Priority Programme 'Epidemiological Research using Cancer Registry Data' Applicants' Guidelines

Introduction

Deutsche Krebshilfe has supported the development of epidemiological cancer registries in Germany because of their significant role in cancer research. Only with the help of cancer registries it is possible to monitor changes over time and regional differences in incidence, prevalence and mortality of cancer. Studying cancer registry data allows not only to measure screening effects and evaluate care concepts, but also to examine quality of life of cancer patients and of long-term survivors.

Within the first call of applications, launched in 2007, ten epidemiological research projects were funded, which closely collaborated with epidemiological and clinical cancer registries. With this second call, and in accordance with the German National Cancer Plan, Deutsche Krebshilfe now intends

- to further support epidemiological research based on cancer registry data, therewith improving quality of life and health care for cancer patients as well as long-term survivors,
- to establish a training programme for graduates in the field of cancer epidemiology, aiming at ensuring sustainability of high quality epidemiological research in Germany.

The 'Graduate Programme in Cancer Epidemiology' will be established through the future network of funded epidemiological study teams. All applications for research projects must therefore include graduate positions, statements of supervisors and the commitment to take part in the programme (see section C.2.4 of these guidelines: 'Obligatory information on participation in the graduate programme'). Additionally, applicants are invited to apply for the position of the coordinator of the graduate programme. The application for the coordinator position is optional (see section C.3).

The success of this priority programme 'Epidemiological Research Using Cancer Registry Data' depends on the future project teams and coordinator of the graduate programme. Deutsche Krebshilfe would like to encourage you to deliver high quality applications and internationally competitive research ideas, following strictly all criteria given in these guidelines.
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General Procedure

The procedure for application and evaluation consists of three steps. Prospective applicants must submit a letter of intent to German Cancer Aid by 14 Mar 2014, 13:00. Project outlines in English must be submitted by 07 Apr 2014, 13:00. If the preliminary evaluation is favourable, full applications must be submitted by 21 Jan 2015, 13:00 to German Cancer Aid.

The project outlines and applications submitted will be evaluated by an international committee of experts. For this reason, all project outlines and applications must be in English. The requirements for project outlines are described in detail within the following sections.

Please submit all required documents in writing by post to the office of German Cancer Aid:

Deutsche Krebshilfe e. V.
Abteilung Förderung
Buschstraße 32
53113 Bonn

Letter of intents, outlines and applications may not be sent by e-mail or fax.

Within two weeks of receipt of the documents by the Cancer Aid Office, the applicant/principal investigator will receive a written confirmation of receipt, together with a reference number. If you fail to receive confirmation of receipt, please send an e-mail to the Funding Department of German Cancer Aid (foerderung@krebshilfe.de), giving the full project title and your telephone number. If you have any questions, please contact:
Carolin Lange, 0228 / 72990-219, e-mail: lange@krebshilfe.de
A. Guideline for Letter of Intent

You are requested to notify German Cancer Aid of your intent to submit an application. This notification has to be provided by letter no later than 14 Mar 2014, 13:00 (e-mail and faxes are NOT accepted). German Cancer Aid office acknowledges receipt of every Letter of Intent by letter within two weeks.

The Letter of Intent must include:
• contact information on the (principal) applicant: full name, institution (in German), full address, phone, fax and email-address
• information on all remaining applicants: full name, institution (in German), place
• information on the collaborators: full name, institution (in German), place
• the project title in English
• the project title in German

Please note that this Letter of Intent is a prerequisite for submission of an application, i.e. project outlines will only be accepted from applicants who submitted a Letter of Intent earlier.
B. Guideline for Project Outlines

As second step, please submit 10 copies of the project outline (one unbound version with original signatures and nine bound copies) as well as a CD-ROM with a pdf-Version (1 single file incl. attachments) of the complete project outline by 07 Apr 2014, 13:00 to the office of German Cancer Aid (e-mails and faxes are NOT accepted). Bound copies are intended to be sent to the experts of the evaluation team. Please note that bound copies are NOT checked for completeness by Cancer Aid Office.

Based in part on the Applicants' Guidelines for Full Applications (section C), we ask you to arrange the project outline as follows, using the given reference numbers:

1. General information

Include all information from section C.1.2 of the guidelines for full applications.

2. Study within Cancer Epidemiology

2.1 Project summary in English
(max. ½ page)

2.2 Study synopsis
Include all information from section C.2.1.

2.3 Concise description of the proposed study
Provide information on background, preliminary work, expected results/benefit, plan of investigation (study design, target population etc.) (max. 4 pages).

2.4 Obligatory information on participation in the graduate programme
Outline of the graduate's project (max ½ page).
Name of the supervisor/mentor of the graduate student, including the following signed statement: "In case of a favourable evaluation of this project outline, I would fully support a full application and my commitment as a supervisor/mentor within the foreseen graduate programme according to the terms of the Applicants' Guidelines."

2.5 Financial summary
Rough estimate of the costs for the entire study (staff, consumables etc.) (max. ½ page).

3. Coordination of the Graduate Programme in Cancer Epidemiology (optional)

Name, institution of the applicant applying for the position of the coordinator of the graduate programme as well as a vision for the graduate programme (max. ½ page). If you do not wish to apply as coordinator of the programme, please continue in section B.4.
4. Signatures and attachments

4.1 Signatures of all applicants

4.2 CVs and publications
Curriculum Vitae (max. 1 page of each applicant) and list of publications (max. 10 publications of each applicant).

4.3 Collaboration partners
List of all collaboration partners (name, institution, place) and a letter of intent from each collaboration partner (digital signatures are sufficient for project outlines).
C. **Guideline for Full Applications**

If the preliminary evaluation is favourable, full applications must be submitted by **21 Nov 2014**, 13:00 to German Cancer Aid.

Application documents must contain the information and attachments as outlined below. Please use **all** reference numbers and corresponding titles as indicated in this guideline. If a section or point is not applicable, please designate it with 'not applicable', adding a brief explanation if necessary.

Keep your application short and concise. Observe all given page limits (1 page corresponds to: 1 DIN A 4 page, single spaced, equivalent font to Arial, size 11pt).

Applications will be evaluated by an international evaluation team of experts. Please submit your application incl. all attachments (e. g. CVs) **in English**. However, we ask you to submit the 'Project Title', the 'Summary', the 'Summary of requested funding' and the name of institutions of all applicants **also** in German.

Please submit **10 copies** of the application (one unbound version with original signatures and nine bound copies) no later than **21 Jan 2015**, 13:00 to the office of German Cancer Aid (e-mails and faxes are NOT accepted). Bound copies are intended to be sent to the experts of the evaluation team. Please note that bound copies are NOT checked for completeness by Cancer Aid Office.

We ask you to also include a CD-ROM with the following files:
- the complete application as **one single** pdf-file, including signatures and attachments (maximum 8 MB)
- information on sections C.1.2, C.2.1 and C.2.2 ('Information on Applicants, 'Study Synopsis' and 'Summary' ) as a Word- or RTF-document

Please submit all required documents **by post** to the office of German Cancer Aid:
Deutsche Krebshilfe e. V.
Abteilung Förderung
Buschstraße 32
53113 Bonn
1. General Information

1.1 Table of contents with page numbers
Please indicate each section with page numbers, using all reference numbers and corresponding titles as given in these guidelines.

1.2 Information on applicant(s)

PLEASE NOTE:
- Applications are not accepted from members of profit-making organisations or from persons not permitted to publish results in a generally accessible form.
- Cancer registries must be included as either applicants or close collaborators.
- If your application is submitted by several applicants, please indicate the principal investigator. German Cancer Aid will regard the principal investigator as the person assigned for corresponding with German Cancer Aid on behalf of all applicants.

1.2.1 Address Information in English
All applicants are expected to provide the following information:
- First name, surname, academic degree, date of birth
- Full name of the institution/organisation
- Postal address
- Telephone and fax numbers, e-mail address
- Reference numbers of all previous applications to German Cancer Aid for project funding

Please inform us at once if you change your address.

1.2.2 Address Information in German
Provide the full name of the institution/organisation of each applicant also in German.
2. Study within Cancer Epidemiology

PLEASE NOTE: All applicants are asked to follow GEP-Guidelines ("Leitlinien und Empfehlungen zur Sicherung von Guter Epidemiologischerxis", [http://dgepi.de/berichte-und-publikationen/leitlinien-und-empfehlungen.html](http://dgepi.de/berichte-und-publikationen/leitlinien-und-empfehlungen.html)).

2.1 Study synopsis
Give a synopsis of your planned study, using this **tabular** form:

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Name, Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project title in English</td>
<td>(max. 160 characters)</td>
</tr>
<tr>
<td>Project title in German</td>
<td>(max. 160 characters)</td>
</tr>
<tr>
<td>Study Duration</td>
<td>Information on the total duration of the study and the (provisional) dates of the application period.</td>
</tr>
<tr>
<td>Type of application</td>
<td>State whether your application is an initial or a follow-up proposal. In case of the latter, provide detailed information on previous work and results within section 'Own preliminary work' (C.2.3.2).</td>
</tr>
<tr>
<td>Objective(s)/Hypotheses</td>
<td>Which principal research questions are to be addressed? Specify clearly the primary hypotheses of the study.</td>
</tr>
</tbody>
</table>
| Outcome(s) | • Primary endpoint(s)  
• Key secondary endpoint(s) |
| Study/Target population | • Key inclusion criteria  
• Key exclusion criteria |
| Sample size | Specify the sample size and its rationale. |
| Data collection | • Type of data  
• Main instruments/methods for data collection  
• Explanatory/main response variables |
| Study design | e. g. experimental, observational (case-control, cohort, ecological ...) |
| Statistical analysis | • Main procedures/analytical tools  
• possible confounders/effect modifiers |
| Main benefit/output | Expected result in terms of main benefit for cancer patients |
| Participating centres/collaborators and participating cancer registries | Brief list of all involved collaborators (name of institution, place) |

2.2 Project Summary

2.2.1 Project summary in English
Please give a short description of the whole project, including the aims and objectives. The summary must not be longer than 1 page. It will be included in the submissions for the expert committees and advisory boards.

2.2.2 Project summary in German
(German translation of the above)
2.3 Information on the proposed project
This section must not exceed 12 pages.

2.3.1 Background/State of the art
Give a brief description of the primary research focus or foci of the host institutes, in order to illustrate the setting in which the research will take place. Summarise the relevant literature, from which the research question for the current application emerges. Which oncological problem is to be addressed? What is the novel aspect of the proposed study? Which principal research questions are to be addressed? Bring them into order indicating major and minor motivations/starting hypotheses of the investigation planned.

Please also set your project into perspective. Which studies have already been conducted and what is the relevance of their results? Give references to any relevant systematic review(s) and/or feasibility studies, relevant previous/ongoing research. However, the text should be comprehensible without reading the cited articles.

2.3.2 Own preliminary work
Preliminary work of the applicants should be specified completely, including a description of expertise and capacities in managing epidemiological studies.
You might also like to refer to the most important publications of the applicant(s) which are specifically related to the subject or methods of the proposed project. However, a complete list of the current publications of the applicant(s) should be added as an attachment to your proposal (see section C.5.2).

2.3.3 Expected results/main benefit of the study
Present a brief description of the objectives, hypotheses as well as the outcomes of the planned project and give statements on the following: Are the chosen endpoints/outcome measures suitable? Which results will be of immediate benefit for cancer patients and how could they be implemented in clinical practice/public health services? What is the perspective after your project is finished?

2.3.4 Plan of investigation
Provide a detailed but concise description of the planned project to be conducted during the application period. Give detailed information on the following criteria:
- Study population
- Study design
- Data collection
- Outcome measures
- Sample size calculation
- Statistical analyses
- Possible bias/confounders
- Quality assurance within the study
Please note: The quality of this part of your application is of critical importance in deciding whether the project deserves funding. The GEP-guidelines are to be considered.

2.3.5 Time schedule and milestones
Present a time-table/flow chart of the study. Set measurable milestones and describe them.
2.4 Obligatory information on participation in the graduate programme

As stated in the call for application, Deutsche Krebshilfe intends to support a 'Graduate Programme in Cancer Epidemiology'. This graduate programme will be established through the network of funded research projects (Part I of this call). Participants of the graduate programme will be graduate students as well as supervisors/mentors of the graduates. Both groups must be part of the funded research teams. This is obligatory for all applicants within this call.

Therefore, each application must contain the following information/statements on graduate students as well as supervisors/mentors:

2.4.1 Graduate student
All applicants must include a graduate position in their research project.
Give an outline of the graduate's project (max. 2 pages).

2.4.2 Supervisor/Mentor of graduate student
a) A training concept of the supervisor for the graduate student.
b) The previous training experience of the supervisor (number of PhD students, diploma students).
c) Following statements/declarations of the supervisor:
   - A declaration that the graduate will be able to spend in total 3 months (2 x 6 weeks or 1 x 3 months) at another institution within the framework of the graduate programme or at a partner institution abroad during the training period.
   - A declaration that the graduate will participate in the modules of the graduate programme (minimum 4 weeks).
   - A declaration that the supervisor will participate in one annual retreat and one annual scientific meeting of the graduate programme.
   - A declaration that the supervisor is prepared to act as a mentor for the graduate student of another institution and is prepared to host a graduate student at his/her institution for a period up to 3 months.
   - A declaration that the supervisor is prepared to teach within the graduate programme (please indicate your preferred teaching area(s) within cancer epidemiology).
   - A statement whether the supervisor is interested in participating in the governing board of the graduate programme.
d) Signature of the supervisor.

2.5 Requested Funding

2.5.1 Personnel
The following information is needed:
• Designation of the requested position (e.g. 'Scientific Assistant', 'Technician', 'Doctoral Student', 'Physician')
• The requested duration of employment (e.g. 'for 3 years')
• The salary grade according to the Wage Agreements for Public Employees (TVöD, TV-L, TV-Ä; please do not give payments in Euros for staff members, Cancer Aid Office will calculate the necessary personnel funds)
• An exact description of the duties of each position requested (a reference to the work schedule is not sufficient)
• If the persons requested are already known to you, please indicate their names, otherwise state N.N.

PLEASE NOTE: The graduate's position will be funded as a 65 %-position (TV-L E13).

**Applicants' own position**
German Cancer Aid assumes that the financial support for all applicants is guaranteed up to the end of the project to be funded. It is nevertheless possible for the applicant to request funding for his or her own position in the application. In this context, please note the following points:

An applicant who applies for his or her own position must document on the basis of publications that he or she has already established a reputation in the field of cancer research. The project for which funding is applied must be of extraordinarily high quality. The facility in which the applicant works must make a written statement clearly expressing its special interest in the applicant and in his or her research project. In addition, a statement must be presented which makes it clear that all the necessary preconditions are present for the performance of the research project and that the required basic equipment is available. Applicants who work in health care in a clinical department must be released from their clinical obligations during the period of the project. This must be confirmed in writing by the Head or Director of the Clinic.

In conclusion, it is pointed out that applications for projects in which the applicant - or one of several applicants - applies for his or her own job will be evaluated unusually strictly.

2.5.2 Funds for equipment/non-recurring investments
In particular, this includes scientific instrumentation. The following information is required:
• The name of the equipment or instrument
• Purchasing price in € including VAT, deducting discounts, together with a current tender or cost estimate from a possible supplier (copies of company catalogues or an Internet page are not accepted)
• A detailed explanation of why you need the requested instruments to perform the project, with reference to currently available equipment

Please bear in mind that German Cancer Aid does not in principle fund instruments which are part of the basic equipment of an institute or hospital (e. g. computers, printers, office software etc.).

2.5.3 Funds for consumables
Please describe the consumables (e.g. printing/mailing costs for questionnaires), with the total costs in € of each item requested.

2.5.4 Travel expenses
Funds can be requested for travel which is absolutely essential for the successful completion of the project (e.g. travel to collaboration partners, travel to participate in graduate programme). If you are applying for travel expenses, please state the amount and rationale (number of persons, estimated amount each way etc.) on each position and justify the necessity.

2.5.5 Other costs
These include, for example, commissions to third parties. In these cases, include an offer of the third party with detailed descriptions of tasks carried out.
2.5.6 Summary of requested funding (in English)
(PLEASE NOTE: if your project includes several working groups at different institutions which require separate financial administration, please give a separate summary for each working group.)

Application period: x years

Personnel:
1 Scientific Assistant, TV-L 13 (50 %), for x years (for Dr. ...)
1 Technician, TV-L 8 (100 %), for x years (N.N.)

Equipment (non-recurring):
<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
<th>Cost</th>
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</thead>
<tbody>
<tr>
<td>Instrument</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instrument</td>
<td></td>
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</tbody>
</table>

Consumables:
<table>
<thead>
<tr>
<th>Item</th>
<th>Cost</th>
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<tr>
<td>For .......</td>
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<tr>
<td>For .......</td>
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Travel expenses:
<table>
<thead>
<tr>
<th>Item</th>
<th>Cost</th>
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</thead>
<tbody>
<tr>
<td>For travels to collaboration partners</td>
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</table>

Other costs:
<table>
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<th>Item</th>
<th>Cost</th>
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<tbody>
<tr>
<td>For .......</td>
<td></td>
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</tbody>
</table>

2.5.7 Summary of requested funding (in German)

Beantragte Förderungsdauer: x Jahre

Personalmitte
1 Wiss. Mitarbeiter/in, TV-L 13 (50 %-Stelle), für x Jahre (für Dr. ...)
1 Techn. Assist., TV-L 8 (100 %-Stelle), für x Jahre (N.N.)

Investitionsmittel (einmalig)
<table>
<thead>
<tr>
<th>Item</th>
<th>Cost</th>
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<tr>
<td>Gerät .......</td>
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</table>

Mittel für Verbrauchsmaterialien
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<th>Item</th>
<th>Cost</th>
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<tr>
<td>Für .......</td>
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Reisemittel
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<th>Item</th>
<th>Cost</th>
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<tr>
<td>Für Reisen zu Kooperationspartnern</td>
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Mittel für Sonstiges
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<tr>
<th>Item</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Für .......</td>
<td></td>
</tr>
</tbody>
</table>
2.6 Prerequisites for carrying out the project

2.6.1 Your team
Please indicate name, academic degree and professional position of all participants (scientists, assistants, employees) who may work on the planned project. Please give a short and well-defined description of the duties of each project participant. Indicate the contribution of each project participant to the project, including applicant(s), as percentage of their working hours.

2.6.2 Collaborations
Please only name those cancer registries, scientists, physicians or other collaboration partners with whom you have or have agreed on specific collaboration in the project for which funding is requested. Include a signed statement of intent of each collaboration partner in section C.5.5.

2.6.3 Collaboration with companies
Please state whether you are cooperating with an industrial partner as part of the planned project and, if so, to what extent. Include the confirmation of the industrial partner in section C.5.5.

2.6.4 Statistical expertise
A statistician, biometrician or scientist with corresponding qualifications must be closely involved in carrying out the project. Please state the name, institution and qualification of the responsible statistician/scientist. In case he/she is not an applicant, please include a signed statement in section C.5.5.

2.6.5 External data sources
In case you plan to include external data sources for your project, please give written proof that they are available for the study. If applicable, include the statement of the collaborators in section C.5.5.

2.6.6 Your institution's contribution to basic equipment
Please indicate the contribution of the participating institution(s) to the basic equipment (e.g. provision of personnel, of funds for consumables or of equipment for the planned project).

2.7 Further particulars

2.7.1 Statement of the ethics committee (if necessary)
A statement on the planned research project from the ethics committee of your institution is necessary, if investigations are to be performed in individual persons (e.g. qualitative interviews, if individual personal data are involved), or if human material (e.g. blood or tissue sample) is used. The statement of the ethics committee must make it clear that there are no reservations about conducting the project applied for funding by German Cancer Aid. Include the statement of the ethics committee as an attachment or, if applicable, write that the ethics committee statement will be submitted subsequently. Approval of the study by the ethics committee must be available before the start of the project funding.

If several sites are involved in the research project for which funding is requested, corresponding statements from the responsible ethics committees may have to be presented.
2.7.2 Third party funding
A list of all third party funding for other current projects which the applicants receive at the time of the application (containing each project title, the source of funding, the duration, start and end date of funding). Please also list all planned projects for which you have applied for funding, each with the project title and the funding organisation to which you have applied.

3. Coordination of the 'Graduate Programme in Cancer Epidemiology' (optional)

PLEASE NOTE: As stated above, applicants are invited to apply for the position of the coordinator of the envisaged ‘Graduate Programme in Cancer Epidemiology’. The application for the coordinator position is optional. If you do not wish to apply for this position, please continue in section 4 of these guidelines.

3.1.1 General information and statement
• Indicate the name and institution of the applicant who is applying for the coordinator position. He/she must be one of the applicants for the research project (part I of the call).
• Provide reasons (e.g., qualification, motivation) for applying for this position and how much of your working time (in %) you will be able to invest in this programme.

3.1.2 Outline of the graduate programme
The coordinator of the graduate programme will be responsible to establish the organisation and content of the programme in collaboration with the (yet unknown) network of funded project teams. Each project team will contribute to the programme with graduate students and supervisors (see also section C.2.4). As a rough guideline, the programme should span 2 years, include a maximum of 12 graduate students and the same amount of supervisors/mentors from different institutions.

We ask you to:
• State how you would coordinate the process of establishing the programme in collaboration with the supervisors from the (yet unknown) network of project teams.
• Give your brief vision and an idea for the teaching curriculum of the programme.
(max. 4 pages)

3.1.3 Requested funding for coordination of the graduate programme
You can apply for funding in order to receive administrative support for the coordination of the graduate programme. State a summary in German and English of requested funding in line with the formal instructions in section C.2.5.6 and C.2.5.7. Furthermore, give for each requested position (staff, consumables, travel etc) a detailed justification. If you require administrative personnel, provide a detailed description of tasks.

4. Declaration and Signatures

4.1 Declaration
German Cancer Aid must be informed if you have submitted the application or parts hereof to another funding organisation before. In all cases, the following declaration must be made:
'A request for funding this or a similar project has not been submitted to any other addressee. The same or a similar request for funding will not be submitted to other institutions during the review process. German Cancer Aid reserves the right to inquire at other funding organisations about the submission of this or a similar application and to request further information hereof.'

4.2 Signature(s)
Place, date and original signatures of all applicants.

5. Attachments

The following attachments are to be included with the application.

Please remember to include the attachments with each hard copy of the application as well as within the pdf-version. Regarding the pdf-version, take care to compile one single file, including the whole application, signatures and all attachments.

5.1 Curriculum vitae
Curricula vitae of all applicants, emphasising their scientific careers (table format).

5.2 Current list of publications
Please give a list of all articles published by the applicants within the last five years. Publications which have not yet appeared should be designated as 'in print in..', 'accepted by..' or 'submitted to...'. Manuscripts may be included as an attachment. Please do not include any publications which are still in preparation.

5.3 Approval of the application by the head of the institution
Please attach a signed approval from the director or head of the institution/organisation at which the project in the application is to be performed. This should clarify that the director or head of the unit has been informed of the application and agrees that the project can be conducted with participation of the applicant. This approval must not be submitted if the director or head of the unit is himself the applicant. If the project is to be performed at several institutions/organisations, equivalent approvals may have to be submitted by the heads of all units involved.

5.4 Statement(s) of the ethics committee(s) (if necessary)
These can be submitted later, see section C.2.7.1.

5.5 Letters of Intent by Collaborating Parties
Attach all letters of intent by collaboration partners, see sections C.2.6.2, C.2.6.3, C.2.6.4 and C.2.6.5.

5.6 Further attachments
e.g., reprints and manuscripts, information for study participants, questionnaires
6. Further information

We wish to point out that the acceptance of funding obligates the recipient(s) to comply with the rules of good scientific practice. The rules of good scientific practice are described in detail in the German Research Foundation's Guidelines for the Use of Funding (DFG forms 2.01 or 2.02, www.dfg.de/formulare).

In the event of scientific misbehaviour, sanctions may be taken. In particular, scientific misbehaviour is present when false information is supplied in a scientific context, either deliberately or as the result of gross negligence, the intellectual property of others is violated or their research work is impaired. The circumstances of the individual case are decisive.

German Cancer Aid reserves the right to disclose information on the application (name of the applicant(s), topic and objectives of the planned project) to other funding organisations in order to avoid double funding.

A submission of application to German Cancer Aid does not constitute a legal claim to funding. Furthermore, the applicant has no right to claim the return of the application.

Status: 02.05.2014