



Guideline of the German Crohn's Disease/Ulcerative Colitis Association (DCCV) on Research Funding for Primary Sclerosing Cholangitis

This guideline forms part of the approval.

Preliminary remarks:

Funding by the DCCV of research for primary sclerosing cholangitis (PSC) comprises € 150,000. The DCCV's Board of Directors reserves the right of reducing the amount of the award and of dispensing with the granting of it.

The decisive basis of the grant shall be the content-related focuses of research funding mentioned in the programme description.

PSC research funding by the DCCV will be granted to scientists with a degree in science (normally, the degree reached by a doctorate, PhD) in Germany, in German-speaking countries and in the Benelux countries, who discuss new projects on matters of pathogenesis, diagnostics or therapy of PSC in accordance with the programme description. The first objective is to promote research projects that can be assigned to the field of basic research and of which the development of new approaches to PSC therapy can be expected. Furthermore, this research funding programme is open to applicants with innovative project ideas in the diagnostics of PSC (e.g. for (further) development of non-invasive diagnostic methods), for early recognition of PSC complications (e.g. of cholangiocarcinoma) or for therapy of PSC.

The applications will be assessed with regard to scientific quality, the novelty of the study hypothesis, the care paid to the study design, the scope of possible results regarding an improvement in the quality of life of PSC patients in the foreseeable future. The applicant has to describe the significance of the project for the further development of the current state of knowledge and of the possibilities in PSC therapy or diagnostics. Moreover, the assessment of the relevant application will include the scientific qualification of the applicant and the suitability of the research institution for the relevant project.

Grant Conditions:

The DCCV's PSC research funding shall serve for the execution of a research project limited in terms of subject and time. The financial means applied for can be used for paying staff, subject-related costs and travel costs. The grants do not constitute a contract of employment or a service agreement with the DCCV.

The research grant shall exclude the following:

1. the personal salary of the applicant,
2. the salary of clerical staff,
3. funds for building works and equipment installation, rent,

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Steuernummer
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4. funds for general furnishings of the institute (e.g. office furniture, tools, working clothing), stationary,
5. operating and maintenance costs (e.g. electricity, gas, water, maintenance agreements),
6. contributions made to business insurances,
7. means for using university-owned computing centres,
8. means for devices required as part of a modern basic equipment (of the relevant field)
9. means for the complementation or repair of devices not owned by the DCCV and/or not acquired with funds granted by the DCCV,
10. and all other costs either (having to be) assumed by other responsible bodies or bearing no relation to the research project.

The PSC research grant shall be bound by the specific project and not by the financial year.

As the project manager, the applicant shall be responsible towards the DCCV for the proposed research project with regard to the execution of the project as well as for management and invoicing of the funds.

The DCCV expects the applicant to reasonably subject to the rules of the German Research Foundation (DFG), especially to:

- form 1.02 of the DFG: "Merkblatt für Anträge auf Sachbeihilfen mit Leitfaden für Antragstellung" [Instruction leaflet for the application of benefits including a guideline for preparation of the application] and
- form 2.02 of the DFG: "Verwendungsrichtlinien für Sachbeihilfen – Drittmittel - mit Leitfaden für Abschlussberichte und Regeln guter wissenschaftlicher Praxis" [Guidelines of use of benefits and third-party funds, including a guideline for final reports and codes of good scientific practice].

The relevant valid version of these forms can be downloaded from the Internet on the website of the DFG (www.dfg.de).

On the last page of this guideline, you will find a list of the most important differences between the conditions of research funding by the DCCV deviate from the guidelines of the DFG. Any deviations from these stipulations will not inevitably exclude funding by the DCCV but shall be clearly marked as deviations and justified in the application.

Any changes concerning the applicant (a change of the institution, etc.), in the work schedule of the project, the financing conditions (e.g. funding by another institution) or other changes referring to an aspect concerning the awarding of the grant for the research project shall immediately be communicated to the DCCV.

Report of results: A scientific report of results and a description of the results in a manner as to ensure that it can also be understood by a layman (the latter not being longer than two DIN A4 pages) shall be submitted within two months upon expiration of the project period and normally **up to the end to the calendar year following the awarding of the grant at the latest.**



Referring to the DCCV: Furthermore, the applicant undertakes to see to referring to the "Deutsche Morbus Crohn/Colitis ulcerosa Vereinigung (DCCV e.V.)" by its full name including the abbreviation DCCV e.V. in all publications, poster presentations and lectures in relation to the funded project. The DCCV asks to obtain an author's specimen copy of all publications.

Report on the utilization of the funds: Evidence of the utilization of the individual funds shall also be submitted within two months upon expiration of the project, normally until the end of the calendar year following the award of the grant at the latest. Payment of the research grant will be made to the account of a university and/or another research institution. The applicant shall provide to the administration of the institution a copy of the cost and finance plan arising from the application. Towards the DCCV, the calculation evidence of utilization shall be sufficient.

Should the financial means for a project be provided institutions, the DCCV reserves the right to require the applicant and the institution via which the funds are invoiced to provide a detailed break-up of all project funds and evidence of utilization of the individual funds and to review these documents.

Furthermore, the DCCV reserves the right of revoking the grant in whole or in part and to claim reimbursement in case of important reasons requiring reimbursement. This shall especially apply if the application contains incorrect or incomplete information if the funds have not or not exclusively been used for the project described in the application or if the evidence of utilization has not been provided in time or if it has not been maintained in a proper or complete manner.

Grant Procedure:

The research funds are granted after a two-stage application and expert opinion procedure. In the first stage of application, **10 copies of informal project drafts, the scope of which shall not exceed 3 to 6 pages in the English language, must be submitted** to the office of the DCCV **by 31st March 2009**. Subsequent submissions are only allowed within two weeks as of this date.

These application drafts will be assessed by an independent and international expert committee. This expert committee will be appointed by a relevantly commissioned scientist (e. g. the Chairman of the Advisory Board of the DCCV) in close coordination with the member of the DCCV Board of Directors responsible for this field of research.

They will appoint a circle of qualified and unbiased experts renowned in the relevant field of research as well as a chairperson of this committee.

Based on the general target criteria for research funding of the DCCV and the issues focused on in the invitation to application, the expert committee will by majority decision prepare a list stating the priority of the projects to be funded.

The result of the assessment can be expected in June 2009 at the latest. In case of a positive assessment of their project drafts, the applicants will be requested to present a detailed project application (approx. 20 DIN A4 pages) in the English language in the framework of the second application level stating a deadline (3 months as of announcement). The formal funding applications presented will then be assessed again by the international expert committee.

Like during the first stage of the procedure, such expert committee will by majority decision prepare a list stating the priority of the projects based on the general target criteria of research funding of the DCCV and the issues focused on in the invitation to application.

Funding will be granted in the framework of an adequate event depending on the resolution of the Board of Directors. The project manager is expected to be present at the award event.

Form of the application:

1st stage: Informal project draft (3 to 6 pages)

The application shall include the following:

- the designation of the project
- reference of the application to the programme description of the DCCV research funding for "PSC"
- personal data and information on the applicant's current employment
- information on the institution at which the applicant works
- framework of the time for the project stating the date of planned start and end and estimates on the financial expenses of the project
- information on applications with the same or similar subject matters at other institutions

The presentation of the project should not exceed 3 to 6 pages (DIN A4, simple line spacing, type size not smaller than 10 pt) and shall deal with the following issues as to ensure that these can be assessed by the experts:

- the purpose and the scientific aim of the project
- considerations and data used as a basis
- research objectives and design, methods applied
- schedule of the project steps
- short financial plan stating the expenses required for the project
- persons involved stating their field of specialisation, their scientific qualification, the institution and the planned contribution to the project
- significance of the project in relation to PSC and persons affected by PSC
- as an attachment: scientific curriculum vitae of the applicant including an index of his/her publications

The project draft must be signed by the applicant.

2nd stage: Detailed project application

The presentation of the project in the framework of the 2nd stage of the procedure shall comprise 20 pages (DIN A4, simple line spacing, type size not smaller than 10 pt).

Beside a more detailed presentation of the individual contents of the project draft, the project application shall also contain the following:

- Comprehensible summary of the essential targets of the project comprising no more than 20 lines (max. 2000 characters) including the relevance in relation to PSC and persons affected by PSC



- Considerations and data (state of research, targets of the planned project)
- Research design and detailed work schedule
- Detailed schedule of the project steps (if applicable, with definition of the relevant milestones, e.g. completion of the pre-investigations, inclusion of the first or last patient)
- Methods applied, materials used, involvement of test persons or experimental animals
- Detailed financial plan with information about:
 - the expenses required for staff, devices, consumables, travels, any insurances, third-party services (e.g. biometry, data management) and publications and the total costs, including information about the stage of the project in which such expenses are required
 - the amount of funds provided for the project by the applicant's institution
 - other planned or already existing funds for the project (institutions, amount of the funds)
- if applicable, the names of all cooperation partners
- letters of intent of the cooperation partners
- if required, the positive vote of the Institutional Review Board (ethics committee), to be enclosed as an attachment or to be presented to the DCCV by the start of the project at the latest
- if applicable, information on data protection and information backflow to the study participants
- if applicable, information about the draft on the patient / test person information including the patient / test person approval to be attached
- In case of animal tests being planned it must be explained why these cannot be avoided. In this context, the required official permissions shall be applied for and presented to the DCCV prior to the project start at the latest.

The project application must be signed by the applicant.

The most important differences of the rules for DCCV research funding and the guidelines of the German Research Foundation:

- Those scientists are entitled to submit an application, who are working in Germany, in German-speaking countries or in the Benelux countries.
- Normally, the DCCV will not consider any continuation applications.
- Invoicing extra costs exceeding the granted amount of funding is not admissible.
- The DCCV will not pay any lump sum for the programme (or overhead costs, structural fee) exceeding the maximum amount of the grant. If the payment of such a lump sum is stipulated at the research institute this shall be communicated and taken into account for calculation already in the financial plan.
- The DCCV expects that the staff costs included in an application are stated as estimated sums in EURO.
- The acquisition of new devices shall be realised by the applicant or the economic department of the institution by which he/she is employed.
- Normally, acquired devices become the possession of the institution, in the rooms of which they are operated for the duration of the research project, unless otherwise expressly stipulated in the letter of approval for the individual grant. The DCCV reserves the right of requiring the handing over of devices to itself or third parties or to claim compensation for their values if the applicant changes to the institution of another responsible body during the term of his/her research studies. A device will become the inventory of the DCCV only in exceptional cases.
- The costs for travels required in the framework of the research project can only be paid from the means of a DCCV research grant if the individual journey had already been applied for in the application and had been integrated into the cost estimates. Travel costs are only admissible to the amount of the ticket prices of public transport in accordance with the legal travel costs stipulations, unless there are special reasons requiring the use of a car.
- Normally, financing journeys may only include the travel costs but no costs for accommodation or daily allowances.
- The funds of the DCCV research grant shall only be used for congress fees if this has been expressly allowed in the letter of approval.
- Normally, no specialised literature is allowed to be acquired by means of the DCCV funds.

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