**QUESTIONNAIRE**

**A. Principal of Research**

1. KI: Is KI the [research principal](https://staff.ki.se/checklist-for-clinical-research-projects#heading-1)?

2. Are there several research principals participating in the research project?

**B. Consent**

1. Have the study participants given their consent to the transfer of personal data?

**C. Ethical approval**

1. Has the transfer of personal data been approved by the ethical approval committee?

2. If applicable, does the recipient of the personal data have an ethical permit?

**D. Recipient**

1. Who is the recipient of the data?

2. Is the recipient stated in the ethics application and is it clear what the recipient is going to do within the research project?

3. Is there a cooperation agreement?

**E. Country**

1. To / from which country should the data be transferred?

*When transferring outside the EU / ESS, special agreements (*[*Standard Contractual Clause*](https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en)*) are required*

*For transfers outside the EU / ESS,* [*special conditions*](https://staff.ki.se/transfer-of-personal-data-to-third-country-or-international-organizations) *must be met.*

**F. Assignment description**

*The agreements need to be adapted to each situation depending on, among other things, what type of personal data processing the recipient is to perform, purpose, etc. Select one or more alternatives below and develop.*

1. KI sends or receives human material for analysis (personal data follows with the material). What is the material and where was it originally collected? Is KI the owner of the samples? Are there biobank agreements? *Keep in mind that an MTA Material Transfer Agreement must be established for the samples.*

2. Purchase of a new service where personal data will be stored in a cloud solution. In which country are the servers located?

3. KI sends or receives personal data for data processing. Will data that originally comes from patient records from e.g. a hospital be sent by KI? In that case, has the data been disclosed (“utlämnad” to KI?

4. External persons shall process personal data in KI's premises and with KI's equipment

5. Personal data must be stored elsewhere

6. Other

**G. Information about the processing of personal data**

1. Has the personal data processing been reported via [KI's form](https://registeranmalan.ki.se/)?

2. Where will the data be stored? (RedCap, ELN, BASS, P, other)?

3. How will the data be sent? Will a [KI system](https://staff.ki.se/store-and-share-files) be used for the transfer?

4. Where were the data / samples collected?

5. Has a data management plan been established?

6. Will the personal data recipient need to hire sub-assistants to carry out their tasks?

7. Has a risk analysis and impact assessment been performed and documented? [(Data Protection Impact Assessment (DPIA))](https://staff.ki.se/instructions-for-data-protection-impact-assessments). *DPIA is needed e.g. for transfer to the United States or to share sensitive personal information*

8. Are there any contracts related to the transfer/sharing of the data or the human samples? For example a consortium agreement, an MTA.

9. If applicable, who is the funder of the project? For example Swedish Research Council, FORTE, Vinnova, NIH, EU.