# PERSIMUNE Project Proposal Form

Date of submission:

Before submission please make sure that the following prerequisites have been met:

1. **Will your project need data from other hospital departments than your own?**

🞎 Yes 🞎 No

*If yes, please specify which:*

*If yes, please obtain written approval from head of departments listed above before submitting project proposal to PERSIMUNE. Please submit approvals together with project proposal*.

1. **Required regulatory approvals before project initiation:**

*Mark all that apply for your project*

**Project specific:**

🞎 National ethics committee 🞎 obtained 🞎 pending 🞎 NA

🞎 Regional ethics committee 🞎 obtained 🞎 pending 🞎 NA

🞎 Danish data protection agency 🞎 obtained 🞎 pending 🞎 NA

🞎 Danish patient safety authority 🞎 obtained 🞎 pending 🞎 NA

🞎 Sundhedsdatastyrelsen: Forskerservice 🞎 obtained 🞎 pending 🞎 NA

🞎 **Project to be covered by PERSIMUNE approvals for historical cohort**

(Danish Data Protection Agency (data available 01-JAN-2005 to 28-SEP-2015) and Danish Patient Safety Authority)

*Please submit copies of all available Project specific approvals and the application for Danish data protection agency together with this form*

1. **Feasibility assessment with regards to sufficient patient and data coverage in PERSIMUNE Data warehouse, has been performed in collaboration with PERSIMUNE IT** 🞎 Yes 🞎 No
2. **The project is seeking funding from the DNRF grant** 🞎 Yes 🞎 No
3. **The project is requesting biological material from the PM biobank**  🞎 Yes 🞎 No
4. **The project is requesting biological material from another biobank** 🞎 Yes 🞎 No
5. **Review by the Scientific Advisory Group is requested** 🞎 Yes 🞎 No

# PERSIMUNE Project Proposal Form

Please complete the following form to allow the Executive Committee (EC) to evaluate your proposal.

If you intent to use graphics, please indicate in the text where the graphic should be displayed by e.g. writing <fig. 1> and supply the graphic files in the submission email.

|  |  |
| --- | --- |
| Proposal title(max. 120 characters) |        |
| Proposal short title |       |
| Submitted by | Name | eMail |
| Affiliation, if applicable |       |
| Project group | Name | eMail |
| Name | eMail |
| Name | eMail |
| Name | eMail |
| Name | eMail |
| Name | eMail |
| Name | eMail |
| Name | eMail |
| Background and scientific hypotheses(max. 4000 characters) |       |
| Objectives(max. 1000 characters) |       |
| Feasibility(max. 1000 characters) |       |
| Study population, Sample size/power calculations(max. 1000 characters) |       |
| Analysis Plan(if additional relevant confounders need to be adjusted for, please include them as well)(max. 2500 characters) |       |
| Justification for use of PERSIMUNE(max. 1000 characters) |       |
| Significance (added value compared to current scientific consensus and ongoing projects in individual clinics and collaborations)(max. 1000 characters) |       |
| Deliverables and timelines, including potential journal submis­sions.(max. 1000 characters) |       |
| Please describe authorship rules(max. 1000 characters) |       |
| Possible limitations and overlap with other projects(1000 characters) |       |
| Data items to be included(max. 1000 characters) |       |
| Relevant references (max. 4000 characters) |       |
| Details on how this study will be funded | Please use the budget table next page. (ONLY IF FUNDING IS REQUESTED FROM THE DNRF GRANT) |

**Budget (DKK)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| YEAR 1Post  | Details | Applied from PERSIMUNE | Applied from other funds | Received from RH | Received from other funds |
| Salary VIP |       |       |       |       |       |
| Salary TAP |       |       |       |       |       |
| Equipment |       |       |       |       |       |
| Operating expense |       |       |       |       |       |
| Other cost |       |       |       |       |       |
| Total YEAR 1 |  |  0 |  0 |  0 |  0 |
|  |  |  |  |  |  |
| YEAR 2Post  | Details | Applied from PERSIMUNE | Applied from other funds | Received from RH | Received from other funds |
| Salary VIP |       |       |       |       |       |
| Salary TAP |       |       |       |       |       |
| Equipment |       |       |       |       |       |
| Operating expense |       |       |       |       |       |
| Other cost |       |       |       |       |       |
| Total YEAR 2 |  |  0 |  0 |  0 |  0 |
|  |  |  |  |  |  |
| YEAR 3Post  | Details | Applied from PERSIMUNE | Applied from other funds | Received from RH | Received from other funds |
| Salary VIP |       |       |       |       |       |
| Salary TAP |       |       |       |       |       |
| Equipment |       |       |       |       |       |
| Operating expense |       |       |       |       |       |
| Other cost |       |       |       |       |       |
| Total YEAR 3 |  |  0 |  0 |  0 |  0 |
| GRAN Total |   |  0 |  0 |  0 |  0 |

In order to be endorsed, please note that proposals must comply with other PERSIMUNE principles:

1. The proposals should not threaten the scientific plans of individual participating clinics or compete with existing cross clinic collaborations.
2. The scientific question to be addressed in DNRF funded proposals must be scientific issues not already addressed by individual clinics or other PERSIMUNE collaborations. The scientific question proposed should therefore carry added value as compared to current scientific plans of clinics and collaborations.
3. Individual clinics and departments contributing data will receive proposals for review and offered participation as part of the approval process.
4. Proposers must be willing to contribute with resource for data standardization/validation in case the parameters requested from the data warehouse have not yet undergone standardization/validation.

Please observe that new ideas generated within approved PERSIMUNE projects, at a clinical or collaboration must be submitted for approval in line with other proposals.

Please send this proposal to the PERSIMUNE CORE:

RH-FP-PERSIMUNE Proposal, persimuneproposal.rigshospitalet@regionh.dk

**Checklist for new project proposals**

|  |  |  |
| --- | --- | --- |
| Step | Responsible | Deadline |
| Complete project proposal form | Project Lead |  |
| Submit proposal form to PM Core | Project Lead |  |
| If SAC review is requested Suggest an ad hoc lead of the Scientific Advisory Committee (SAC) for the proposal and circulate the proposal to the SAC. | PM CORE | Immediately |
| Review of proposal - if concerns are raised, PM Core or SAC lead returns proposal to Project Lead for revision | PM CORE and SAC | 2 weeks |
| Review comments from SAC reviewers and send anonymized summary to the SAC lead | PM CORE | 1 day |
| SAC lead draft a review conclusion and obtains SAC agreement on recommendation | SAC lead | 2 days |
| SAC submits recommendation for the PM Executive Committee final decision | SAC lead | 1 day |

Next Steps after EC Endorsement:

The Project Lead, with the assistance of the CORE, assembles a Project Group and schedules an initiatory meeting/TC to discuss the analysis plan, contribution to data standardization and validation work, and next steps for the project. All clinics are allowed to participate in the Project Group.

Once the Project Lead has received the dataset, distribution of data should be assessed in order to determine which clinics should be represented on the Writing Group. Only clinics who have contributed data to the project and other members of the Project Group who have made a significant contribution (e.g. statisticians, bioinformaticians, other scientific experts – to be determined by Project Lead) are included in the Writing Group and thus listed as co-authors.

Any deviations in terms of representation on the Writing Group or any other authorship issues must be addressed within the first trimester after reception of dataset; otherwise, standard authorship rules must be applied.