Guidelines to applicants for the funding measure
“Gender-sensitive Studies
in Prevention- and Health Services Research”

Module 2:
Development and Testing/Setting into Practise of Gender-
sensible Concepts on Health Care, Prevention and Health
Promotion – Interventional Studies on Gender-related
Differences

Within module 2 will be granted for interventional studies which lead to a better
understanding of gender-related differences concerning the effectiveness of therapeutic
regimens in routine clinical (health care/prevention/health promotion) practise. Trials should
apply mixed-methods (quantitative and qualitative) for assessing gender-related differences.

Please prepare your project outline not exceeding 20 pages for the headings 1 to 10 (DIN
A4, one-sided, 11 point Arial, 1.5-lined, references in numerical order), plus a maximum of 1
page of references. Structure your project outline using the headings listed below. Make an
entry under every heading/subheading (fill in n.a. if not applicable). Please confirm the
correctness of the information given in the project outline within a cover letter for submission
signed by all cooperation partners. The legally binding signature(s) has/have to be
handwritten. A scan of the cover letter has to be attached to the project outline (see heading
12).

Please delete the italic comments when finalizing your project outline.

Please put project outline and appendice(s) in one pdf document for upload in pt-outline.

Note: Project outlines that fail to comply with these requirements will be considered
incomplete and will constitute grounds to be rejected without peer review.
## 1 STUDY SYNOPSIS

| APPLICANT/COORDINATING INVESTIGATOR | Institution  
| Name of coordinating investigator, employment status, institution and department (complete name).  
In case of multiple applicants the coordinating investigator should be listed first. |
| TITLE | The title of the study (not exceeding 140 characters) should be as precise as possible. |
| ACRONYM | Please give an acronym for the title of your study as well. |
| TOPIC(S) | The main research field being studied (health services research or prevention research or health promotion research). If applicable the health condition being studied is to be addressed as well (e.g. diabetes, depression, asthma). |
| OBJECTIVE(S) | Which principal research questions are to be addressed? Specify clearly the primary research question of the study that determine the research method, size and study population. |
| STUDY TYPE | E.g. randomized/non-randomized controlled study, controlled before-after-study, mixed-methods-study, qualitative study. |
| INTERVENTION | Describe the experimental as well as the control intervention if applicable. |
| TARGET POPULATION/SAMPLE SIZE | Describe the population which will be in the focus of the study.  
What is the proposed sample size?  
For quantitative studies:  
To be assessed for eligibility (n = …)  
To be allocated to study (n = …)  
Expected to be analysed (n = …) |
| DATA COLLECTION | Describe the methodological approach used for data collection. Comment shortly on the feasibility of recruitment and main methods against bias which will be used within this study. |
| DATA ANALYSIS | Describe the methodological approach used for data analysis.  
If applicable give a short description of statistical methods to be used. |
| OUTCOME VARIABLES | Primary and secondary patient-relevant/target-group-relevant outcomes of the study. |
| DURATION | Requested duration of funding indicated in months (only whole numbers). |
| PARTICIPATING CENTERS | Which recruiting/participating centres will be involved? |
| FUNDING APPLIED FOR | Total amount of funding applied for including lump sum/overhead costs, if applicable. |

### 1.1 KEY WORDS
2 RESEARCH QUESTION AND EVIDENCE FROM INTERNATIONAL RESEARCH

2.1 HEALTH CARE ISSUES RELATED TO GENDER

Which health problem in German health care is to be addressed? Describe shortly the existing situation in health care/prevention/health promotion and why you assume gender to have a decisive influence on the subject.

2.2 AIM OF THE STUDY AND THEORETICAL FRAMEWORK

Which principal research questions are to be addressed? Bring them into order indicating major and minor motivations/starting hypotheses of the investigation planned. What is the novel aspect of the proposed study? Discuss your choice of the target population. Indicate how gender specific aspects are addressed regarding the research questions, the analyses and the relevance of the results. Indicate the theoretical framework/the detailed concept the study is built on.

2.3 EVIDENCE/CURRENT STATE OF RESEARCH

Set your study into perspective. What is the rationale for the intervention? Be aware that the efficacy of the intervention has to be substantiated. Explicitly outline the scientific innovation of the proposed project. Which studies have been conducted either by you or by others? What is the relevance of their results? Give references to any relevant systematic review(s) and/or (own) pilot studies, feasibility studies, relevant previous/ongoing trials, case reports/series. If there are existing international studies on the topic to be investigated, discuss the applicability of the international study results for the German health system, and outline the necessity to conduct the study in Germany. Describe how directly the existing evidence applies to the German context. If the evidence is not direct enough, describe why. If you believe that no relevant previous studies have been done, give details on your search strategy for existing information. This should both detail the background of the major research question and the feasibility of the study.

2.4 PATIENT AND PUBLIC INVOLVEMENT

How were the target population’s needs, goals and preferences considered in the decision about the focus of the research question? How will future target populations benefit from the results of the systematic review? How have patient representatives/patient advocacy groups/representatives of the target population been involved?

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2 For definition of a systematic review, see Oxman, AD (1994). Checklists for review articles, BMJ; 309; 648-51.
3 EPIDEMIOLOGICAL AND ECONOMICAL RELEVANCE OF THE STUDY AND IMPACT ON HEALTH SERVICES

What impact will the results have on health services/prevention/health promotion? Why is the study needed now? How often does the problem which is addressed by the study occur? How will the individual target population as well as the health care system benefit from the study?

How does the intervention investigated compare to other interventions for the same condition?

4 DESIGN AND RESEARCH METHODS

4.1 REASONS FOR THE CHOSEN STUDY DESIGN

Give an overview of the study design of the trial. Please justify your choice shortly. Describe the intervention and give a schematic diagram (flow chart) of design, procedures, and stages.

4.2 TARGET/STUDY POPULATION, SAMPLING

Justify the population to be studied, the proposed sample size, the sampling strategy and the decisive factors/criteria for defining the sampling.

Make sure that inclusion and exclusion criteria are representative for the population that receives/is going to receive the intervention within the regular health care setting (external validity). Justify the choice of control(s)/comparison(s): Is there a gold standard?

What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include a comprehensible, checkable description of the power calculations and sample sizes detailing the outcome measures on which these have been based for both control and experimental groups; give event rates, means and medians etc., as appropriate. Justify the size of difference that the trial is powered to detect, or in case of a non-inferiority or equivalence study, the size of difference that the trial is powered to exclude. It is important that the sample size calculations take into account anticipated rates of non-compliance and losses to follow up.

4.3 INTERVENTIONS OR EXPOSURES

Please describe the planned intervention or exposure in detail.
4.4 COMPARATORS AND OUTCOMES

Name the comparators and outcomes. Describe the choice of primary and/or secondary outcomes of interest for each research question.

Justify the endpoints chosen. Discuss the clinical relevance of the outcome measures for the target population. If you use outcome parameters other than mortality, morbidity, or health-related quality of life as primary endpoints, please explain why you consider them to be appropriate and valid for measuring patient-relevant/target-group-relevant outcome. Justify appropriateness and limitations of composite endpoints, if applicable.

4.5 FIELD ACCESS AND FEASIBILITY JUSTIFICATION

Describe and justify your field access. Please give details how to overcome access barriers. What is the evidence that the intended recruitment is achievable? Demonstrate conclusively the potential for recruiting the required number of study subjects (the best piece of evidence being pilot studies and preceding studies in a similar population/same institutions). In case of a multicentre study, show justification of numbers of eligible patients/participants per trial site in a table. The recruitment plan should show the projected recruitment including the criteria for the selection of trial sites. Justify that the analysed situation is comparable to the situation in usual health care.

4.6 DATA COLLECTION

Describe in detail your methods of data collection. Give the theoretical background and explanations for the data collection chosen. What is the impact of the method chosen for your data? How do you document the data? Which instruments will be used to record the data? Are the instruments validated and reliable?

4.7 METHOD OF DATA ANALYSIS

Illustrate your method of data analysis and data interpretation in detail and provide the methodological background. Explain why this method is chosen and describe the planned steps of data analysis.

What is the proposed strategy of statistical analysis? Which data items and variables will be included in the analysis? Which are the independent and dependent variables? Which additional information will be documented to adjust for confounding? Please provide
examples of the statistical models and assumptions that will be used. Justify clearly the size of the sample and/or the number of study subjects/objects necessary for this analysis.

4.8 METHODS AGAINST BIAS

Is randomisation feasible? Which prognostic factors need to be regarded in the randomisation scheme and the analysis? What are the proposed practical arrangements for allocating study subjects to trial groups? If you find that randomisation is not possible, please justify in detail and explain which other methods are used to guarantee consistency of the control(s) and comparable(s).

What measures against bias due to selection or confounding will be implemented? Which additional information will be documented to uncover or avoid confounding? Please comment on anticipated non-response or missing data. Give details on methods to avoid biased assessment of results (e.g. blinded assessment of outcome)?

4.9 EXPECTED RESULTS

Give a brief overview of the expected results and their scope and significance. What gain of knowledge can be expected? Indicate the possibilities and the goals of generalisation of your planned study.

5 WORK PLAN

How is the study put into practice? Illustrate the necessary steps and responsibilities. Please describe the intended working operations and time frame for establishing the cooperation network (Gantt-Chart). Milestones indicating the working progress have to be defined (include in Gantt-Chart).
6 QUALITY ASSURANCE AND SAFETY

What are the proposed measures for quality assurance? Describe the actual organisational and technical measures for quality assurance and quality control. How and when will they be implemented? Are these e.g. outlined in a special quality manual or Standard Operating Protocol? Comment on the necessity of an external quality assurance/monitoring.

Please comment on the planned supervision of the trial. Arrangements for the management of the trials will vary according to the nature of the study proposed. However, all should include an element of expert advice and monitoring, that is entirely independent of the coordinating investigator and the institution(s) involved. This will normally take the form of a scientific advisory board/trial steering committee. Applicants should submit their proposed arrangements for overseeing of the trial and, if applicable, a suggested membership for a committee (name and affiliation of independent members).

Describe what measures will be implemented to ensure data management, maintenance and long-term accessibility of your results for future reuse (also by third parties). Please use existing standards and data repositories where appropriate.

7 ETHICAL AND LEGAL CONSIDERATIONS

Give a description of ethical considerations relating to the study (assessment of risks and benefits, care and protection for research participants, protection of research participants’ confidentiality, informed consent process, and crisis intervention) and how to address them adequately. A final version of the study protocol has to be submitted to the funding organisation together with the statement by the ethics committee before possible funding.

Please give an explanation on the legal situation concerning the data set (e.g. owner of data). How will the existing legal requirements for data safety be met?

8 DISSEMINATION AND IMPLEMENTATION OF RESEARCH RESULTS

Beyond regular research publication the research results should be brought to larger audiences and the actors involved (e.g. sickness funds, professional societies, general practitioners). Identification of the audience relevant for this research is important. Strategies and actions of dissemination and implementation should be tailored to the audience needs and context of use.
Please clearly state achievable goals regarding the translation of your results during the grant and after the end of the grant. To reach these goals, how will partners be engaged during the projects and how are the results of the work put into action at the end of the projects? Please outline intended strategies and measures to disseminate and implement the results within the health care system.

9 STUDY MANAGEMENT

9.1 MAJOR PARTICIPANTS

Please indicate roles of major participants, including persons responsible for design, management and analysis of the study. The role of the coordinating investigator has to be defined as specific as possible. It is important that his/her role can be distinguished clearly from the roles/functions of co-investigators in the study.

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<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>Affiliation</th>
<th>Responsibility/Role</th>
<th>Signature</th>
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<td>Principal/Coordinating Investigator</td>
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<td>Responsible for Special Methodological Aspects/Statistics</td>
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<td>Recruiting centres (e.g. hospitals, nursing homes, network of health care providers)</td>
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<td>Study supporting facilities/institutions (e.g. sickness funds, central laboratories)</td>
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<td>Responsible for Quality Assurance/Data Management</td>
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<td>Self-help, support and advocacy organizations of patients (if applicable)</td>
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Please indicate the expertise of all above-mentioned participants by citing own relevant publications and/or specifying their major role in ongoing comparable studies (list only publications of the last 5 years, about 5 publications per person, and/or a maximum of 5 relevant third party funded projects conducted in the area during the five past years). Give the professional background of all participants. Ensure that the team of investigators has the necessary ranges of disciplines and expertise to carry out the study.

Include tabular scientific Curricula vitae (max. 1 page per person) for academic staff members playing a leading role (i.e. applicant and co-applicants, methodological expert) under 12.
Note: Any potential conflicts of interest must be disclosed in the appendix. The rules set forth in the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" have to be observed by analogy (www.thelancet.com).

9.2 RECRUITING CENTRES/STUDY-SUPPORTING FACILITIES AND INSTITUTIONS

Recruiting centres must detail their commitment on a separate sheet (cf. appendix no. 1) as detailed under 12. If an umbrella organisation or a network of several recruiting centres is involved, it is sufficient that the authorised representative of the organisation or the network enters the commitment. If secondary data of a sickness fund to be 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 (cf. appendix no. 2). Issues of data protection need to be addressed.

Which specific facilities and other resources are available for conducting the study?

9.3 INTERNATIONAL COLLABORATIONS

If the proposed study includes collaboration with organisations in other countries, please give full details of funding arrangements agreed or under consideration in the appendix. Please detail the power of the German component of the study on its own as well as part of the international study.
10 FINANCIAL DETAILS OF THE STUDY

10.1 FINANCIAL SUMMARY

Indicate total duration of the study, the period of time for which funding is requested, and when funding should begin. The funding is usually granted for up to four years.

Funds can only be granted for research activities. Do not include patient care costs.

<table>
<thead>
<tr>
<th>Justification of funding requested*</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Sum</th>
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<td>Personnel (Person Month)</td>
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<td>Scientific</td>
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<td>Project coordination</td>
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<td>PhD students</td>
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<td>Etc.</td>
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<tr>
<td>Non-scientific</td>
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<td>Study nurses</td>
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<td>Documentarists</td>
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<td>Other</td>
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<td>Student assistants</td>
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<tr>
<td>Consumables</td>
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<td>Subcontracts</td>
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<td>Case Payment</td>
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<td>Travel</td>
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<td>Equipment</td>
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<td>Overhead/lump sum** (if applicable)</td>
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<td>Total amount</td>
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* 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
  - Subcontracts (why are they necessary? For which work packages?)
  - Consumables (brief statement regarding the items needed, including case payment)
  - Travel costs (list of intended journeys)
  - Equipment (can only be funded when it is not included in the basic equipment, or when existing equipment is not available for the project).

** Academic institutions (Hochschulen und Fachhochschulen) can apply for a lump sum up to 20% of total for indirect costs

10.2 CO-FINANCING BY INDUSTRY AND/OR OTHER THIRD PARTIES

Co-financing by industry, sickness funds 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 project outline should briefly describe the type and volume of the intended 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, drugs or medical products for the study).
- 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.

After notion of award has been 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.

10.3 OTHER FUNDING

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

If this is not the case please declare:

"A request for funding this study has not been submitted to any other address. In case I submit such a request I will inform the Federal Ministry of Education and Research immediately".

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3 Detailed information can be found in particular in the “Gemeinsamer Standpunkt zur strafrechtlichen Bewertung der Zusammenarbeit zwischen Industrie, medizinischen Einrichtungen und deren Mitarbeitern” (Common position concerning the consideration of cooperation between industry, medical institutions and their staff from the aspect of criminal law) published by the Verband forschender Arzneimittelhersteller (Association of Research-Based Pharmaceutical Companies) (http://www.vfa.de/de/vfa/gemeinsamerstandpunkt.html)
11 REFERENCES

Please list publications you have quoted within your project outline. References should be listed according to numerical appearance in the text.

12 APPENDICES

In addition to the supplements listed below, further supplements may be attached, if necessary.

1. Declarations of commitment of participating centres

Participating/recruiting centres must declare their commitment on a separate sheet including their signatures (if an umbrella organisation or a network of several recruiting centres is involved, it is sufficient that the authorised representative of the organisation or the network, signs the sheet) and giving the following details, if applicable:

a) Name of investigator
b) Institution
c) Trial name
d) Trial duration
e) Inclusion/exclusion criteria
f) Strategy for the determination of recruitment figures at the recruiting centre
g) Number of patients expected to be recruited for the trial under the above mentioned criteria
h) Detailed description of the working package conducted by each/the participating centre(s)
i) Conflict of interest
j) Signature

2. Declarations of commitment of sickness funds or other institutions providing data (e.g. German Pension Fund)

If data from sickness funds or other institutions is used for the study, the access to data needs to be clarified and documented.

a) Contact person
b) Institution
c) Study name
d) Data provided (inclusion/exclusion criteria, number of patients)
e) Data protection  
f) Conflict of interest  
g) Signature  

3. CVs of academic staff members of participating institutions  

Include tabular scientific CVs (max. 1 page per person) for academic staff members playing a leading role (i.e. applicant and co-applicants, study statistician, not all collaborating partners at all study sites).  

4. Declaration of conflicts of interest  

Any potential conflicts of interest must be disclosed. The rules set forth in the “Uniform Requirements for Manuscripts Submitted to Biomedical Journals” have to be observed by analogy (www.thelancet.com).  

5. Cover letter  

Please confirm the correctness of the information given in the project outline within a cover letter for submission signed by all cooperation partners. The legally binding signature(s) has/have to be handwritten. A scan of the cover letter has to be attached to the project outline.