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

Module 3: Systematic Reviews of Gender-sensitive Studies

Within module 3 funding will be granted for systematic reviews of gender sensitive studies on health care provision/prevention/health promotion.

Please prepare your project outline **not exceeding 15 pages for the headings 1. to 8.** (DIN A4, one-sided, 11 point Arial, 1.5-lined, references in numerical order), plus references, plus appendices. 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 10).

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 SYNOPSIS

| **APPLICANT** | Institution  
|              | Name of project leader, employment status, institution and department (complete name).  
|              | In case of multiple applicants the project leader should be listed first.  |
| **TITLE OF REVIEW** | The title of the review (not exceeding 140 characters) should be as precise as possible.  |
| **TOPIC(S)** | The main research field being studied (health services research or prevention research or health promotion research).  |
| **CONDITION** | The health condition being studied (e.g. asthma, myocardial infarction, depression, obesity).  |
| **OBJECTIVE(S)** | Which principal research questions are to be addressed? Does the project outline aim at methodological progress in the field of reviews?  |
| **TYPE OF REVIEW** | Key words only (e.g. IPD-analysis, prognostic review, update of an existing systematic review, scoping review).  |
| **INTERVENTION(S)/EXPOSURE(S)** | Describe the experimental, the control interventions and exposure(s). For reviews on diagnostic test accuracy, index test and reference standard should appear in this section.  |
| **STUDY SELECTION** | Specify key inclusion and exclusion criteria.  
| | Population:  
| | Comparator(s):  
| | Outcomes:  
| | Design of primary studies:  |
| **SEARCH STRATEGY** | Describe the search strategy to identify relevant research, i.e. specify databases and other sources to be searched.  |
| **QUALITY ASSESSMENT** | Describe the strategies to assess the quality of primary studies (methodological quality, systematic error, validity, generalisability, applicability).  |
| **DATA EXTRACTION** | Specify extraction process and detail quality assessment of extracted data.  |
| **DATA SYNTHESIS** | Specify strategy for data synthesis (effect measures) and presentation of results (forest plots) taking into account possible heterogeneity, publication bias and subgroup analysis.  |
| **SAMPLE SIZE** | Estimate the number of eligible primary studies (and individual patient data, if applicable) to be included.  |
| **COOPERATING CENTERS** | Which centers will be involved?  |
| **DURATION** | Requested duration of funding indicated in months (only whole numbers)  |
| **FUNDING APPLIED FOR** | Total amount of funding applied for including lump sum/overhead costs, if applicable.  |

### 1.1 KEY WORDS

### 2 RELEVANCE

*Which health problem is to be addressed? Which principal research questions are to be addressed? Please justify the relevance of the health problem and the choice of the research*

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1 Only for this table 9 point Arial, single-line may be used.
questions. Describe shortly the existing situation in health care/prevention/health promotion
and why you assume gender to have a decisive influence on the subject.

2.1 PREVALENCE, INCIDENCE, MORTALITY

Please state the prevalence, e.g. per 100.000 residents, incidence, e.g. per 100.000 residents per year and mortality (case fatality rate) of the addressed health condition, according to most reliable data. Please provide information on the socioeconomical burden of health condition.

2.2 BURDEN OF DISEASE

Please provide suitable indicators to describe the burden of health condition, e.g. DALYs (disability-adjusted life years).

2.3 NEED FOR THE SYSTEMATIC REVIEW

How significant is the systematic review in terms of its potential impact of relieving the burden of health condition and/or burden of treatment (e.g. dose reduction, avoiding adverse effects) and/or improving quality of life?

Did you search for already existing systematic reviews in your field of interest? What is the novel aspect of the proposed systematic review in comparison to already existing reviews? Which therapy options are available for treatment of the disease? How can the systematic review influence evidence-based treatment decisions in clinical practise in Germany? How significant is the review for planning of further clinical research? Does the review contribute to methodological progress in the field of systematic reviews?

2.4 PATIENT AND PUBLIC INVOLVEMENT

How were the target population’s need, 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?
3 THE HEALTH PROBLEM

3.1 EVIDENCE

Set your review into perspective. What research has been conducted either by you or by others? For a review update please state the present need (e.g. novel publications of clinical trials,...) What is the relevance of the results? Give references.

3.2 STRATEGIES FOR THE DISSEMINATION AND IMPLEMENTATION OF 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.

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.

4 JUSTIFICATION OF DESIGN ASPECTS

4.1 POPULATION

Justify the population of patients to be studied. Include reflections on generalisability and representativeness. In case of an individual patient data meta-analysis please justify feasibility of individual patient data acquisition in detail.

4.2 INTERVENTION(S)/EXPOSURE(S)

Justify the intervention(s)/exposure(s) to be studied. Describe the intervention(s)/exposure(s) as exactly as possible. Address important potential adverse effects of the intervention(s).
4.3 COMPARATOR(S)

Justify the choice of comparator(s) being used by primary studies. Which evidence establishes the appropriateness of the chosen comparator(s)? Describe the control interventions as exactly as possible.

4.4 OUTCOMES

Justify the outcomes chosen: Are there other reviews that have utilized them? Are there any guidelines proposing them? Are they relevant for patients? Discuss the clinical relevance of the outcomes for the target population. Have they been validated? Define the timing of outcome measurements.

4.5 DESIGN OF PRIMARY STUDIES

Justify the design of the primary studies to be included/excluded. Are there any restrictions, e.g. a minimal time of follow-up?

4.6 SEARCH STRATEGIES

Justify the search strategies to identify relevant research: Are all relevant bibliographic databases considered? Is a hand search planned? Will authors, sponsors or other experts be contacted? Present a full electronic search strategy for one bibliographic database, including any limits used, such that it could be repeated. How many eligible primary studies do you expect to be included? How did you assess their number (provide and critically evaluate published data)?

4.7 DATA EXTRACTION AND QUALITY ASSESSMENT

Justify the data extraction strategies. Describe the tool(s) used for risk of bias assessment. Detail consequences possibly arising from quality assessment.

5 STATISTICAL ANALYSES

What is the proposed strategy of information synthesis? Will the calculation of a summary measure be justified? If yes, specify effect measures and statistical models. Describe how to investigate heterogeneity/homogeneity and publication bias based on the expected number of primary studies (sample size of your review). Are there any planned subgroup or sensitivity analyses? If applicable describe the methods for “Summary of findings” tables.
6 EXPERTISE

Please indicate persons responsible for the review.

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<th>#</th>
<th>Name</th>
<th>Affiliation</th>
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<td>Clinical expertise</td>
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<td>Cooperation partner</td>
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Please indicate expertise of all above-mentioned participants by citing relevant publications and/or specifying major role in ongoing research (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 participating investigators has the necessary range of disciplines and expertise to carry out the systematic review (i.e. multiple treatments meta-analysis, diagnostic test accuracy review).

Include tabular scientific Curricula vitae (max. 1 page per person) for academic staff members playing a leading role (i.e. clinical expert, methodological expert) under 10.

7 WORK PLAN

Please describe the estimated time plan considering, e.g. work packages, cooperation with the adjacent Cochrane review group, individual patient data acquisition (if applicable). 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).
8 FINANCIAL DETAILS OF THE REVIEW

8.1 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 two years.*

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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)

** Please note: Equipment cannot be funded. Publication costs can only be funded if an open access publication is planned.

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

8.2 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.²

8.3 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".

9 REFERENCES

Please list publications you have quoted within your project outline. A maximum of 1 page references should be listed according to numerical appearance in the text.

² 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)
10 APPENDICES

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

1. Declarations of commitment of collaborating partners

Partners 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) Detailed description of the working package conducted by each partner
d) Conflict of interest
e) Signature

2. 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).

3. 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).

4. 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.