**Annex No. 1 – Sample request for an ethics project assessment**

**Request for ethics project assessment**

**Project description**

|  |  |
| --- | --- |
| **Name** |  |
| **Funded by** |  |
| **Principal**  **investigator** |  |
| **Basic part** |  |
| **Contact e-mail** |  |
| **Telephone** |  |
| **Description (max. 2000 characters)** |  |

**Questions on the ethical aspects of the project**

**1. Does your research include human participants?**

YES/NO

**If YES**

**a. Do they participate in the research by their own decision?**

YES/NO

Describe how the participants are addressed and what the criteria are for their involvement in the research and the process of obtaining informed consent.

**b. Are they participants who cannot provide informed consent (including children and adolescents?**

YES/NO

Describe how you obtain consent with your participation in the research from the legal representatives of children and adolescents. How do you make sure that the participants are put under no pressure to participate in the research? What measures do you plan to protect children in the course of the research? Justify the involvement of children and adolescents in the research.

**c. Do the participants belong among especially vulnerable persons or groups?**

YES/NO

What kind of disadvantage/threat is involved?

Describe how participants are addressed, what the criteria are for their involvement in the research and the process of obtaining informed consent.

**d. Are the participants patients?**

YES/NO

What is the character of their disease or health limitation? Describe how the participants are addressed and what the criteria are for their involvement in the research and the process of obtaining informed consent.

**2. Does your research work with personal information of the participants? Does it collect and process this information?**

YES/NO

**If YES**

**a. What is the process of data collection, its storage and protection, transmission and final deletion? How will the data be stored (LAN, cloud, etc.)? What will be the structure of the obtained data and its protection (coding, anonymisation, etc.)? How will the data be processed or further used?**

**b. What security measures to protect data are you planning for?**

**c. Do the data obtained contain sensitive information (e.g. health condition, sexual orientation, ethnicity, political opinions, religious beliefs, etc.)?**

YES/NO

Which specifically?

**d. Does the research include the monitoring or observation of participants? (e.g. tracking the movement of persons, data on location, IP addresses, etc.)?**

YES/NO

Describe how the participants will be monitored or observed.

**e. Will your research process personal information obtained earlier?**

YES/NO

Which databases or sources will you use? What will be the data processing procedure? How will you secure data against misuse? Confirm that the data is publicly available and can be used for further processing or that you have consent with their use. How was the consent obtained? Attach confirmation from the data owner and the consent with its use.

**3. Will the obtained data be provided to other subjects?**

YES/NO

**If YES**

**a. To which other subjects in the CR will the data be provided?**

Describe the reasons for sharing the data with another subject. Describe the process of data transmission with regard to its protection. Confirm that you have consent with the sharing of the data with another subject. How was the consent obtained?

**b. To which other subjects abroad will the data be provided?**

Describe the reasons for sharing data with another subject. Describe the process of data transmission with regard to its protection. Confirm that you have consent with sharing the data with another subject. How was the consent obtained?

***4. Other supplementary questions.***