***Modul 1- Anreizsetzung für neu einzurichtende Professuren in der Pflegewissenschaft***

***Projektskizze***

***Teil B***

*Bitte machen Sie zu jeder Überschrift und Unter-Überschrift entsprechende Angaben. Wenn eine Überschrift auf Sie nicht zutrifft, tragen Sie n.a. (not applicable) ein. Der Umfang von Teil B darf 25 Seiten [DIN-A4-Format, 1,5-zeilig (1-zeilig für die Synopse) Arial 11 Punkt (Arial 9 Punkt in der Synopse), Randbreite 2 cm] zzgl. Anhänge und Anschreiben nicht überschreiten.*

*Bitte löschen Sie die in kursiver Schrift verfassten Hinweise.*

***Bitte erstellen Sie Teil B erst nachdem der Projektträger Sie dazu aufgefordert hat.***

*[insert here:* Name of University*]*

Proposal – Part B, outline research project

for

Module 1 – BMBF funding guideline for the

strengthening of nursing research

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# Synopsis

|  |  |
| --- | --- |
| **Principal Investigator** | *New professor / candidate**Name, employment status, institution, department, postal address, telephone, fax, e-mail* |
| **Appointment for professorship** | *Please indicate the (planned) date of appointment for professorship.* |
| **Title of the research project** | *Max. 140 characters* |
| **Acronym** | *Please enter acronym.* |
| **Keywords** | *Max. 5 keywords* |
| **Project duration** | *In months (max. 36)* |
| **Funding volume**  | *Requested funding volume for the first funding phase up to 3 years, including overhead costs / lump sum (if applicable)*  |
| **Objective(s)**  | *Which main research questions are addressed? Specify the primary goal of the project. Which (main) results are expected?* |
| **Study type** | *E.g. analysis of secondary data, prospective or retrospective study, controlled study* |
| **Intervention(s)** | *If you carry out an interventional study, briefly describe of the experimental and control intervention(s).* |
| **Target and study population, sample size** | *Describe the population which will be in focus of the study, selection of study population, comment on estimated sample size.* |
| **Outcome variables** | *Primary and secondary patient-relevant outcomes of the study* |
| **Methods** | *Description of methodological approaches (data collection, statistical analysis, …)* |
| **Cooperating partners** | *List of cooperating partners (e.g. responsible for recruitment, data/methods (name, institution, city)*  |

*For this table 9 point Arial, single-line may be used. Do not exceed one page.*

# Detailed outline of the research project

## Description of the working group and qualification

*Please describe the thematic focus of the research project and its contribution to the research profile of the new full professorship / new department.*

*Please comment on the qualification, professional background and expertise of the principal investigator (new professor). Please provide a tabular scientific CV and list all relevant publications and third party funded projects on a second page (see C Appendices).*

## Relevance and aims

*Which main research questions will be addressed in the project? Please rank the research questions according to importance, indicating major and minor hypotheses of the study.*

*What are novel aspects of the proposed study?*

*Which results are expected? Explain how the results oft he project benefit nursing care presumably?*

*Place your study in the context of the national and international state of the art. Discuss the relevance of international studies for German nursing care research. Compare to similar studies. Refer to relevant systematic review(s) and/or (own) pilot studies, feasibility studies, or relevant previous / current trials ore studies.*

## Study design

*Explain the study design chosen.*

*State why you chose your approach(es) as opposed to others.*

*Describe the experimental and control interventions.*

Collaboration

*Describe the interdisciplinary, multiprofessional and international collaboration in your project. Explain how your collaborations contribute to study’s aims and innovation.*

*Please describe your participatory research approaches. Explain how patients and other relevant parties (for instance relatives or representatives) will be involved.*

Gender issues

*Please identify and explain how gender issues are addressed in your research. Define gender differences and inequalities, for instance with respect to accessibility or utilization of health care services.*

Targets / study population

*The inclusion and exclusion criteria should make up the eligibility criteria that rule in or out the participants in a research study. Please specify the target population. The inclusion and exclusion criteria must be comparable to standard care or treatment-as-usual condition (external validity).*

*Comment on the sample size calculation and sample size justification. Reflect upon possible generalisations.*

Endpoints

*Explain the patient-relevant endpoints chosen. Can you name other trials that utilized these endpoints? Are there any guidelines proposing these endpoints?*

*Please discuss the clinical relevance and validation of endpoints for the target population.*

Field access and feasibility

*Please explain the sample size determination. Please explain your strategy for the recruitment of sufficient patients-numbers. Please demonstrate the likelihood for recruiting the required number of suitable subjects (for instance through pilot studies and preceding trials) and comment on the methodical approach and sample issues. Comment on your strategies to overcome barriers to access to health care institutions and patients.*

Data collection

*Describe your methods and instruments for data collection. State why you chose your approach(es) as opposed to others. How do you record and document the data? Are the instruments validated and reliable?*

*If you plan to use existing data: Define the datasets to be used. Specify the type of dataset, e.g. routine data from sickness funds. Comment on the quality of the existing data. Which characteristics / items of the existing data will be used for this study? How generalizable are the expected results derived from this dataset?*

*Please describe strategies to reduce the influence of implicit bias. Please comment on anticipated non-response and missing data as well.*

Data analysis

*Illustrate your methods of data analysis and state why you chose your approach(es) as opposed to others. Explain your selection of research methods and describe the stages of data analysis. Explain the statistical analysis in terms of data items and variables. What are the independent and dependent variables?*

*Please provide examples of statistical models and assumptions that will be used.*

Quality assurance and safety

*Describe the measures for quality assurance and quality control with respect to organisational and technical implementation.*

*Comment on the necessity of an external quality assurance / monitoring of the study / expert advice (entirely independent of the coordinating investigator and the institution(s) involved, e.g. scientific advisory board/trial steering committee).*

*The registration in a national or an international study registry has to be confirmed at the beginning of the study.*

*The study protocol has to be published at the beginning of the study preferably in a scientific journal. All results of the study (also negative ones) have to be published in scientific journals.*

## Work plan

*Describe the intended working operations (work pakages (WP)) with milestones (M) and the time frame for the subproject in detail, additianialy fill in a Gantt-Chart.*

|  |  |  |  |
| --- | --- | --- | --- |
| Workpakages (WP) | Year 1 | Year 2 | Year 3 |
|  | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| WP 1 – xyz |  |  |  | **M1** |  |  |  |  |  |  |  |  |
| WP n – xyz |  |  |  |  |  |  | **Mn** |  |  |  |  |  |
| WP n – xyz |  |  |  |  |  |  |  |  |  |  |  |  |
| WP n – xyz |  |  |  |  |  |  |  |  |  |  |  |  |

M1: *Milestone xyz …*

Mn: *Milestone xyz*

## Plans for a potential second funding phase

*Please also briefly (max. 1/2 page) describe how you would continue the project if funding would be granted for up to three more years.*

## Dissemination and implementation

*Explicate your strategies for dissemination of results among the scientific community, the public and actors involved (e.g. sickness funds, professional societies, general practitioners).*

*Please state achievable goals regarding the translation and transfer of results of your project to nursing care. How will actors, e.g. from health care and nursing care, be engaged during the project and how are the results implemented after the end of the project?*

*Outline strategies and measures to disseminate and implement the results within the German health care system.*

## Ethical and legal considerations

*Comment on ethical and legal considerations related to the study and discuss briefly whether they are adequate and justified (e. g. assessment of risks and benefits, care and protection for research participants, protection of research participants’ confidentiality, data protection, informed consent process).*

*Identify patients’ needs, perspectives, and preferences. Explain the involvement of patient-representatives / patient advocacy groups.*

*A final version of the study protocol and a statement by the ethics committee will be required by the funding organisation before the conduction of the study.*

## Project management

### Major scientific partners

*Please list major scientific partners and indicate tasks / responsibilities, including people responsible for design, management and analysis of the study. Describe the professional background and expertise of all participants. Cite relevant publications and/or specify their major role in ongoing comparable studies.*

|  |  |  |
| --- | --- | --- |
| Name | affiliation *(only institution and city)* | responsibility / task |
|  |  | Principal investigator |
|  |  | … |
|  |  | … |
|  |  | Responsible for study statistics / qualitative methods |
|  |  | Responsible for quality assurance/data management |

*For this table 9 point Arial, single-line may be used. Responsibilities indicated are examples. Lines can be changed/deleted.*

*Please briefly comment on the professional background and expertise of the scientific partners*

*Briefly explain the responsibilities and tasks of each scientific partner.*

*Please provide a tabular scientific CV for academic staff (e.g. professor/principal investigator, co-investigator, study statistician) (see C Appendices)*.

### Cooperating partners

*Please list all essential non-scientific cooperating partners and indicate their tasks / responsibilities, e.g. including partners responsible for recruitment or supporting transfer of results into health care. Cooperating partners have to declare their commitment on a separate sheet (see C Appendices)*

|  |  |  |  |
| --- | --- | --- | --- |
| **Name / Responsible Person** | **Affiliation** *(only institution and city, no complete address)* | **Responsibility /Task** | **#****Declaration of commitment** *(see appendix no. IV.4).*  |
|  |  | *Recruiting centres (e.g. hospitals, nursing homes, network of health care providers)* |  |
|  |  | *Study-supporting facilities/ institutions (e.g. sickness funds)* |  |
|  |  | *Supporting transfer of results into health care* |  |
|  |  | *Support and advocacy organisations of patients*  |  |
| … | … | *…* | … |

### Personel applied for

*How many human resources do you need for the research project?*

|  |  |  |
| --- | --- | --- |
| **Position** | **PM\*** | **tasks** |
| Scientific |  |  |
| Senior researcher\*\* |  |  |
| Researcher |  |  |
| PhD student |  |  |
| Non-scientific |  |  |
| Study nurse |  |  |
| Documentalist |  |  |
| OtherStudent assistant | (hours) |  |

\*PM = personal month – full time eqivalents, sum for 3 years

\*\* has to be justified thru special responsibility

*For this table 9 point Arial, single-line may be used. Positions indicated are examples. Lines can be changed/deleted.*

## Financial details

### Financial plan

*Total costs for the project have to be assigned in the table below.*

*Costs for basic equipment as well as service deliveries are not applicable for funding.*

*Funds applied for have to be justified according to the work plan.*

|  |  |  |
| --- | --- | --- |
| **Position** | **Person months** | **Sum EURO** |
| Personnel |  |  |
|  Scientific |  |  |
|  Non-scientific |  |  |
|  Other | (hours) |  |
| Subcontracts  |  |  |
| Consumables |  |  |
| Case payment |  |  |
| Travel costs |  |  |
| Equipment\* |  |  |
| **Sum** |  |  |
| lump sum(Projektpauschale 20%) |  |  |
| **Total amount** |  |  |

\* Equipment (can only be funded when it is not included in the basic equipment, or when existing equipment is not available for the project)

*Please state what is included in the position and comment if necessary on:*

*Personnel (responsibilities); Justify the level of the position, the time necessary to achieve tasks, state the duration of employment (person months, PM = full time eqivalents) or working hours for student assitants;*

*Subcontracts (why are they necessary? For which work packages?);*

*Consumables (brief statement regarding the items needed, including case payment);*

*Case payment (calculate assays/examinations per patient, hours of staff per patient: €/patient x no. of patients);*

*Travel costs (list of intended journeys);*

*Equipment (can only be funded if it is not included in the basic equipment, or when existing equipment is not available for the project).*

### Co-Financing by industry and / or other third parties

*Co-financing by industry, health insurances or other third parties is possible, if*

* *the independence of investigators is ensured and*
* *terms and conditions of the financial commitment are disclosed*

*If co-financing is intended, the application should briefly describe the type and volume of the co-financing, indicating the respective company or other third party.*

*Details are to be specified:*

* *Describe the type and volume of support (including any services or consumables provided free of charge, e.g. travelling costs).*
* *Indicate the amount of support to be provided and assure in writing that the third party will render these services, stating their terms and conditions, if any.*
* *Assure that the coordinating investigator is independent, in particular with regard to the analysis of the study and the publication of its results. A statement giving such assurances will be demanded after the review process is finished.*

*If approval of funding of the second phase is made, appropriate agreements on intellectual property rights, confidentiality and publication of results are to be concluded between all those playing a leading part in the conduct of the study.*

*Reference is made to the legal provisions relevant to cooperation between industry, medical institutions and their staff.*

### Other funding

*In case you have already submitted the same request for financial support or parts hereof to other institutions, please mention this here. Indicate those parties which will provide funds, free services, or consumables such as drugs or medical products.*

*If this is not the case please declare: “A request for funding this project has not been submitted to any other addressee. In case I submit such a request, I will inform the Federal Ministry of Education and Research immediately”.*

# Attachments

*Refer to the page number of the attachment as “C-1”, “C-2” etc. in the proposal above.*

## References

*Please list publications you have quoted within your application. References should be listed according to their numerical appearance in the text. Those references given in connection with the research profile of a person or institution should be listed with the CVs in section C2.*

## Curriculum vitae

*Include tabular scientific CVs for academic staff members playing a leading role and further relevant persons in the consortium and the subprojects as indicated in the project outline above.*

*Publications as reference for expertise have to be attached to the CV.*

## Declaration of commitments

*Number and list the declaration of commitments in numerical order.*

* + 1. Recruiting centres or cooperating partners

*Recruiting centres and additional cooperating partners must declare their commitment on a separate sheet. The commitment should indicate the following details, if applicable:*

*a) Name of investigator / representative / contact person*

*b) Institution and address*

*c) Phone and E-Mail*

*d) Study name*

*e) Recruitment period / study duration*

*f) Inclusion/exclusion criteria*

*g) Number of patients expected to be recruited for the study under the above mentioned criteria. Briefly explain your calculation of expected recruitment numbers.*

*h) Describe of the working tasks conducted by each/the participating centre(s)/partner(s)*

*i) Commitment to participate*

*j) Conflict of interest regarding the proposed study (e.g. private, economical, financial)*

*k) Signature, place and date*

* + 1. Sickness / nursing care funds or other institutions providing data

*If data of a sickness fund is used for the study, the access to data must be assured. Sickness funds need to declare that the necessary data is available and will be provided. Issues of data protection need to be addressed. A commitment with the following details (if applicable) has to be enclosed:*

*a) Contact person*

*b) Institution and address*

*c) Phone and E-Mail*

*d) Study name*

*e) Data provided (inclusion/ exclusion criteria, number of patients)*

*f) Data protection*

*g) Conflict of interest regarding the proposed study (e.g. private, economic, financial)*

*h) Signature, place and date*

* + 1. Finance commitment of third parties

*If co-financing by third parties is intended, a financial commitment has to be enclosed with the following details:*

*a) Contact person*

*b) Institution and address*

*c) Phone and E-Mail*

*d) Study name*

*e) Type and amount of financial support (including any services or consumables provided free of charge)*

*f) Signature, place and date*