**PROJECT REQUEST FORM FOR THE USE OF pre-GMP FACILITY AT KAROLINSKA INSTITUTET**

The pre-GMP steering committee evaluates all projects that request the use of the pre-GMP facility at Karolinska Institute. The committee meets once per month.

To evaluate the project the committee needs the information requested below at least 2 weeks in advance (the meeting dates are announced on the pre-GMP KI webpage).

The result of the evaluation is communicated through the pre-GMP managing director.

The committee shall handle all requests and any document received (containing sensitive information and data) with strict confidentiality. All received documents shall have continued protection by secrecy unless otherwise required by mandatory rules (under the Swedish principle of public access to official records, Sw. offentlighetsprincipen; the public Access and Secrecy Act (2009:400) and the Freedom of the Press Act).

1. **Is there need for confidentiality within the facility? (use of curtains/shielded storage of equipment or consumables).**   
    YES  NO
2. **Project title**Write here.
3. **PI or Responsible person**

Write here. Name, affiliation and contacts.

1. **Sponsor or funding information**Write here.
2. **Scientific background and preliminary data (max 1 A4 page)**Write here. Describe the scientific background and the data collected in vivo and in vitro if appropriate.
3. **Is specific scientific support needed for the elaboration of a project plan?**

Write here. Indicate what type of support is needed and at what step.

1. **Summary of the project**

*Fill all the relevant sections to the best of knowledge*

* 1. **Rationale**Write here.
  2. **Process/flow including currents methods used**Write here.
  3. **Equipment required (inside the pre-GMP and in other KI facilities)**Write here.
  4. **Reagents required**Write here.
  5. **Estimated time requested (range) and proposed starting date**Write here.
  6. **Expected results/outcome**Write here.

1. **Ethical approval and biobank**

*Indicate the filing number, what the permit covers and approval date of any existing ethical permits. If the project contains biobank samples please indicate how they are handled.*Write here.

***Karolinska Universitetssjukhuset and Karolinska Institutet have a common form for principal responsibility (Intyg on ansvarsfördelning) that shall be filled in for each research study that requires ethical approval. The form can be downloaded from Inuti and shall be filled in, signed and appended to this request form.***

1. **Risk assessment for the project**

Write here. Please refer to…

1. **Other comments/requests**Write here.