Checklist for contract processing



Here is a list to guide you through what you need to do before and after a contract is reviewed by the legal counsels at KI.

Before the review by the legal counsel:

- 1. Get confirmation from those responsible for the department (e.g. Head of Department or Head of Administration) that:
 - o the proposed scientific and financial terms of the contract are acceptable
 - the contract is appropriate for the activities, guidelines and ethical principles of KI and of the department.
 - KI is the contractual party and not a researcher through a secondary occupation (see <u>Rules for handling secondary occupations</u>)
 - the counterparty is suitable. An assessment of the risks associated with the collaborator should be made e.g. if KI's reputation can be damaged by being associated with the collaborator or its operations.
 - a responsible contract administrator is appointed
- 2. The responsible contract administrator must:
 - Have good knowledge about the content of the <u>Guidelines for research related</u> contracts
 - Coordinate contacts with the counterparty and internal communication with the legal counsel and other support functions
 - Have good knowledge of the Rules governing Conflict of Interest at Karolinska Institutet <u>Guidelines on conflict of interest</u>
 - Have good knowledge of the contents of the <u>Guidelines on intellectual property</u> and <u>corporate collaborations</u> (IP Policy)
- 3. Determine the type of contract (check the brochure <u>To collaborate with KI a medical university</u> / Research Data Office (<u>rdo@ki.se</u>) / <u>External Engagement Office</u>), for example:
 - Confidentiality agreement
 - Commissioned research agreement
 - Research Collaboration Agreement
 - Material Transfer Agreement
 - Consortium Agreement
 - o Data transfer agreement
 - Purchase of goods or services (contact the Purchase and Procurement Unit)
 - Donation/sponsorship (<u>Regler om donationer och sponsring</u>, contact
 Development Office do@ki.se)
 - Grant agreement (contact Grants Office (grantsoffice@ki.se) for international grants)
 - o Other

- 4. Determine the ownership of results and the parties' right to use results (check the brochure <u>To collaborate with KI a medical university</u>, <u>Guidelines on intellectual property and corporate collaborations (IP Policy)</u>, <u>SUHF Principles for managing intellectual property in research contracts</u>, <u>Recommendation 2016:3</u>.
- 5. Decide how the results will be published, for example individually by one of the parties or jointly by all parties.
- 6. Decide which persons at KI will participate in the conduct of the project
 - o Inform the other party of any affiliated participants
- 7. Ensure there is a correct budget for the type of contract with the department's economy administrator
 - Financial contributor
 - o Client, full cost coverage is required for commissioned research
 - o Ensure a suitable payment plan
- 8. Prepare a detailed research plan
 - Describe the responsibilities and tasks of each party (project plan, milestones, etc.)
 - List KI's Background (for further guidance check <u>Guide till Vinnovas villkor om</u> nyttjanderätt)
- 9. Verify if ethical or animal permits are required (contact <u>Compliance Data Office</u> for help)
 - Verify if KI must be the research principal
- 10. Ensure that clinical research studies regarding patients at the clinic are anchored and approved by the clinic where they are going to be carried out. Determine the respective roles and responsibilities of KI and the clinic (Checklist for clinical research projects)
- 11. Find out if prior approval for the transfer of material or data is required (<u>Export control of dual-use items</u>)
- 12. Identify the need for insurance (contact Compliance Data Office or <u>HR</u> where necessary). For more information check:
 - o <u>Insurance for research subjects</u>
 - o Insurance
 - o <u>Insurance for international students</u>
- 13. Where the project involves the processing of personal data (contact Research Data Office orKI:s <u>Data Protection Officer</u> where necessary)
 - o Prepare a Data Management Plan
 - Carry out a data protection impact assessment where necessary according to Instructions

- o Determine which role/responsibility KI and each of the other parties has
- Register the personal data processing activities at KI (<u>registeranmälan</u>) to KI's
 Data Protection Officer
- 14. Where biobank materials are handled (KI Biobank, SMB, annan biobank)
 - Conclude an MTA(s)
- 15. Decide the duration of the contract
 - Start date
 - End date

The legal review by a legal counsel will take place after the above steps have been completed and information provided.

After the review by the legal counsel:

- 16. Make sure that the final version is approved by the authorised signatories
- 17. Check who will sign the contract and how (see <u>Delegation rules for Karolinska</u> Institutet)
 - o Electronic signatures (see <u>Guidelines for digital signatures</u>)
 - o Date and sign the contract
- 18. Upon signature of the contract, send the researcher consent form to all the participating KI-researchers for their signature
- 19. Register and archive the fully signed contract and the researcher consent forms.