Karolinska Comprehensive Cancer Center

Information Letter 2026 – Cancer Study Unit, Karolinska University Hospital, Huddinge

Dear Sponsor and Partner,

We would like to provide you with practical information about how the Cancer Study Unit in Huddinge at Karolinska University Hospital operates. This overview is intended to facilitate a smooth and fast study start-up, efficient communication, and mutual understanding between our site and your organization.

📌 Please make sure you have familiarized yourself and relevant staff members with the Code of Conduct. This is a thorough guidance on how clinical trials are managed at our site and a mutual agreement between Lif (Swedish pharma organization), ASCRO (Swedish CRO organization) and NASTRO (network for all Oncology Clinical Trial Units at the University Hospitals in Sweden) Nastro | Code of Conduct

📌 We do not allocate formal resources to the study before it has passed through the Research Council Review, please see further details under section 1.

📌 Please also pay close attention to the different addresses to be used (section 12 of this document) This causes challenges at our site if not adhered to.

📌 Confidentiality Disclosure Form is not required between our site and the sponsor as the public healthcare sector is covered by OSL (the Swedish Public Access to Information and Secrecy Act), providing an equivalent level of confidentiality, please see the Code of Conduct for further information.

📌 Please be aware that e-Investigator Site File is currently not allowed per internal Karolinska University Hospital requirements.

1. Research Council Review

All studies involving patients from Theme Cancer must be presented and reviewed at the Theme Cancer Research Council, which meets every Friday (13:00–14:00). Sponsor will be informed immediately after the meeting about the decision. Each meeting accommodates up to four study presentations. The Principal Investigator (PI) presents the study. Sponsors may provide 3–4 PowerPoint slides to support the presentation. External representatives cannot attend. For meeting details, please visit the Theme Cancer Research Council webpage. Forskningsråd Tema Cancer

A Study Coordinator is assigned to your study when it has passed the Research Council Review and thereafter study specific activities can commence.

For ATMP-related studies, the study must also be presented to the Karolinska Center for Cell Therapy (KCC) Review Board. The Principal Investigator will coordinate the submission to the KCC Review Board and may invite a Sponsor representative to participate in the presentation. Support from the Sponsor may also be required in preparing the application documentation. KCC review board

2. CTIS Application and Pre-meeting Documents

To secure an efficient start-up phase, the following documents **can be collected** to facilitate the CTIS application **before the Research Council meeting**.

- PI's CV (in Swedish)
- Site Suitability Statement
- Declaration of Interest

If Cancer Study Unit will not participate, the sponsor will be informed directly after the Research Council review.

3. Study Start-up

We need to have the most updated timelines available to provide the necessary resources and the best planning for study execution.

Please provide planned dates for Submission to CTIS, planned approval dates, planned dates for Site Initiation Visits and any other important milestones. Please note that it is very important to communicate any changes to planned dates. We do understand the complexity, and it can be difficult to set confirmed dates, but please communicate any changes as soon as they are available.

Please provide the following documents to the Study Coordinator (even if they are in draft) for us to speed up our internal processes to be ready to start at the agreed timelines. Please make sure to send updated documents as soon as they become available.

- Protocol
- Patient information sheets
- Biobank submission
- Lab/imaging manuals
- Pharmacy manual including information on what Pharmacy will be used in the study
- Study title
- Site number

We need to have a clear view on the contact persons from your side. Please provide name, title, contact details and role in the study.

4. Collection of Documents

The following documents can be collected before Site Initiation Visit, if deemed necessary: CV, GCP certificate and Financial Disclosure Form for PI (and one Sub-Investigator if deemed necessary from sponsor.)
CV and GCP certificate for Study Coordinator.
Remaining documents will be collected at the Site Initiation Visit when the complete study-team is selected.

5. Study Contract and Budget

The management of all Contract and Budgets are under the responsibility of the Head of Cancer Study Unit. Contact details: Sofie Sibia (sofie.sibia@regionstockholm.se).

The allocated Study Coordinator needs to initiate the start-up process and understand the study execution before the budget negotiation can start.

If the sponsor has a Master Service Agreement in place with Karolinska University Hospital this should be used, and no separate Clinical Trial Agreement is required. The Lif-agreement templates (Ladda ned rapporter, avtal och mallar) will be added to the final document before signature process is initiated. (**Please note for CROs to check if the sponsor has a Master Service Agreement in place.**)

If Master Service Agreement is not in place the following process applies:

All Clinical Trial Agreements are reviewed by the legal department at Karolinska. Data Transfer Agreement must be attached, and Standard Clauses are added if needed.

We need the following documents to start the negotiation process:

- Clinical Trial Agreement
- Protocol
- Patient information
- Budget in an excel sheet with per visit specification

Karolinska University Hospital are working with official price lists for clinical trials. Please find them here: Forskningsprislistor

All study agreements are signed by the respective Head of the Department and the Head of Theme Cancer. Principal Investigator signs the contract as “read and acknowledged” only

Please note that each Department is a unique site and should be the counterpart of the Clinical Trial Agreement. This is where the P.I is employed. See addresses in section 12.

6. Internal Agreements

We will establish Internal agreements and coordinates necessary planning meetings with other units at Karolinska such as; Radiology, Pathology, Laboratory Medicine, MR/Imaging units, and other hospital departments involved in study procedures. Please ensure all study-related requirements are clearly communicated early to avoid delays.

If central reading is needed, sponsor needs to reach out directly to:
rtg.klinprov.karolinska@regionstockholm.se

Our site holds a JACIE accreditation.

7. Local Laboratory and Biobank Applications

The address to the local laboratory is:
Karolinska Universitetslaboratoriet, Karolinska Universitetssjukhuset, SE 171 76 Stockholm

This is the accreditation information: SWEDAC SS-EN ISO 15189, GLP, CLIA, CAP, ISO
If the accreditation certificate is needed, please ask the Study Coordinator.
Local Laboratory Reference Ranges can be found at the hospital web page: Provtagningsanvisningar A-Ö

The application to the Biobank is the sponsor's responsibility.
For information on the Biobank, please see A national infrastructure for biobanking – Biobank Sverige
We would like to review the application form before submission.

Stockholm Medical Biobank ID is: 914. If you need contact with the Pathology unit before the submission, please contact:
puc-info.karolinska@regionstockholm.se

8. Investigational Medicinal Product (IMP) and Pharmacy Agreement

IMP management generally follows Karolinska University Hospitals processes. Patients receive treatment in monitored infusion chairs or beds, and vital signs are assessed before, during, and after infusion according to protocol. Emergency equipment is available at the unit. Infusions are supervised on-site, and any infusion-related reactions are managed per clinical routine.

Oral administration is managed by the designated Study Coordinator.
IMP (tablets) is stored at the Pharmacy and requested as per our internal processes as we have limited storage capacity at our treatment unit, M62

IMP as Cytostatic and similar is prescribed and required through our internal system CytoDos. Our responsible Chief Medical Officer is responsible to enter applicable IMP information according to the study protocol in CytoDos.

The Pharmacy agreement is the sponsor's responsibility. Please note that a separate Pharmacy agreement is mandatory in Sweden. Please start the agreement process with the Pharmacy early in the start-up phase as the agreement needs to be in place before the Site Initiation Visit. We need the information on what IMPs are provided by the sponsor.

For all IMP that needs preparation, agreement with Medovia at Karolinska is mandatory. Please contact Medovia at kpavtal.stockholm@medovia.se

Address to Medovia:

Medovia Clinical Trial Unit
Karolinska University Hospital
Eugeniavägen 23, C3:27
SE-171 64 Huddinge
SWEDEN

Internal address for delivery to treatment unit, M62 (only for Pharmacy distribution to site-please add in the Pharmacy Agreement)

Cancerstudieenheten
M62
Karolinska Huddinge

For other IMP that does not require preparation, agreement can be made with other Pharmacies/Vendors as applicable per Swedish regulation.

General information: Please make sure to confirm with the Study Coordinator the IMP management for the study and any study specific procedures. This should be done in parallel with the Pharmacy Agreement and before the Site Initiation Visit. Please provide us a copy of the finalized pharmacy agreement. You will receive information on who will have the right to order IMP from the Pharmacy during the Site Initiation Visit.

9. Equipment and Calibration

If no sponsor equipment is provided, hospital equipment is used. All devices are calibrated annually per our internal process by the MedTech department at Karolinska University Hospital. All individual equipment is labelled with the latest calibration date. Additional documents related to the calibration can be provided upon request. All our freezers, refrigerators and cabinets are temperature controlled, alarmed and monitored via OpenLogger. This is our internal electronic system with measurement every minute. Documentation on the temperature for a given period can be provided upon request.
In addition, sponsor-provided equipment must be listed in the Site Equipment Log and undergo technical approval by the MedTech department before use. Calibration certificates and maintenance documentation must accompany any sponsor devices. Any equipment requiring special installation or temperature/environmental stability must be coordinated in advance with the Study Coordinator.

10. Site Initiation Visit (SIV)

We would like to get the Investigator Site File (ISF) and all other study specific material and documents **approximately 2-3 weeks before the Site Initiation Visit**. The ISF will be stored at Cancerstudieenheten Huddinge, M62 during the study.

Please make sure to send to the correct addresses, see section 12. Please be aware that e-ISF is currently not allowed per internal Karolinska University Hospital requirements.

We would ask to get all study documentation sent to us both electronically and per mail with clear filing instructions. Please address documents to Study Coordinator ONLY. Study Coordinator will arrange with PI signature as needed.

Please plan and schedule for SIV well in advance when the following is fulfilled:

- Regulatory approval available
- Biobank approval available
- Signed CTA and budget approvals
- Preferably signed Pharmacy Agreement
- System training and accesses provided

Preferred time for Site Initiation Visit with ALL participants should be between 12:00–13:00 to avoid too much interruption. For the lunch meeting staff from radiology, pathology and other stakeholders can participate. This time should be devoted to the most important parts of the study. Please consider that the PI can devote additional 1-2 hours and the Study Coordinator 3 hours.

It is the Study Coordinator responsibility to invite other staff at Karolinska University Hospital.

We will provide you with remaining site staff documents during the SIV.

11.Monitoring, access to medical records and confidentiality

Please make sure that the confidentiality agreement for access to medical records is provided to Cancer Study Unit for signature by the Head of Department **at least one week in advance of the first monitoring visit.** No access to patient medical records can be given without the confidentiality agreement in place. Please find a template for the confidentiality agreement template. Mallar för kliniska prövningar - Apotekarsocieteten

Our electronic medical record system is called **Take Care**. Due to system design and Swedish data protection regulations, individual monitor access cannot be granted. Therefore, the Study Coordinator will print the relevant source documentation for each monitoring visit. Please ensure that required source data verification is performed during the on-site visit, as remote access is not possible.

We ask you to make sure that all necessary copying and access to data is made during the on-site visit to prevent unnecessary scanning of documents between visits.

12.Addresses

Below addresses are valid for study documentation, lab kit and supplies, Investigational Medical Product to site from external Pharmacy as well as for collection of lab samples and dry ice delivery

Address (Hematology and Cell therapy and allogen stem cell transplantation trials) :
Karolinska University Hospital
Att: Name of PI and Study Coordinator
Cancerstudieenheten Huddinge
M62
Hälsovägen 13
141 86 Stockholm

Karolinska Comprehensive Cancer Center

Address (Upper Gastrointestinal trials):
Karolinska University Hospital
Att: Name of PI and Study Coordinator
Cancerstudieenheten Huddinge
C1:77
Hälsovägen 13
141 86 Stockholm

For Clinical Trial Agreement please use the respective Department

- Department of Hematology
- Department of Upper Gastrointestinal
- Department of Cell therapy and allogen stem cell transplantation

All with the address:
Karolinska University Hospital
Cancerstudieenheten Huddinge
M62
Hälsovägen 13
141 86 Stockholm

OMS-number for CTIS submission (Karolinska University Hospital Huddinge)
Karolinska University Hospital

Hälsovägen, 141 86 Stockholm
ORG-100 000 573
LOCATION-number: LOC-100 005 687

We look forward to collaborating with you and your team, ensuring high-quality, efficient clinical trial conduct at Karolinska University Hospital, Huddinge.

Warm regards,

Sofie Sibia

Head of Cancer Study Unit
Karolinska University Hospital, Huddinge