



R O T R F

*Roche Organ Transplantation
Research Foundation*



C H A R T E R



Table of Contents

1. Introduction	2
1.1 Description of Research Foundation	2
1.2 Mission	2
1.3 Priority	2
1.4 Research Focus	2
2. Foundation Structure	4
2.1 Chairman	4
2.2 Board of Trustees	4
2.3 Scientific Advisory Committee	4
2.4 Administration	5
3. Grant Application	6
3.1 Review Process	6
3.2 Submission Deadline	7
3.3 Extension of Projects	7
4. Grant Awards	8
4.1 Notice	8
4.2 Grant Budgets	8
4.3 Funds Disbursement	9
5. Application Regulations	10
5.1 Eligibility	10
5.2 Start Date of Awards	10
5.3 Progress Reports	10
5.4 Final Scientific Report	11
5.5 Publications	11
5.6 Patents/Commercial Activities	11
5.7 Equipment	11
5.8 Ethics	12
5.9 Reimbursements	12
5.10 Frequently Asked Questions (FAQ)	12
6. Commencement	12



1. Introduction

1.1 Description of Research Foundation

The Roche Organ Transplantation Research Foundation (hereafter the 'ROTRF') was established by F. Hoffmann-La Roche Ltd in 1998 under Swiss law and registered in Basel, Switzerland. The funding of the Foundation consists of donations from F. Hoffmann-La Roche Ltd, with an initial sum of 25 million Swiss Francs over the first five years and renewal donations of 15, 10 and 17.5 million Swiss Francs for the following eight and a half years (a total of 67.5 million Swiss Francs over 13.5 years).

The ROTRF is a non-profit, autonomous and legally independent medical research charity, which provides operating grants to academic staff at universities, transplant centres and research institutes. The Foundation supports research in solid organ transplantation, particularly where there is an unmet medical need. The Foundation is legally independent from F. Hoffmann-La Roche Ltd and is solely guided by the Board of Trustees according to its charter.

1.2 Mission

The mission of the ROTRF is to advance the science of solid organ transplantation in order to improve the care of the thousands of patients undergoing transplantation every year. The results of the funded research projects will contribute to the knowledge about many aspects of clinical and scientific transplantation, e.g. the mechanisms of long-term organ deterioration, the consequence of tissue injury, and the opportunities to intervene in these processes.

1.3 Priority

The priority of the ROTRF is to support clinically oriented research projects, such as observational clinical studies or studies that use human transplant samples for laboratory examinations.

1.4 Research Focus

The ROTRF supports important and innovative projects in clinical research applicable to the understanding and care of human organ transplant recipients and related tissue transplants, such as islet transplantation. The ROTRF gives priority to projects focusing on understanding the pathogenesis and prevention of human transplantation diseases, including organ injury and rejection, viral

infection, and late graft deterioration. Furthermore, the ROTRF may consider funding research that addresses related clinical issues in non-transplant patients, including hepatitis C infection and inflammatory processes relevant to human organ transplantation. The ROTRF also considers supporting research in new emerging technologies, such as genomics, proteomics and metabolomics, examining the pathogenesis of human disease states in organ transplantation. When animal models are used, the priority will be higher if they simulate the usual human counterpart, e.g. MHC plus non-MHC incompatibilities developing typical lesions seen in human transplants.

If needed, other research areas may be prioritised for further development and support by the Board of Trustees.

The ROTRF funds the following research areas:

- Improvement of long-term graft survival and prevention of chronic organ dysfunction;
- Relevant immune recognition, regulation and effector mechanisms;
- Histocompatibility;
- Inflammation and tissue injury in transplantation;
- Development of new agents for use in transplantation;
- Prospective and specific analysis of human organ transplant populations;
- Induction of antigen-specific unresponsiveness;
- New clinical trial methods and surrogate endpoints;
- Tissue injury and organ preservation relevant to transplantation;
- Cell or tissue transplantation relevant to organ transplantation.

While the ROTRF does not support operating costs for registries, it will consider providing limited support for unique initiatives, such as international databases of general interest to transplant researchers.

Of note:

Research in human cloning is not considered for funding.

Applications for funding of research into transplantation of solid organs that are not yet transplanted in the clinic will not be considered.



2. Foundation Structure

2.1 Chairman

The ROTRF is chaired by an independent Chairman appointed initially for a period of five (5) years by F. Hoffmann-La Roche Ltd.

It is the Chairman's responsibility to oversee that the Foundation's mission and charter are adhered to at all times.

2.2 Board of Trustees

The Board of Trustees (BT) consists of eight (8) Trustees initially appointed by F. Hoffmann-La Roche Ltd. Thereafter the BT will be self-constituting, provided that F. Hoffmann-La Roche Ltd has the right to appoint one (1) Trustee. All of them but one (incl. the Chairman) will be selected as acknowledged leaders in medical and/or scientific aspects of transplantation, and one will be selected to represent the scientific interests of F. Hoffmann-La Roche Ltd. Trustees are appointed for a period of five (5) years. They can be re-elected. The Trustees have the task of developing the strategy for the ROTRF, interpreting the charter, developing the policy by revising the charter, and providing the framework within which the scientific decisions of the SAC will be made. The SAC can refer problematic issues to the Trustees for a final decision.

The BT will give final approval for the number, size and distribution of the grants and has to approve all decisions concerning the budget.

The BT is responsible for the Secretariat, including appointment and operation.

2.3 Scientific Advisory Committee

The Scientific Advisory Committee (SAC) consists of medical and/or scientific professionals who are active and recognised in the field of organ transplantation and the allied sciences. SAC members are appointed by the BT. There are twelve (12) Scientific Advisors¹ whose function is to evaluate, score and comment on the Letters of Intent and the Full Paper Applications submitted to them.

¹ This number may be decreased or increased depending on the workload.

2.4 Administration

The ROTRF grant application procedure is administered electronically via the Internet for the initial Letter of Intent and after a pre-selection via a conventional Full Paper Application.

These activities are co-ordinated through the Secretariat.

The Secretariat can be contacted directly at:

ROTRF

P.O. Box 222

6045 Meggen - Switzerland

Telephone: +41 41 377 53 35

Fax: +41 41 377 53 34

E-mail: admin@rotrf.org

<http://www.rotrf.org>



3. Grant Application

3.1 Review Process

There is a two-stage process:

- Letter of Intent to submit Full Paper Application (electronically via www.rotrf.org)
- Full Paper Application (paper submission)

Initially, all Letters of Intent applications are submitted electronically via the Internet. The Letter of Intent form can be found at the Foundation homepage:

<http://www.rotrf.org>

LETTER OF INTENT

Letters of Intent will contain a brief description of the research project and information regarding the principal investigator and his/her institution. A provisional budget is submitted as part of the Letter of Intent.

Letters of Intent are reviewed by at least 3, normally 4, members of the SAC to assess and score the applications on

1. Relevance to solid organ transplantation
2. Scientific excellence
3. Originality
4. Realistic potential for near term clinical application

A score will be submitted by each of the reviewers to the Secretariat. With these scores, a ranking list will be created. The ranking will be taken into consideration for determining whether an applicant will be invited to submit a detailed grant application. The ranking will be reported to those applicants who were not selected to submit a Full Paper Application.

There is no right of appeal against the decisions.

Within the funding constraints, the ROTRF will try to give each applicant invited for submission of a Full Paper Application a +/- 50% chance for funding. Those applicants invited by the ROTRF to submit this more detailed project will prepare Full Paper Applications for further rigorous review by members of the SAC.

FULL PAPER APPLICATION

The Full Paper Applications will be judged on the same grounds as the Letters of Intent by at least 3, normally 4, members of the SAC and/or ad hoc reviewers. The BT will then review the rankings, evaluations and recommendations of the SAC, but will not generally overrule them, except when requested to rule on problematic issues. The final decision on the number and size of the grants will be made by the BT, usually on the basis of the SAC ranking, evaluations and budget recommendations. A summary of the reviewers' assessments will be provided to the applicants.

There is no right of appeal against the decisions.

Unsuccessful applicants may resubmit new Letters of Intent.

Grants are awarded annually on the date set by the BT.

3.2 Submission Deadline

The Letter of Intent submission deadline is **1st October** of each year.

3.3 Extension of Projects

The BT may, in connection with projects to which a grant has been awarded in accordance with this Charter, approve grant award applications for a project extension, which are submitted together with the final project report and subsequent payment of the last grant instalment (clause 4.3 and 5.4). The BT shall determine the terms and conditions, which such an application will have to meet, as well as define the evaluation process and submission deadlines which will be published on the Foundation website (<http://www.rotrf.org>).

In any case, an application for a project extension shall contain a project motivation, a description of the project, an experimental plan including timelines, and a budget.

The final decision on the size of the grants for project extension will be made by the BT. There is no right of appeal against the BT's decision.



4. Grant Awards

4.1 Notice

Successful grant applicants will be notified by a letter sent from the Secretariat and endorsed by the Chairman of the ROTRF. This notice includes, amongst other things, the dates of the budget period and the amount of the funds authorised for the grantee during the period indicated. Award notices also contain special terms and conditions binding upon the award and refer to all general terms applicable to the award.

4.2 Grant Budgets

Budgets must be specific and should be realistic estimates of the funds required for the proposed research. Budgets must be submitted in Swiss Francs (CHF). The duration of funding is evaluated for each grant individually based on the project parameters involved. Awards are, however, made without assurance of continued support beyond the initial term designated. The maximum amount per grant, which can be awarded for a research project, is a total of 300,000 CHF for a period of 2 years and for a project extension 100,000 CHF for a period of 1 year; most awards will be less than this amount.

The grant is not necessarily designated to cover the total cost of the research proposed. The grantee's institution is expected to provide the required physical facilities and administration services normally available in a research institution. However, each grant (including grants for project extensions) will automatically provide a 10% supplement for overheads, which is included in the total sum awarded, the disposition of which is the responsibility of the host institution and the applicant.

Whenever possible it is hoped that the institution will agree to permit this overheads allocation to be spent on the research project.

The ROTRF does not provide funds for the following items:

- Institutional overheads above the 10% flat rate;
- Salaries of principal investigator and co-investigators;
- Career support grants;
- Tuition;
- Purchase of journals and books;

- Purchase of office furniture;
- Payment of dues and memberships in professional societies;
- Recruiting and relocation expenses;
- Construction and maintenance of buildings;
- Payment of non-medical or personal services to patient;
- Payment of per diem charges for hospital beds;
- Purchase of reprints/copies.

Travel related directly to the research project to communicate new research results is allowed up to a maximum of 2,000 CHF per year.

In assessing the overlap between the grant submitted to the ROTRF and other grants held or submitted by the applicant, the ROTRF relies on the integrity of the applicants. The ROTRF intends to fund independent research projects/sub-projects. The ROTRF will not provide additional funds to a research project already fully funded by another agency. Overlap between the grant proposals submitted and the existing research of the applicant must be specifically addressed by the applicants. Copies of the summary and specific aims of each grant held or submitted by the applicant must be provided, and the applicant must provide a statement of the degree of overlap. If the same project submitted to the Foundation is also funded by another agency the applicant must choose which grant to accept.

4.3 Funds Disbursement

The BT will decide at the time of granting the funds on the manner of funds disbursement depending on the duration and type of research approved for funding. In principle the following process will form the basis: Fifty percent (50%) of the grant is paid 2 weeks after the effective start date of the grant agreement. All but ten percent (10%) of the balance of the grant is provided as progress payments contingent on receipt of agreed interim progress reports. The final ten percent (10%) payment is provided upon satisfactory receipt of a final report by the Secretariat, as per clause 5.4.

All funds are disbursed in Swiss Francs (CHF).



5. Application Regulations

5.1 Eligibility

Candidates must be engaged principally in academic research within the field of transplantation or immunobiology. Grants are awarded to holders of a faculty appointment at a university or institution. However, funds are not awarded to individuals whose salary is derived principally from a commercial organisation in the pharmaceutical or an allied industry.

A principle investigator cannot submit more than 1 Letter of Intent per cycle of 6 months (the same name cannot appear on a Letter of Intent and subsequently on a different Full Paper Application). More than one Letter of Intent may be submitted per university or research centre.

Of note: Post-doctoral investigators are not eligible as principal applicants, but may be co-applicants on an application from their laboratory head.

5.2 Start Date of Awards

Research has to start as soon as possible or within 6 months of approval. Failure to initiate the research study within this period will result in the possible withdrawal of the grant.

5.3 Progress Reports²

Before the end of the first half of the grant period, or earlier if appropriate, an interim progress report must be submitted to the ROTRF Secretariat with attached abstracts, reprints and manuscripts of the project. If there are no published materials credited to the project, the report can be sent via the Internet to the ROTRF Secretariat at admin@rotrf.org. The progress report should be approximately 500 words in length (excluding attachments of no more than one key figure and a reference list) and should describe any progress made on the specific aims of the project as described in the research proposal.

Failure to submit an interim progress report will result in funds being held in abeyance and possible termination of this agreement.

² Progress and final reports are considered critical by the ROTRF to monitor and account for funds which have been disbursed as grants.

5.4 Final Scientific Report

Payment of the final ten percent of the grant award is contingent upon the ROTRF's receipt of a satisfactory final project report within sixty (60) days of the Estimated Completion Date, or in no event later than ninety (90) days. The final project report should be approximately 250 words in length (excluding attachments of no more than one key figure and a reference list). Copies of reprints, abstracts or manuscripts in press must be included with the final project report.

Final reports are essential for the function of the Foundation. Failure to submit final project reports may affect both the applicant's and institution's eligibility for subsequent funding from the ROTRF.

5.5 Publications

The publication rights of the grant-holder are in no way restricted by the support of the ROTRF. However, the support received from the ROTRF must be acknowledged in every relevant publication and presentation, and the ROTRF's name given in full. A reprint or electronic copy of every publication is to be sent to the Secretariat.

5.6 Patents/Commercial Activities

In the event of a research project giving rise to utilisable discoveries, it is the task of the beneficiaries to settle the property rights amongst themselves or with a third party and to inform the ROTRF accordingly. F. Hoffmann-La Roche Ltd makes no claim to participation, but must be considered equal to third parties in the commercial exploitation of such discoveries.

5.7 Equipment

All equipment requested must be for research purposes. Applicants must give a full description of all equipment including cost and technical data. The equipment will become the property of the host institution, which will be responsible for its accommodation, operating, servicing and insurance costs. Items of equipment costing less than 20,000 CHF will normally be considered part of the project grant application.

5.8 Ethics

The ROTRF is bound by its objectives to maintain and promulgate the highest ethical standards in experimentation and clinical research and to maintain the highest standards in the conduct and assessment of research.

RESEARCH INVOLVING HUMAN SUBJECTS

All research involving human subjects should be performed in line with the World Medical Association Declaration of Helsinki amendment 2000 and note of clarification 2002 and 2004 or as expressed in the latest version of the World Medical Association Declaration of Helsinki (available at <http://www.wma.net>).

RESEARCH INVOLVING LABORATORY ANIMALS

The proper care and humane treatment of laboratory animals involved in activities supported by grants from the ROTRF is the responsibility of the institution that receives the funds awarded. In order to provide for the adequate discharge of this institutional responsibility, no grant for an activity involving laboratory animals shall be approved unless the application for such support has been reviewed and approved by an appropriate institutional committee according to national standards.

5.9 Reimbursements

The BT may demand the reimbursement of funds, which either have been or will be used contrary to the aims of the ROTRF or in contravention of agreed conditions.

5.10 Frequently Asked Questions (FAQ)

The FAQ section on the Foundation homepage (FAQ) (<http://www.rotrf.org>) contains updated answers to frequently asked questions.

6. Commencement

This revised Charter becomes effective as of 22nd July 2013. This revised Charter may be amended by the BT at any time. Any changes will be published on the Internet site of the Foundation (<http://www.rotrf.org>).



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