

Leitfaden für die Erstellung von Projektskizzen zur „Richtlinie zur Stärkung der Forschung in der Geriatrie und Gerontologie“

Modul 1: Anreizsetzung für neu einzurichtende Professuren in der Geriatrie und Gerontologie

Version vom 28. Oktober 2016

Dieser Leitfaden stellt die Anforderungen für die Erstellung einer beurteilungsfähigen Projektskizze für Modul 1 dar. Er ergänzt die am 24. Oktober 2016 im Bundesanzeiger veröffentlichte o. g. Förderrichtlinie (<http://www.gesundheitsforschung-bmbf.de/de/6597.php>) und soll offene Fragen im Vorfeld der Einreichung klären.

Projektskizzen, die den Vorgaben der zugrunde liegenden Förderrichtlinie und dieses Leitfadens nicht entsprechen, können ohne weitere Prüfung abgelehnt werden.

Es wird empfohlen, zur Beratung Kontakt mit dem DLR Projektträger aufzunehmen. Weitere Informationen und Erläuterungen sind dort erhältlich.

Ansprechpersonen sind:

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Verfahren

Zunächst sind ausschließlich Projektskizzen einzureichen, **welche die Erfüllung der standortbezogenen Kriterien darlegen (Teil A).**

Im Fall einer positiven Bewertung wird vom Projektträger zur Einreichung von Teil B aufgefordert. Der Inhaberin bzw. dem Inhaber der neuen Professur für Geriatrie oder Gerontologie obliegt die Konzeption und Leitung des Forschungsprojekts sowie die Erfüllung der projektbezogenen Kriterien (Teil B). Der Abgabetermin für Teil B ist mit dem Projektträger zu vereinbaren und sollte spätestens zwei Jahre nach der Einreichung von Teil A vorgelegt werden.

Die nach diesem Leitfaden erstellten Projektskizzen werden unter Beteiligung eines externen Begutachtungsgremiums bewertet (siehe auch Punkt 7.2.1 der Förderrichtlinie). **Es erfolgt zunächst die Bewertung von Teil A** und zu einem späteren Zeitpunkt die Bewertung der vollständigen Projektskizzen (Teil A und Teil B).

Im Fall einer positiven Bewertung der vollständigen Projektskizze (Teil A und Teil B) werden Sie in einem zweiten Verfahrensschritt aufgefordert, einen förmlichen Förderantrag vorzulegen, der bewertet und geprüft wird (siehe Punkt 7.2.2 der Förderrichtlinie). Das Berufungsverfahren der neuen Professur für Geriatrie oder Gerontologie muss bei Vorlage des förmlichen Antrages abgeschlossen sein.

Formale Vorgaben für die Einreichung der Projektskizze

Die **vollständigen Unterlagen für Teil A** müssen folgende Teile umfassen:

1. die **Projektskizze (Teil A)** inklusive Anhang und inklusive Anschreiben als ein PDF-Dokument
2. die Projektübersicht (Kontaktdaten, Kurzbeschreibung usw.), die über ein Internet-Formular in „PT-Outline“ erstellt wird.

Diese Unterlagen sind elektronisch über das Internet-Portal „**PT-Outline**“ (https://secure.pt-dlr.de/ptoutline/PROFESSUREN_ALTERSFORSCHUNG) einzureichen. Vor der Erstbenutzung ist eine Registrierung notwendig. Bitte folgen Sie den Anweisungen des Programms während der Registrierung, dem Ausfüllen des Online-Formulars und der verbindlichen Einreichung im Portal.

Die Eingaben in das Internet-Formular (Projektübersicht) und die verbindliche Einreichung der Projektskizze (Teil A) müssen

bis spätestens 19. April 2017

elektronisch erfolgt sein. Die Vorlage eines Druckexemplars ist nicht erforderlich. Die elektronisch eingereichte Projektskizze und Projektübersicht sind Grundlage der Bewertung unter Beteiligung eines externen Begutachtungsgremiums.

Entscheidend für die Fristwahrung ist die auf elektronischem Wege über das Internet-Portal „PT-Outline“ verbindlich eingereichte Projektskizze. Verspätet eingehende Projektskizzen können aus Verfahrensgründen möglicherweise nicht mehr berücksichtigt werden. Eine Vorlage per E-Mail oder FAX ist nicht möglich. Aus der Vorlage der Projektskizze kann kein Rechtsanspruch auf Förderung abgeleitet werden.

Allgemeine Hinweise

Die nachfolgenden Hinweise sind insbesondere im Hinblick auf die Planung und Einreichung der Projektskizze für Teil B (Beschreibung des Forschungsprojekts) zu beachten.

Merkblätter und Richtlinien des BMBF

Neben diesem Leitfaden gelten weiterhin die entsprechenden Merkblätter und Richtlinien des BMBF, soweit in diesem Leitfaden nicht ausdrücklich andere Regelungen getroffen sind. Weiterführende Links für die Antragstellung finden Sie auf den Internetseiten des BMBF¹. Die dort veröffentlichten Anforderungen / Informationen werden regelmäßig aktualisiert.

Wissenschaftliche Standards und Arbeitshilfen

Die Antragstellenden sind verpflichtet, die nationalen und internationalen Standards zur Qualitätssicherung der Forschung einzuhalten. Hierzu sind insbesondere die nachfolgenden Dokumente in der jeweils geltenden Fassung zu berücksichtigen (die Aufzählung ist nicht abschließend):

- Deklaration von Helsinki
- ICH-Leitlinie zur Guten Klinischen Praxis (GCP)
- Memorandum zur Sicherung der guten wissenschaftlichen Praxis (DFG)

¹ <http://www.foerderportal.bund.de/>

- Richtlinien des CIOMS (Council for International Organization of Medical Sciences) in Zusammenarbeit mit der WHO (World Health Organization): "International Ethical Guidelines for Biomedical Research Involving Human Subjects"
- CONSORT Statement (Consolidated Statement of Reporting Trials)
- Leitfaden des Medical Research Council (MRC): „Developing and evaluating complex interventions - new guidance“
- Gute Praxis Sekundärdatenanalyse (GPS): Leitlinien und Empfehlungen

Darüber hinaus können z. B. die folgenden Arbeitshilfen bei der Planung der Projektskizze herangezogen werden (die Aufzählung ist nicht abschließend):

- Memorandum III „Methoden für die Versorgungsforschung“ des Deutschen Netzwerkes Versorgungsforschung e.V.
- Memorandum IV „Theoretische und normative Fundierung der Versorgungsforschung“ des Deutschen Netzwerkes Versorgungsforschung e.V.
- Arbeitshilfen der TMF [Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V.], z. B. zu Datenschutz oder Patienteneinwilligung, Sicherung der Datenqualität.

Gliederungsschema für die Projektskizze

Mit Blick auf das internationale Begutachtungsverfahren wird dringend empfohlen, die Projektskizze in **englischer Sprache** einzureichen.

Der Umfang der **Projektskizze für Teil A darf 10 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. Anhang und Anschreiben nicht überschreiten. In Teil B ist das Forschungsprojekt zu einem späteren Zeitpunkt (s.o.) näher zu beschreiben [Teil B: maximal 25 Seiten (Formatierung analog zu Teil A) zzgl. Anhang und Anschreiben].

Die **Projektskizze für Teil A** besteht aus:

- einem **Anschreiben**, auf dem die Vertreter aller Projektpartner (in der Regel die Projektleitungen) mittels rechtsverbindlicher Unterschrift die Kenntnisnahme sowie Richtigkeit der in der Skizze gemachten Angaben bestätigen;
- der **Beschreibung der standortbezogenen Kriterien inkl. Anhang** (s. Gliederungsvorlage S. 4-6).

Die Unterlagen müssen selbsterklärend und aussagekräftig sein sowie alle Informationen beinhalten, die für eine sachgerechte Bewertung erforderlich sind. Sie müssen ohne weitere Informationen/Recherchen bzw. ohne Lektüre der zitierten Literatur eine Beurteilung zulassen.

Bitte halten Sie sich für die Beschreibung an die im Folgenden angefügte Gliederungsvorlage (siehe S. 4 ff). **Diese Gliederungsvorlage ist verbindlich.** Die vorhandenen Eintragungen in kursiver Schrift sollen Hinweise auf die Art der geforderten Informationen geben. Sie sind vor dem Einreichen der Projektskizze zu löschen.

Für die Erstellung der Projektskizze verwenden Sie bitte die vorbereitete Mustervorlage (Word-Dokument), die sie unter <http://www.gesundheitsforschung-bmbf.de/de/6597.php> herunterladen können.

Module 1: Incentive for the Establishment of Professorships in Geriatrics or Gerontology

Important: Please submit part A only.

PART A

SYNOPSIS

Applicant	Name of university, postal address, telephone, fax, e-mail Contact person: name, postal address, telephone, fax, e-mail
Structural aim	Please tick: <input type="checkbox"/> Establishment of a new full professorship (Lehrstuhl) <input type="checkbox"/> Establishment of a new independent department (Abteilung)
Designation of new full professorship / new department	Please indicate the designation of new full professorship (Lehrstuhl) or new independent department (Abteilung) Assignment of full professorship / new independent department (please tick): <input type="checkbox"/> Geriatrics <input type="checkbox"/> Gerontology
Faculty	Name of faculty Head of the faculty (name, employment status, postal address, telephone, e-mail)

I. LOCAL SITUATION: STRUCTURES, RESEARCH AND SUSTAINABILITY

1. RELEVANCE

- Please describe the relevance and necessity to establish a new full professorship (Lehrstuhl) or a new independent department (Abteilung) of geriatrics / gerontology.
- Please describe the expected benefit and added value for the university (Hochschulstandort) and for the region.
- Please also comment on how the new full professorship or new department will benefit health care and health services or nursing for old and very old people.

2. LOCAL STRUCTURES

- Please comment on the process of the establishment of a new full professorship or new department of geriatrics / gerontology (see appendix no. II.3).
- Please describe the faculty where the new full professorship or new department will belong to.
- If other working groups relevant for the field of geriatrics / gerontology exist at the faculty, please name and briefly describe them.
- Comment on the long-term perspectives for research in geriatrics / gerontology at the university (Hochschulstandort).

3. RESEARCH PROFILE AND SCIENTIFIC EXPERTISE ON-SITE

- Please present the existing research profile and research activities at the faculty, also regarding the promotion of young scientists.

- *Please describe the scientific concept and research profile of the new full professorship or new department of geriatrics / gerontology.*
- *Please comment on the future development of the faculty, especially with regard to the role of the requested new full professorship / new department and its contribution to promote research in geriatrics / gerontology at the university (Hochschulstandort).*
- *Please list relevant publications and third party funded projects that have been published and conducted during the last 5 years of the institution or faculty with relevance for geriatrics / gerontology in the appendices (see appendix no. II.2).*

4. PROMOTION OF YOUNG SCIENTISTS IN GERIATRICS / GERONTOLOGY

- *Please comment on the added value of the new full professorship or new department regarding career opportunities for young scientists in geriatrics / gerontology.*

5. INTEGRATION IN EXISTING STRUCTURES AND SUSTAINABILITY

- *Please present the integration of the new full professorship / new department into existing structures of the faculty (e.g. planned or established measures, interconnectedness, collaboration).*
- *Please comment on accompanying support by the faculty or institution for the new full professorship / new department, especially with regard to allocation of basic equipment / infrastructure.*
- *Statement of the faculty / university regarding sustainability of the professorship / department after BMBF funding. The university has to finance at least half of the BMBF-funded personnel for at least six years after BMBF funding. Further financing of the professorship / department also includes adequate material resources / infrastructure by the faculty / university. An appropriate legally signed commitment has to be provided (see appendix no. II.4).*

II. APPENDICES

DIN-A4 format, 9 point, Arial, margins of at least 2 cm and single-spaced lines.

1. REFERENCES (one page maximum,)

Please list all references that you have quoted within your application. References should be listed according to their numerical appearance in the text.

2. RELEVANT PUBLICATIONS AND THIRD PARTY FUNDED PROJECTS

Please list relevant publications and third party funded projects that have been published and conducted during the last 5 years of the faculty or institution with relevance for geriatrics / gerontology (see A I.3).

3. FACULTY DECISION

Please hand in the protocol of the faculty decision regarding the establishment of a new full professorship or new department of geriatrics / gerontology (see A II.2).

4. COMMITMENT OF THE FACULTY / UNIVERSITY

A legally signed commitment of the faculty / university regarding sustainability has to be submitted (see A I.5).

PART B

OUTLINE OF THE RESEARCH PROJECT

A signature of a methodological expert (e.g. clinical trial centre, biostatistical or epidemiological expertise) is mandatory. This expert should be involved in the planning as well as in the implementation of the study (see *Appendix No. IV.4*).

Important: Please submit part B only after we have notified you about the positive evaluation of part A.

SYNOPSIS (1 page max.)

Principal Investigator	<i>New professor / candidate Name, employment status, institution, department, postal address, telephone, fax, e-mail</i>
Appointment for professorship	<i>Please indicate the planned date of appointment for professorship.</i>
Title of the research project	<i>Max. 140 characters</i>
Acronym	<i>Please enter acronym.</i>
Keywords	<i>Max. 5 keywords</i>
Funding volume	<i>Requested funding volume for the first funding phase up to 3 years, including overhead costs / lump sum (if applicable)</i>
Objective(s)	<i>Which main research questions are addressed? Specify the primary goal of the project. Which (main) results are expected?</i>
Intervention(s)	<i>If you carry out an interventional study, briefly describe of the experimental and control intervention(s).</i>
Summary	<i>Brief summary of the research questions, main goals, study type and methodical approach and expected outcomes/benefits in concise and understandable terms (max. 1600 characters, including spaces). The project summary will inform the interdisciplinary review committee of the main aims.</i>
Cooperating partners	<i>List of cooperating partners (e.g. responsible for recruitment, data/methods (name, institution, city))</i>

I. 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 Appendix No. IV.3).*

II. RELEVANCE, AIM AND NOVELTY

1. RELEVANCE

- *Which issues in German health care and health services are addressed in your proposal?*
- *Briefly explain the current state of German health care and health services for old and very old people. Please describe the relevance of the study.*

2. AIM(S) AND NOVELTY

- *Which main research questions will be addressed? Please rank the research questions according to importance, indicating major and minor hypotheses of the study.*
- *What are novel aspects / scientific innovations of the proposed study?*
- *Which results are expected from the study? Explain how the results benefit health care of old and very old people?*

3. STATE-OF-THE-ART AND EVIDENCE

- *Place your study in the context of the national and international state of the art. Which studies have been conducted by yourself or by others. Refer to relevant systematic review(s) and/or (own) pilot studies, feasibility studies, or relevant previous / current studies.*
- *Discuss the relevance and applicability of international studies for German health services research. Please outline why the proposed study needs to be conducted in Germany.*
- *If you believe that no relevant previous studies have been done yet, please explain your research strategy with respect to existing information. Please comment on the background of the major research question and the feasibility of the study.*
- *If you carry out an interventional study: What is the rationale for the intervention? Please compare to similar studies. Please comment on research or evaluation studies that substantiate the efficacy of the intervention.*

4. COLLABORATION

Participatory approaches

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

Interdisciplinary

- *If any, describe the interdisciplinary collaboration in your proposal. Explain how your interdisciplinary approach contributes to study's aims and innovation. Please also comment on synergistic effects.*

International collaborations

- *If any, please comment on international collaborations (e.g. international scientific advisory board).*

5. GENDER ISSUES AND SOCIAL INEQUALITY

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

III. DESIGN AND RESEARCH METHODS

Please explain and describe the research design and methods in detail.

1. STUDY DESIGN (AND INTERVENTIONS)

- *Explain the study design chosen. State why you chose your approach(es) as opposed to others.*
- *Please provide a schematic diagram (flow chart) of design, procedures, and stages.*
- *If you carry out an intervention, describe the experimental and control interventions.*

2. TARGET / 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.*

3. ENDPOINTS

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

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

4. 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 studies) and comment on the methodical approach and sample issues. Comment on your strategies to overcome barriers to access to health care institutions and patients.*
- *For multicentre studies please define numbers of eligible patients per study site in a table. The recruitment schedule includes criteria for the selection of study sites.*
- *Comment on whether your study reflects standard health care / health services in practice.*

5. DATA COLLECTION

- *Describe your methods and instruments for data collection in detail. Explain the theoretical background and rationale for the data collection-strategy chosen. 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.*

6. METHODS OF 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.*

7. 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/study steering committee).*
- *Please register in a national or an international study registry. The registration has to be confirmed at the beginning of the study.*
- *To reduce publication bias, 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.*

IV. WORK SCHEDULE, TIME FRAME AND MILESTONES

Please describe in detail your proposed work programme for the first 3 years of funding:

- *Please outline your work schedule and describe each task.*
- *Please outline the responsibilities for the different tasks.*
- *Define milestones indicating major progress points.*
- *Provide a “Gantt-Chart” displaying tasks and milestones.*

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.

V. DISSEMINATION AND IMPLEMENTATION

1. SCIENTIFIC DISSEMINATION

- *The obtained scientific findings should be published preferably in Open-Access Journals. Publication expenditures can only be granted for Open-Access Journals that apply recognized, strict quality assurance processes. That means that the publication has to be immediately accessible and free of charge for users.*
- *In addition, research data should be archived for long-term preservation and (as far as possible) made accessible. Please describe your strategies concerning data quality assurance, data handling and long-term data storage (data types, standards, chosen repositories, other forms concerning long-term preservation). The concept should clarify in which processing stage and in which time frame the research data could be made accessible (considering third party rights, data protection and copyrights) in order to enable a useful application by third parties. Project data should be retained for at least 10 years in your institution or in a relevant, supra-regional infrastructure after the funding period ends.*

2. PUBLIC DISSEMINATION, TRANSFER AND IMPLEMENTATION

- *Please explicate the/your strategies for dissemination among the public and actors involved (e.g. sickness funds, professional societies, clinical routine, general practitioners).*

- Please state achievable goals regarding the translation and transfer of results of your project into health 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?
- Please also outline strategies and measures to disseminate and implement the results within the German health care system.

VI. 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, 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.

VII. PROJECT MANAGEMENT

1. RESPONSIBLE SCIENTISTS FOR PROJECT

Please list the major scientific partners and indicate their tasks / responsibilities, including people responsible for design, management and analysis of the study. The role of the principal investigator / professor has to be defined as specific as possible.

Name / Responsible Person	Affiliation (only institution and city, no complete address)	Responsibility /Task	Signature
Professor		Principal Investigator	
		Responsible for study statistics	
...

- 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 appendix no. IV.3).

2. 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 appendix no. IV.4)

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	
...

VIII. FINANCIAL DETAILS

1. FINANCIAL SUMMARY

- Total costs for the project have to be listed in the table below.
- Funds can only be granted for research activities. Regular patient care costs are not included.
- Costs for basic equipment are not applicable for funding.
- Applied funds have to be justified according to the work plan.

Position	PM	Sum
Personnel	X	€
Scientific		€
Non-scientific		€
Other		€
Subcontracts	X	€
Consumables	X	€
Case payment	X	€
Travel costs	X	€
Equipment	X	€
Overhead / lump sum*	X	€
Total amount	x	€

PM: Person Months, indicate full-time equivalents

Please explain **each position in detail** and comment on:

- *Personnel (scientific, non-scientific and other personnel)*
Please comment on the qualification (e.g. professor/principal investigator, PhD, PhD student, technical assistant, study nurse, student research assistant)
Please describe the tasks and state the duration of employment (person months, PM) or working hours
- *Subcontracts (necessity)*
- *Consumables (items / material needed)*
- *Case payment (calculate assays/examinations per patient, hours of staff per patient: €/patient x no. of patients)*
- *Travel costs (list of intended travels to e.g. meetings, monitoring)*
- *Equipment (BMBF does not finance infrastructure or basic equipment at research institutions)*
- **lump sum (universities and universities of applied sciences can apply for a lump sum up to 20% of total for indirect costs)*

2. CO-FINANCING BY THIRD PARTIES

The above being applicable, comment on any co-financing by third parties:

- *the type and volume of co-financing (see appendix no. IV.4)*
- *the independence of investigators*
- *terms and conditions of the financial commitment*

3. OTHER FUNDING

- *Please state if you have already submitted the same request for financial support or parts hereof to other institutions.*
- *If not, 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”.*

IV. APPENDICES

DIN-A4 format, 9 point, Arial, margins of at least 2 cm and single-spaced lines.

Please provide a table of contents for the appendices with page numbering.

1. REFERENCES (one page maximum)

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

2. RELEVANT PUBLICATIONS AND THIRD PARTY FUNDED PROJECTS

Please provide an updated list of relevant publications and third party funded projects that have been published and conducted during the last 5 years of the faculty or institution with relevance for geriatrics / gerontology (see part A, I.3)

3. CURRICULA VITAE OF PROFESSOR / PRINCIPAL INVESTIGATOR AND ACADEMIC STAFF

Please provide a tabular scientific CV (max. 1 page) for responsible academic staff (e.g. professor/principal investigator, trial statistician, etc.)

Please include information on:

- a) Contact details
- b) Current position
- c) Qualification and professional career
- d) Research interests
- e) Memberships (e.g. boards, (inter-)national scientific societies)
- f) List of a maximum of 5 relevant publications and third party funded projects published or conducted during the last 5 years

The professor/principal investigator has to list relevant publications and third party funded projects on a second page of the CV (see B I.).

4. DECLARATION OF COMMITMENTS

Number and list the declaration of commitments in numerical order.

4.1 DECLARATION OF COMMITMENT OF 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

4.2 DECLARATION OF COMMITMENT OF SICKNESS 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*

4.3 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*

4.4 METHODOLOGICAL EXPERTISE

A signature of a methodological expert (e.g. clinical trial centre, biostatistical or epidemiological expertise) is mandatory. This expert should be involved in the planning as well as in the implementation of the study (*see part B "Outline of research project".*)