with information in the protocol and will be archived in the study file. It must be clear for each assessment if PA/NP are qualified to conduct a specific study related activity safely and independently.

2.3.4. Personnel facilitating departments

When study procedures are performed by facilitating department (e.g. Radiology, Laboratory Clinical Chemistry and Haematologie (LKCH)), only the staff member with final responsibility will be recorded on the delegation log and a CV from this staff member is filed. This staff member ensures that all other staff members are qualified and trained for their tasks.

2.4. CTIS information for EU Clinical Trial Regulation (CTR)

- Address: Heidelberglaan 100, 3584 CX Utrecht The Netherlands
- Organization ID: ORG- 100008351
- Location ID: LOC-100014822

2.5. Informed consent

- All steps of the informed consent procedure (providing the participant information, answering questions, signing) are recorded in the EHR research module.

2.6. Investigator Site File (ISF)

In the interest of sustainability, UMC Utrecht aims to store essential records as much as possible digitally and minimize the use of paper in the ISF. UMC Utrecht's main rules:

- Records with a wet ink signature are stored in the paper study file.
- Records created digitally will 'stay' digital.

For digital storage, UMC Utrecht uses a Research Folder Structure (RFS) on the secured UMC Utrecht network.

- Study team members can only access the RFS for studies which they are involved in. Monitors can access the RFS with a specific monitor account.
- The RFS is backed up automatically daily. UMC Utrecht has a procedure in place to keep track of the changes and version control.
- By using the RFS, UMC Utrecht complies with GDPR.

If the sponsor wishes that UMC Utrecht uses the sponsor's digital ISF, this can be discussed with the study team.

2.7. Source data, access and identification statements

2.7.1. Electronic health records

- The used EHR system is HiX 6.3 from ChipSoft. For patients from the department Women & Baby and the Intensive care, Metavision is the additionally used EHR.
- Information about our EHR systems and digital investigator files can be provided by the study team via the e-source-readinesss assessment tool (eSRA). Sponsor-specific forms that contain the same information are not filled in.
- The certification of the EHR system is available, which can be requested at HIX/ Chipsoft. See also: Certificering.
- Assisted review of EHR is permitted.
- Certified paper copies from the EHR will not be provided, unless the sponsor can clearly motivate why information cannot be received via the queries in the eCRF and or via a site visit.

2.7.2. Access monitor, auditor, authorities

- These persons have read-only access to the EHR limited to participants for a specific study and only accessible for the duration of the visit via a “monitor account”.
- During the first visit a monitor (auditor of inspector) should identify themselves.
- Remote access is not available to monitors, auditors and authorities.
- Printing documents from the EHR is not permitted.

2.8. Equipment & Materials

- UMC Utrecht prefers to work with its own equipment and to keep equipment from outside to a minimum.
- New introduced equipment needed for a study will be examined and must be approved in our hospital by the Department of Medical Technology. This procedure can take six to eight weeks.
- UMC Utrecht only uses the hospital’s disposables vena puncture, intravenous or biopsy materials. Costs are part of the budget for a specific assessment/study visit.

2.9. Archiving

Digital Archive: The digital research archive of UMC Utrecht is based on the Archivematica software. Access to the archive is limited to the data managers of UMC Utrecht. UMC Utrecht has procedures for requesting a copy of archived records in place.

Paper Archive: After a study ends, the paper records will be archived with an external company with whom UMC Utrecht has a contract.

2.10. Biological safety

Activities with genetically modified organisms (GMO) must be reported to the authorities or licensed. New gene therapy studies must be reported by the local study team to the biological safety officer (BSO) of UMC Utrecht. mailto: bvf@umcutrecht.nl. The BSO performs a risk assessment and checks whether activities fall under an already available notification/license. When a new license or amendment is required, the waiting period is
at least 45 days.

2.11. Available facilities on site

As an academic medical center, UMC Utrecht provides all the essential facilities required for conducting clinical research (e.g., trial pharmacy, local laboratory, equipment, 7T MRI, Cell Therapy Facility etc.).

If a sponsor applies for an Organ Bank license (Wvkl recognition as a tissue establishment/organ bank), the most recent overview can be consulted via Wvkl erkenning weefselinstelling/orgaanbank | Farmatec.

Contact information:
Studies & Trials CDL - UMC Utrecht

Medische Microbiologie studies en trials - UMC Utrecht

Klinisch Geneesmiddelonderzoek - UMC Utrecht

Research Policy - Research at UMC Utrecht

3. Annex 1: Information about the national CTA template and SCC's

We appreciate the opportunity to collaborate on the clinical study. Before we proceed with contract negotiations, we would like to outline certain terms and conditions that our institution cannot accept due to applicable laws and regulations, national health and research codes, policies and institutional policies.

University Medical Center Utrecht is focused on complex patient care, medical research, education of medical and biomedical students and training of healthcare professionals. Our institution is a publicly funded institution and a public legal entity by virtue of Dutch law. Our institution collaborates with several non-commercial entities and plays a pivotal role in both medical practice and academic development.

Governing law and penalties

We would like to inform you that in the best interest of our patients, in a clinical study with Dutch patients we can only accept Dutch governing law and jurisdiction.
Secondly, as a publicly funded institution, we are obligated to adhere to stringent financial guidelines. Therefore, we are unable to accept punishments or penalties in the agreement.

Liability

However, we are open to discussing liability terms within reasonable parameters. Our institution can accept liability with a maximum of €500,000. We believe this threshold aligns with our risk management strategies while facilitating a mutually beneficial partnership.

GDPR

Additionally, data protection and privacy concerns must be in accordance with the General Data Protection Regulation (GDPR) when dealing with personal data. If personal data is to be sent to a party or parties located in a country outside the European Economic Area, we need to enter EU-Standard Contractual Clauses (SCCs) without any changes to the clauses. This is only not necessary in case there is another applicable GDPR approved mechanism such as an EU-adequacy ruling or the EU approved Binding Corporate Rules (BCR). These measures are necessary to ensure compliance with GDPR regulations and safeguard the privacy rights of research participants involved in the clinical trial.

Use of national template CTA

Our primary objective is to ensure a smooth and swift contract negotiation process. We are committed to collaborating with you to finalize the agreement in a timely manner, allowing us to commence the clinical trial at the earliest convenience. To expedite the contracting process, we require the use of the Dutch national DCRF template for clinical trials.
DCRF is the Dutch Clinical Research Foundation and DCRF manages the Clinical Trial Agreement (CTA) template. UMCNL (the central collaboration of all University Medical Centers in the Netherlands) participates in this foundation as well as hospital and health care industry associations, including innovative pharma companies and collaborations (such as the VIG previously Nefarma) based in the Netherlands. Together, within DCRF, these organizations have developed this model CTA agreement. This model agreement sets out all the rights and obligations of parties involved in hospital clinical research funded by (pharmaceutical) companies.

In the Netherlands, like other EU countries, it is standard practice for clinical research on human participants to follow the national template to avoid applicable law issues. It is not allowed to change the main body text of the template. Only study specific changes are allowed and these changes must be stated separately in Annex 10. This is similar to other countries such as France and the UK. Especially language on liability, insurance, publication, and termination must be unchanged otherwise it breaches the Dutch Medical Research Involving Human Participants Act (Wet medisch-wetenschappelijk onderzoek met mensen or WMO) and the Clinical Trial Regulation. Furthermore, using this template will speed up our contracting process significantly.

Therefore, it is crucial to use the DCRF CTA national template. We hope these clarifications provide a clear understanding of our institution's limitations and facilitate productive discussions during the negotiation phase. Should you have any questions or require further clarification, please do not hesitate to contact us. Thank you for your attention to this matter. We look forward to reaching a mutually agreeable contract and embarking on this important clinical trial together.

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