

Fondazione Italiana Sclerosi Multipla onlus
[Italian Non-Profit Multiple Sclerosis Foundation]

GENERAL REGULATION

FUNDING OF RESEARCH PROJECTS AND FELLOWSHIPS ON MULTIPLE SCLEROSIS

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un mondo
libero dalla SM

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INTRODUCTION

AISM AND ITS FOUNDATION

The *Associazione Italiana Sclerosi Multipla* [Italian Sclerosis Society] (AISM) was established in 1968 to represent the rights and hopes of people with multiple sclerosis (MS). In over forty five years of activity, the Society has grown to become one of the most important realities in the Italian non-profit area and it is an ONLUS, a Socially Useful Non-profit Organisation. In compliance with the Italian law on non-profit organisations, in 1998 AISM entrusted its commitment to scientific research to the *Fondazione Italiana Sclerosi Multipla* (FISM), also an ONLUS, which is carrying on AISM's efforts.

Directing, fostering and funding scientific research on multiple sclerosis is one of the strategic principles, on which FISM bases its mission for “an MS-free world”. Today the Society, together with its Foundation, is the only Italian organisation that provides all-round action against multiple sclerosis through the promotion and enhancement of scientific research, the promotion and performance of national and local services, the representation and affirmation of the rights of people with MS for their full involvement and autonomy.

The *Associazione Italiana Sclerosi Multipla* has innovated the approach to the selection of excellence scientific research in Italy by introducing the peer – review for the first time in 1986, when it was not in use in our Country. The AISM and FISM acts as a network with the other international Associations and with the Multiple Sclerosis International Federation, MSIF – like the International Progressive MS Alliance. Together, they represent the main funding source in the world for multiple sclerosis research.

In the last 27 years in Italy over 61.3 million Euro have been invested by AISM and FISM in scientific research for research projects, fellowships, special projects and specific initiatives.

The Foundation, in line with the strategic three-year research plan, finances scientific research and the training of researchers through an annual call, calls for special programmes, and special projects, also taking part in international initiatives, as well as through the promotion and funding of centres/networks of excellence, the creation and funding of research infrastructures.

(see also www.aism.it)

GENERAL PRINCIPLES AND RULES

1. GENERAL CRITERIA FOR ELIGIBILITY AND ASSESSMENT OF APPLICATIONS

The FISM researcher must know the strategic goals governing research of the Foundation, as well as funding mechanisms and rules that regulate the research activity and/or access to the resources provided to cover its proposal design. Applications for funding must therefore conform to the mission and institutional objectives of FISM as well as to FISM's Code of Ethics and any derived charters, and comply with the specific indications and provisions intended for the specific funding lines.

Such funding applications must however be of interest and relevance for Multiple Sclerosis.

No funding applications will be admitted, which do not conform to FISM's institutional objectives or are not of interest or relevance for multiple sclerosis. Furthermore, no funding applications from profit organisation or from people, institutions or structures working in connection or on behalf of the aforementioned profit organisations will be admitted.

The relevant assessment shall conform to and comply with the general and specific principles and criteria defined in this Regulation, in full harmony with the *Policies* and *Guidelines* on scientific research issued by the Foundation, as applicable at that moment.

Applications for funding received by the Foundation, which are recognised to be eligible due to their conforming to the above objectives and the correctness and completeness of the documents filed as per the subsequent paragraph, will be evaluated by the Scientific Committee appointed by the Foundation, which will define the list of priority of the proposals to be submitted to the final decision of FISM's Board of Directors.

FISM's appointed Scientific Committee and Board of Directors reserve the right to submit the applications, once they have been included in the priority list by the same Scientific Committee, to the examination of the Ethical Committee appointed by FISM.

2. APPLICATION FILING PROCEDURES

Funding applications are to be made on the forms provided on the www.aism.it/bandifism website after registration of the project manager. **The registered user must necessarily be the same as the proponent of the funding application.**

Applications must be made within the stated periods and uploaded on the software (the software will not allow sending applications after the set deadline). The software will not allow exceeding the space limitations indicated in the "Instructions" per each section of the forms. It is possible to enclose additional documents with the application.

Applications submitted to the Foundation must be complete in all parts. No application shall be considered unless it is complete with all required information, clearly indicated in the proper form, in the instruction for filling in the applications and in this regulation. In particular, providing the information regarding "other available funds" is mandatory.

As applications will be submitted to the assessment of international experts, they are to be presented in English.

IMPORTANT NOTICE. A scan properly signed of the page of acceptance of this regulation and of FISM's By-Laws, Code of Ethics and any derived charters, as well as of the indications concerning personal data processing (FISM rules) must be sent to FISM by registered letter or certified mail, not later than **30 days** from the online application.

In the case of sending the aforementioned documents by e-mail, they shall be signed by digital signature certificate and sent in place of the original.

3. PRINCIPLE OF UNITY OF THE FUNDING APPLICATION

Within the same Call, a researcher/fellow may only submit one funding application for a unitary project/activity.

Unitary project shall mean an organic research and/or study programme, complete in itself even though involving several steps, either successive or simultaneous.

It is therefore not possible to divide a project into various sub-projects coinciding with the single steps of the unitary project, or to break it down into diverse funding lines (even though a single sub-project is led by another researcher).

Also, it is not possible to sub-divide a (two-year or three-year) project into single annual projects.

If a unitary research project provides for lines of development (possibly implying other, separate projects) depending on the possible outcomes of the study, the lead researcher, to the extent known at that time, shall give evidence thereof within the application and within the interim scientific report (progress report).

At the moment of filing the application, in case a researcher is planning to submit also a funding application for a special project during the same year, they undertake to declare it in the application form.

If a research, project or fellowship previously funded through a FISM Call is still in effect, no other application shall be allowed for any of the planned funding lines, except for projects or fellowships that provide their own term in the current year and for the line relevant to special programmes and for those special projects to which, due to their characteristics, FISM has recognised a possibility of development as per the above period.

4. RESEARCH TEAM

Provided that the researcher who has submitted the funding application holds liability and is the reference person for the project, FISM appreciates the involvement of several researcher groups in the same unitary project, as well as collaborations with foreign centres, with a view to enhancing resources and knowledge.

Conversely, it is not possible to change, reduce or extend any of the people indicated in the application as the leaders or contributors of the research team, save for specific, justified requests previously and expressly accepted by FISM, however due to exceptional circumstances and without jeopardising the rational and the objectives and results of the project/activity in any way.

5. IMPLEMENTATION, SCIENTIFIC AND ECONOMIC REPORTS

Execution

The researcher must act in accordance with and subject to the applicable general and specific existing national and international laws, and adopt safe working practices, taking, in particular, the necessary precautions for health and safety and, in any case, respecting the existing rules at the institution in which it operates and the directions given by the Ethics Committees of reference.

The researcher must also ensure full awareness and compliance in its work with local regulations regarding the processing of personal data.

The researcher and the body that houses it undertake not to disclose the personal information of people who have directly participated in the research project. If you need to communicate or otherwise disseminate the results of research that has involved people, the researcher and the Authority undertake to do so only in anonymous and aggregate form, in order to avoid that the individual may be in any way recognized or recognizable. The researcher must also ensure the utmost respect for the dignity of people with MS, resulting in a proper involvement and awareness, through a correct communication plan.

Scientific and Economic Reporting

The researcher must be aware of the nature of the funds used to finance projects, from sources such as private law fundraisers, donations, bequests, or by government grants, if any, FISM wanting and having to account for the best use of funds to different carriers of interest.

The implementation of approved and funded projects and fellowships (especially if financed with public funds) shall conform to and comply with the general and specific principles and criteria defined in this Regulation, in full harmony with the *Policies* and *Guidelines* on scientific research issued by the Foundation, as applicable at that moment. The funding beneficiaries shall therefore comply with the above throughout the study and/or activity. FISM will make them easily known through a dedicated space within its website.

Each contribution granted by the Foundation is identified by a code defined upon the allocation, to be necessarily used in correspondence quotations and relevant publications of results.

Any equipment/apparatus bought through funds granted under this regulation shall however remain the property of FISM, their availability and utilisation by the researcher/fellow at the institution/entity where they operate being intended as a free loan for a duration equal to the duration of the project/fellowship. Upon cessation of the project/fellowship FISM reserves the right to consider a possible extension of the availability of the equipment/apparatus, still as a free loan, or to demand restitution thereof within the date and according to the forms and procedures set forth by the same FISM.

All beneficiaries of funds granted by the Foundation, whatever their nature (research project, research or career fellowship, or special project) shall provide accurate scientific and economic reports of the same.

Such scientific and economic reports shall be made in the forms and within the dates set forth for each funding line. Failing to comply with the reporting obligations shall amount to non-compliance and shall be evaluated to draw the relevant consequences.

It is pointed out, in particular, that apart from complying with the rules and practices of the entities, to which the researchers/fellows belong, the economic reports must respect criteria of:

- a) consistency of each cost with the contents and activities included in the funding: no costs shall be considered if they do not strictly relate to the activities indicated in the application and are not directly aimed at the implementation of the project/fellowship;
- b) matching costs to time: no costs shall be admitted, which were prior to the fund allocation or which exceed the time limits of the activity, even further to extensions, or which occur during a suspension of the activity pursuant to the provisions set forth in the following paragraphs;
- c) accrual and traceability of the cost: each cost shall be duly proven by suitable supporting documents in accordance with the specific rules and administrative procedures set forth by FISM.

In any event, in case of lack of or partial scientific and/or economic reports, FISM shall claim back all unjustified amounts by enforcing, where appropriate, the warranties given under paragraph 14 (Warranties on the transfer of funds).

Lack of or incomplete final reports, either scientific or economic, by the dates set for each funding date, will entail the restitution of any amounts advanced. In case of late or incomplete scientific or economic reports at the interim dates set for each funding line, FISM shall proceed to revocation under paragraph 7 (Suspension, waiver, interruption, revocation) stopping further payments and claiming back any amounts paid before that date.

6. EXTENSION – REFORMULATION - VARIATION

Extension

Projects and grants must be implemented, taking into account the indications contained in the application, within the period set by FISM in its acceptance notice.

For exceptional circumstances of personal or organisational nature, or of force majeure, a researcher who intends to apply for an extension shall file a specific application for extension (respectively endorsed by the reference organisation or, for fellows, by the Mentor) concurrently with the filing of economic or scientific reports, and however promptly, as soon as there is evidence of the extension being actually necessary.

Such extension request must be well-reasoned and justified by the funding holder, meet actual logics of preservation/improvement/enhancement of the usefulness and validity of the study project/activity and in order to be effective, it must be previously and expressly approved by FISM.

Extensions for two-year or three-year projects may have one year validity maximum and it shall be the responsibility of the applicant to prove that the deferment does not impair the rationale, objectives and results of the project/activity.

Annual projects cannot, as a rule, be extended.

Fellowships awarded by the Foundation shall not be extended except for the senior research grants that may be extended for further two years, following a request of extension and a positive assessment of the FISM Scientific Committee.

In any event, no grant shall be automatically extended, the express and prior acceptance by FISM being always required.

Reformulation - Variation

In case of applications concerning research projects, upon filing a progress report, the proponent shall be entitled to request an extension of the funding, with the limits and at the conditions specified above, and a partial reformulation of the research programme steps, or a variation of use of the funds from one cost macro-item to another, if justified by the results achieved in the first year or two years.

However, the reformulation of steps and research activities or the variation of use between cost macro-items, for projects of any duration, must not exceed 20% of the total amount of the contribution, save for exceptional circumstances that may be considered by FISM case by case.

The application for funding extension, in terms of duration but also of further funds in addition to those already granted, shall be considered as a new funding application for a new, distinct project or fellowship, even though connected with the original one to which it refers, and will be taken into consideration only on condition that it complies under all aspects and in all parts with the rules defined in this Regulation,.

In such event, if a new project/fellowship derives from a project already funded, it will be possible to file an application notwithstanding the provisions of paragraph 3 (Principle of unity of the funding application) even though the project/fellowship already funded is still ongoing: the second project/fellowship, if funded, may not then be started until the first project/grant is completed and the relevant scientific and economic reports have been provided.

7. SUSPENSION – WAIVER – INTERRUPTION – REVOCATION

The submission of application for funding involves and implies the applicant's commitment, which, with the communication of any acceptance, takes on the character of a legally binding obligation, to carry out the project/activity according to the canons and criteria of good faith, fairness, specific diligence, responsibility and seriousness.

Therefore, the following hypotheses of suspension, waiver, interruption shall be limited to exceptional situations.

The beneficiary shall therefore not be allowed to withdraw, or to unilaterally modify any of the constitutive elements of the project/activity, or to resolve all or part of the obligations undertaken, unless this occurs within the limits and at the conditions set forth in this Regulation.

The funding granted by FISM shall therefore be binding, to all effects and purposes, for the researcher/fellow and the institution or reference organisation, or the organisation to which they belong, where the research/fellowship takes place/is implemented.

Suspension

Suspension shall mean a temporary, and not final, stop of the research and study activities. The suspension can refer to exceptional circumstances, due to personal or organisational factors, or to force majeure which may for a limited and defined period prevent or hinder the continuation of the activities and therefore reduce or jeopardise the usefulness or validity of the research activity.

The application for suspension made by the researcher/fellow/funding holder must be accompanied by an authorisation of the reference organisation or, for fellows, of the Mentor.

If the suspension is accepted by FISM, it will imply an extension of the time schedules as originally defined.

Requests for suspension must be made without delay, taking in view the time and manner in which the underlying circumstances have materialised and observing the general good faith, fairness and diligence criteria.

Suspension is normally excluded for annual projects.

For fellowships, the suspension shall not, in any event, exceed six months. Suspensions exceeding 6 months shall imply forfeiture of the fellowship. It will however be possible, if one has not completed the period covered by the fellowship, to apply for a new fellowship, but only once.

Notwithstanding the above, based on the reasons and justifications offered by the researcher/fellow and also in view of the rationale and of the confirmation of the targets and results of the project study despite the longer time required, FISM reserves the right to accept or refuse the application. Therefore, the application for suspension shall have no effect if it is not previously and expressly accepted by FISM: failure to accept it shall have the effects of an interruption of the project/activity under the following provisions.

In case of a suspension extending the research/study until a subsequent call, it will not be possible for the beneficiary to make another application on the new call, in accordance with the general rules defined under paragraph 3 of this Regulation (Principle of unity of the funding application).

The suspension of the project/fellowship shall imply the suspension of payments for the period in question.

Applications for suspension for further periods in addition to those already allowed on the same project/fellowship shall not be admitted.

In case of research projects, in accepting the application for suspension, FISM may demand suitable warranties on the amounts already paid under the provisions of paragraph 14 (warranties).

Voluntary waiver and interruption

Unless it depends on exceptional factors, of subjective or objective nature, or on force majeure, voluntary waiver of projects or fellowships has consequences on the assessment of good faith, fairness, diligence in the fulfilment of the obligations undertaken by the applicant as specified in this paragraph and in paragraph 13 (Liability) and will also have a negative impact on the evaluation of any subsequent applications.

In such cases, the researcher/fellow shall forfeit the funding and any residual amount not yet paid will be retained by FISM. If the Foundation has already made an advance payment, any amount not yet spent at the date of the waiver must be returned, within and not later than 30 days after the cessation of the project/fellowship.

The scientific reporting and activity obligations referring to the period of actual performance shall remain unprejudiced.

Interruption of a project/fellowship is treated in the same way as voluntary waiver if it does not depend on reasons or intent of the funding applicant, but on serious external factors of particular importance.

Waiver of project

If the lead researcher withdraws from it, the project ends and the funding is consequently interrupted. Exception is made for the case that the reference Organisation, within 30 days after the lead researcher's waiver, and in agreement with the latter, files a justified application to FISM, obtaining an express approval, for continuing the project under the responsibility of another researcher until the research is completed. Such application must be accompanied by a curriculum vitae of the researcher who should succeed in the project as required by the call document, as well as offer arguments in support of the maintenance of the rationale, objectives and quality of the project and of the actual achievement of the expected results.

In any event, pursuant to paragraph 4 (Research Team) no lead researcher may be replaced by another researcher without a prior written approval by the Foundation.

Waiver of fellowship

A fellow may renounce a Research Fellowship already underway for personal reasons, notifying FISM at least 30 days in advance.

If the fellow expresses an intent to waive the fellowship during the first year:

the fellowship will be interrupted except for the case under item 2;

if it is a research fellowship and the relevant activity is carried out within a research funded by FISM, it will be possible, upon a prior request from the Mentor, to convert the fellowship into another fellowship aimed at continuing the ongoing research activity. Such request must be previously approved by FISM.

If the fellow waives the grant during the last six months, the grant will be interrupted.

Revocation

In case of serious non compliance, for a long time, with the obligations under this Regulation, particularly as regards the compliance of the project/fellowship activities with the object of the funding, the reporting activity, the observance of provisions concerning scientific integrity, notice of the results, protection of property, respect of FISM's code of ethics and any derived charters and, more generally, with all requirements under Law, FISM reserves the right to revoke the project/fellowship with the same effects as those resulting from waiver and/or interruption.

Revocation will also be possible if impediments or significant changes, either of objective or of subjective nature, are found to affect relevant and significant aspects of the project/fellowship to be approved, regardless of any specific faults of the researcher/fellow or of the reference organisation/Mentor; in no event shall the researchers/fellows and their respective reference organisations/hosting institutions modify elements liable to affect the contents subject to assessment.

The following may, for example and without limitation, constitute cases of change/impediment which FISM may consider as reasons for revocation

- changes in the position of the researcher/fellow resulting in possible incompatibility and/or conflict or however in the reduction or loss of autonomy and independence under the principles of FISM'S code of ethics and value charters, policies, or guidelines;
- changes in the identification of the reference institution/hosting organisation, also in view of the nature and characteristics of the same;
- change in the type and nature of the relation between the researcher/fellow and the hosting organisation
- subjective and/or objective impediments preventing actions for a period exceeding the maximum admitted suspension.

In any event, revocation may take place only after a written notice has been sent by FISM, indicating the serious non-compliance or the change/impediment found and provided that no arguments or justifications deemed acceptable by FISM have been given in writing within the stated period, of no less than 15 days.

The situations resulting in the revocation, insofar as they may be ascribed to the researchers/fellows or reference organisations/hosting institutions, may imply liability to FISM under paragraph 13 below (Liability) and are unfavourably considered in the assessment of any subsequent applications; participation in the subsequent call is however excluded..

Revocation of project

FISM will at first hear all parties, in case of research projects, also involving the reference organisation, even though the conducts and facts underlying the charge refer to the single beneficiary researcher. Thus, if – although the conducts and facts with which the researcher is

charged are proven – the reference organisation is not found responsible in any way for the situation charged, FISM may consider, in agreement with the reference organisation, the continuation of the project with another researcher in the same forms and manners as indicated for the cases of succession due to voluntary waiver of project.

Revocation of Fellowship

A fellowship will in any event be revoked for the following reasons:

- 1) if the Mentor asks in writing to interrupt the fellowship, due to unsatisfactory performance of the fellow;
- 2) if the Mentor of the fellow can no longer train the fellow and a substitute previously and expressly accepted by the Foundation is not appointed by the hosting organisation within 30 days.

8. CODE OF CONDUCT AND SCIENTIFIC INTEGRITY

Researchers and fellows, also pursuant to FISM's Code of Ethics and any derived charters, which they declare upon filing their application that they well know and accept, will act with honesty, fairness, seriousness and responsibility and in good faith in each activity relating to research and study activities conducted by the same, as well as those connected therewith (such as, for example and without limitation, during trial design, data generation and analysis, funding applications, publication of results, recognition of direct or indirect contributions of colleagues, collaborators and others, reports on activities and costs, etc.), always keeping scientific integrity and the superior interest of research as their primary reference in their conduct in view of the fight against multiple sclerosis and of the institutional objectives of FISM.

The researcher must ensure that his project does not reproduce research already done, in order not to run into situations of plagiarism. New research aimed at validating the results of previous studies should remain excluded from the concept of plagiarism means, provided that the data to be confirmed are explicitly identified and explained.

Please note, in particular, that:

1. Plagiarism, deception and falsification of results amount to serious non-compliance under this Regulation;
2. Researchers and fellows are encouraged to notify any misconduct in a responsible and appropriate manner;
3. Researchers and fellows are bound to inform FISM of any actual or prospective conflict of interest, either predating or arising during the research/study activity.

Researchers and fellows are required to ensure their independence from any influence, internal and external, that could be relevant in the conduct of research funded by FISM. It remains understood that FISM, in line with its mission, by-laws, policy and guidelines, as well as with this Regulation, reserves the right to coordinate and direct the activity of researchers and fellows, always respecting the scientific and professional autonomy of each of them, both in assessing and accepting applications and during the implementation, so as to favour their maximum usefulness and validity for the general aim of fighting multiple sclerosis and their maximum effectiveness for people suffering from this illness. Depending on the actual contents it takes, such coordination and/or direction activity may count for the purposes of the following paragraph (contribution to inventive activity).

Each researcher finally agrees to interact and agree with other researchers, with a view to network, in order to ensure the exchange of information and sharing their research results, in the best interests of persons with MS and, in this context, the development of the relevant scientific community.

9. RULES AND POLICY ON ANIMAL USE

FISM recognizes that experiments on animals are often necessary in many areas of biomedical research but proposal submitted for the evaluation MUST state precisely what will happen to the animals and that:

- the scientific objectives cannot be achieved without using animals
- the model chosen is the most appropriate
- the source of the animals, the quality of care provided and the standards to which investigations will be conducted comply with the ethical values of the scientific community
- the fewest animals compatible with obtaining a valid scientific result are used. In this regard, in planning your experiments you should carefully estimate the number of animals needed. You should take into account the likely magnitude of the effect you will be studying and the frequency with which that effect will be achieved for given levels of statistical significance and power.

It is also unacceptable:

- to state that the number of animals to be used is based solely on the calculation of the number of experiments that can be carried out at any given time.
- to state that the numbers are based on “previous experience” without additional justification,
- to answer the question on numbers of animals to be used by paraphrases such as “these numbers are chosen as the minimum necessary to achieve statistical significance”. Too few animals is just as unsatisfactory as too many.

Where experiments using animals are necessary, you are required to strictly adhere to the relevant Italian laws, rules and regulations (D.to L.vo 116/92); moreover, approval by your Institutional Ethics Review Body is mandatory. The ethical review process is a means of ensuring that any use of animals within lab animal facilities is carefully considered, adequately justified and carried out as humanely as possible, so that any adverse effects experienced by the animals are more than offset by the benefits that arise from the study.

Measures should be put in place to avoid unnecessary duplication of research/testing and fully implement the Three Rs (Reduction, Replacement and Refinement, from The Principles of Humane Experimental Technique, Russell and Burch, 1959), from the moment it is recognized that an animal experiment will take place, through the period where the animals are sourced and arrive at the facility, and up to the time they are either dead or have been re-homed. This includes optimizing standards of animal husbandry and care and effective training, supervision and management of all personnel involved.

Documentation must be made available upon request. In addition, if needed, FISM could perform monitoring activity in situ.

10. INTELLECTUAL PROPERTY

In the event that the scientific discoveries made are relevant and present potential new requirements to suggest the exercise of intellectual property rights, given the recognition - in the form prescribed by the law – of the paternity of the discovery and results, the researcher and the host Institution he/she belongs to undertake not to disseminate the results of research before they have been properly assessed by the Foundation. Aspects relating to intellectual property are governed by these Regulations, which each researcher and the host institution is required to comply. Researchers, fellows or participants in the research undertake to notify FISM as soon as possible and however with the progress and final reports, in accordance with the good faith and fairness criteria, either

- a) personally
- b) or through the reference Structure

of any invention or result for which it is possible to obtain a patent, protection, industrial rights or similar, fine-tuned and/or developed by availing, even in part, of resources and/or tools procured, supplied or however made available to the Fondazione Italiana Sclerosi Multipla onlus.

It is specified that if more than one members belong to the research team, or more than one research teams are involved in the project, the following provisions on intellectual property shall apply, and shall therefore be undersigned, by each member of the research team.

The above notice shall provide all relevant elements through an exhaustive and appropriate scientific report.

Being aware that the rights resulting from the invention are governed, except where agreed otherwise, by the applicable law on intellectual property (Legislative Decree no. 30 of 10th February 2005) and, insofar as compatible, by the civil code provisions on joint ownership (Arts. 1100 – 1139 It. Civil Code) the Researcher undertakes to consider FISM, in concert with the reference Structure or the Structure to which s/he belongs, if any, as their first partner for a possible joint development of the invention as regards

- the filing of the patent application
- the economic exploitation of the research results and of their technological transfer.

The Researcher and, for what is in its responsibility, the reference Structure or Structure to which they belong shall grant FISM – without prejudice to the right of the Researcher to be recognised as the author of the invention, i.e. the moral right to attribution of authorship

- a) for patents (or patent applications) filed by the same researcher and licensed by the latter, at least 40% of the net profits resulting from the exploitation of the invention. Such amount shall be due even if the Researcher sells, or assigns the right of use of, the invention patent (or patent application) to third parties;
- b) for patents (or patent applications) filed in the name of FISM, a percentage of the net profits resulting from the economic exploitation of the invention specifically agreed upon between the parties and however not lower than 50%.

It remains understood that in the hypothesis of item 3, letter a), after 5 years from the filing of the application patent without any economic exploitation having began on the part of the Researcher and/or the reference Structure or the Structure to which they belong, the Foundation shall be entitled to acquire the patent, or patent application, and the relevant right of economic exploitation of the invention, free of charge, with the right to assign and/or licence it to third parties without prejudice to the inventor's right to the attribution of authorship. If such condition occurs, the inventor shall be ready to sign all documents as may be necessary to register the transfer of ownership of the patent or patent application.

Please note that the amount under letter a) shall be granted to FISM even in case of exploitation of the invention under secrecy.

The researcher also undertakes

- to mention FISM in all documents or publications referred or however connected with or related to the Foundation's funding, as specified in this Regulation;
- to act so as not to jeopardise in any way the suitable protection of their own and of FISM's rights regarding the aforementioned results, expressly undertaking a secrecy and confidentiality obligation, also with regard to what is indicated in paragraph 10 below (Publications and printed materials).

11. PUBLICATIONS AND PRINTED MATERIALS

Given the confidentiality limit of the preceding paragraph, the researcher and the Institution in which it operates are committed to ensure that the results of their research in any case are

adequately disclosed to FISM, thus guaranteeing a right to clear, timely, correct and complete information.

Pursuant to paragraph 9 above (INTELLECTUAL PROPERTY), considering the profiles that may be significant in terms of protection and defence of the intellectual work resulting from the research activity, in order to protect at best, in the mutual interest, the values and results of such activity, all researchers/fellows shall in that event previously send the Foundation a pdf copy of the publication, report or congress paper which they intend to make during and after the period of the research/fellowship and which, therefore, was supported, even in part, through FISM's funding/fellowship.

Such materials are to be sent at least thirty days before the date scheduled for their disclosure, so as to allow the Foundation, in agreement with the researchers, to assess the opportunity to protect the results of the research. Upon sending the materials, the expected publication date and the name of the magazine are to be specified, or the date and place of the congress, where the disclosure should take place.

Upon receiving or becoming aware of such notice, the Foundation reserves all rights to authorise or not the publication in the forms/contents indicated, it being understood that it will not be possible to proceed to the publication/disclosure before the end of such period and however until FISM has decided in that regard.

If FISM finds that there are elements of interest, it will take contact with the researcher and the structure involved in order to reach an agreement, within the following 30 days, on the possible future developments.

At any rate, and leaving aside the above indications for the protection of intellectual property, which apply to all activities supported/funded under this regulation, in each publication and disclosure activity the Foundation's contribution will always be acknowledged through a note included in the publication or materials, formulated as follows and mentioning, where possible, the identification number code:

"..... Supported by FISM - Fondazione Italiana Sclerosi Multipla onlus grant/ research fellowship n°Cod .2018/R/"

and in the event that FISM informs the researcher that the project was financed or co-financed with "5 per mille" public funding, the publication or material shall moreover specify:

" and financed or co-financed with the '5 per mille' public funding".

Sending the draft publication in advance will allow the Foundation – as said above – apart from the mentioned patent protection measures, where appropriate, also to carry out the activities of a press office for particularly significant works.

Failure to comply with the procedure for preventive transmission of materials relevant to possible publications or congress lectures, as well as failure to notify the activity developments in the progress and final reports, in terms of potential results that may be the object of protection and defence, within the deadlines set forth, shall be considered a serious non-compliance liable to imply the liabilities resting on the offender as well as the block of further funding by FISM.

12. MEDIA RELATIONS

The researcher/fellow shall ensure their availability for any press office activity organised by FISM and shall therefore be ready to contact the mass media in the forms and manners deemed appropriate by the same FISM.

All Press Office activities (issue of press releases, press conferences, media relations) shall be operated and organised directly by FISM, in agreement with the researcher/fellow. The researcher/fellow and the Organisation or Institution where they operate undertake, at the same time, not to develop any press office activity relating to the research funded/co-funded by FISM without a prior consent of FISM.

13. MANAGEMENT OF STAFF, COLLABORATIONS AND SUPPLIERS

FISM shall hold no liability whatsoever dependent upon or deriving from the utilisation of staff and/or collaborators of any nature within the project/research activity, as well as with regard to supplies of goods or services or works contracts put in place within or in consequence of the research project/activity.

Therefore, upon signing the acceptance page of the regulation, the reference/hosting organisation expressly exempts FISM from any liability, even joint or indirect, in that regard.

Also, FISM shall not take the role of employer with regard to the staff committed to the project and fellowship, and therefore it shall not answer in any way for the employment obligations, whether they concern contributions, welfare, insurance, or industrial safety.

Exception is made for the case that FISM, for maximising the usefulness and return of the research activity, should avail of staff and/or collaborators related to FISM, for whom, only in such case, it shall answer as employer/client.

Accordingly, after assessing the funded research project needs in agreement with the researcher in charge, the hosting Organisation agrees to avail of the staff it deems to be necessary and suitable for the implementation of the project, undertaking to ensure compliance with the law on employment agreements and on safety.

14. LIABILITY

The funds granted by FISM under the call come from fundraising, legacies, donations, contributions and, where existent, public subsidies, for which FISM has to give prompt and suitable account to all interested persons. Consequently, FISM must ensure that the use of the funds granted fully conforms, in fact, to the approved projects and fellowships.

For such reasons, in case of serious breaches of the principle of honesty, fairness, good faith, specific diligence referred to the nature and complexity of the activity carried out and, in general, of the principles and common rules of this Regulation and of the legal obligations, and in particular in case of breach of the scientific and economic reporting obligations, FISM reserves the right to act as deemed best with respect both to the researchers/fellows and to the reference organisations/hosting institutions for protection of its own rights and interests and in the superior interest of people with multiple sclerosis and of the pursued cause.

15. WARRANTIES ON FUND TRANSFER

FISM shall only allocate the requested funds after signature of a specific agreement between the same Foundation and the University and/or Institution in accordance with Art. 3, Presidential Decree no. 135 of 20th March 2003. The Foundation reserves the right to revoke the funding even while the project or fellowship is underway if the University and/or Institution does not respect such agreement.

In view of the entity of the amounts granted and of those progressively paid, also considering the time and steps of implementation of the project/activity, FISM may upon the allocation or afterwards request from the reference institution suitable guarantees which, if given for a charge (e.g. insurance guarantee), will be included in the project economic frame. Such warranties may

also be requested by FISM during the project/activity if situations occur, such as to give less confidence in the full spending capacity or in the restitution of any amounts paid but not yet used. The warranties requested and made effective may only be released after that suitable and complete account of the activity carried out is given in due time.

16. AUDITING AND MONITORING

In order to ensure a discussion on the progress of the research project/activity while it is ongoing, FISM reserves the right to organise meetings and interviews – also by teleconferencing – and to have “on site” visits made by specially appointed persons. The reference Institution/Hosting Organisation shall ensure due collaboration to allow such meetings and visits to take place.

17. REPORT MEETING

Participation in the progress and final report meetings organised by FISM is required per each annual period of the duration of the project/fellowship and for the year following the closure of the project/fellowship. In particular, during the National Multiple Sclerosis Week, a scientific convention is organised in May every year, attended by all funded researchers and fellows, who are to plan the costs for such participation when preparing the budget for the project.

18. ANNUAL SUMMARY OF RESEARCH FUNDING

Every year, with the publication of the Summary “*Multiple sclerosis research funded by the Fondazione Italiana Sclerosi Multipla*” FISM gives account of the work of the researchers funded through the research call.

On such occasion, a report is required for the projects ended within the reference year, drafted in English and Italian, which is to include rationale-objectives-results of the research, possible effects for people with multiple sclerosis and a list of the publications, if any, resulting from the funded project.

The annual summary of FISM research funding is disclosed during the National Week and the FISM Scientific Convention.

The publication of the reports in the Annual Summary aims exclusively to inform any third parties about the research projects funded by FISM and, therefore, does not represent an approval or positive evaluation of the results the aforementioned research.

19. FINAL PROVISIONS

For all what is not set out in this Regulation, reference is made to the Foundation's By-Laws, Code of Ethics and any derived charters, Policies and Guidelines and to the Italian Law, which shall apply even when the project/fellowship, or part of it, is implemented abroad, or the people and entities variously involved are foreign.

The Italian Court of Genova (‘Foro di Genova’) shall have exclusive rights to deal with any dispute which may arise out, of or in connection with, the present General Regulation.

This General Regulation is written in Italian and English language. In case of discordance between the two versions, the Italian version shall prevail over the English.

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FISM CALLS - SPECIFIC RULES FOR SCIENTIFIC RESEARCH FUNDING

CONTENTS AND DURATION OF THE PROJECTS

The Foundation supports both basic and applied research, clinical and non-clinical studies of excellence, provided that they are innovative.

The Foundation will consider research projects of one year, two years or three years duration. Based on the assessment criteria listed below, the consistency of the proposed project duration (one, two or three years) with the experimental plan for the same project and the proposed objectives will be evaluated.

Three-year projects must be characterised by a research programme requiring more time for completion and the involvement of researchers/research teams also specialising in complementary scientific areas.

Before submitting a complete research funding proposal, if the researcher deems it necessary, s/he may consult FISM by a written communication in order to verify whether his/her research plan falls under the Foundation's purposes.

APPLICATION FILING PROCEDURES

Applications for loans are to be filed in accordance with the procedures under the paragraph entitled "General Principles and Rules"

ASSESSMENT CRITERIA

Applications shall be evaluated for the following areas:

Relevance of the project for Multiple Sclerosis

- Impact on the knowledge of the MS disease ('proximity to find new pathogenic mechanism': time and research plan required for describing new pathogenic mechanisms)
- Impact on treatment for people with SM (proximity to treatment: time and research plan required for the development of a new, better therapy)
- Impact on quality of life of people with MS (proximity to improve quality of life and social-health care: time and research plan required for the development of a better quality of life and/or better social-healthcare services)

Scientific quality and value of the project

- Originality: contents and method.
- Method: study design and statistical analysis.
Clearly stated hypothesis underlying the project (hypothesis-driven project)
Clearly stated training programme proposed for fellowships for recently graduated candidates
- CV of the proponent and of his/her work team.
- Previous activity (publications)

Feasibility

- In financial terms (expected results vs. costs of research and instrumentation, if required)
- Warranties of the institution where the research or training of the fellows is to be carried out

The assessment shall be made through different measurement scales for the various areas indicated above and a **score** will be awarded to the applications. Also, projects will be examined for the potential novelty of the expected results in terms of production of intellectual works which may be the object of patent rights and/or protection and economic exploitation.

A triage step may apply if a high number of applications is submitted. During this selection, the members of the Scientific Committee, based on their expertise, will apply the measurement scales for each of the above areas, and indicate low scoring projects. All other applications will be evaluated in accordance with the Peer Review assessment process, by appropriate national and international referees.

Interviews

Whenever it is deemed necessary by the Foundation, each applicant agrees to be interviewed by a delegation of FISM's Scientific Committee or by specially appointed staff. The Foundation shall refund travelling costs and daily allowances for such interview to the applicant, after verifying the disbursement and its amount and provided that they are supported by suitable accounting documents

Indication of referees to be excluded in the assessment

The project manager is entitled to indicate 1-2 names of potential referees, by whom s/he would rather not be assessed, due to competition or other reasons. This indication – however not binding for FISM's decisions, is confidential and will be separately sent to FISM to the attention of the Scientific Administrative Office (bandifism@aism.it), by e-mail, together with the computer transmission of the project, stating the title and the proponent who makes the request, as well as the relevant reasons.

PROJECT MANAGERS AND BENEFICIARY ORGANISATIONS

Researcher in charge

Is the person who signs the funding application as lead researcher and is responsible for the conduction of the research. Italian nationality is required.

Lead researcher shall not include its own cost (also as collaborator or advisor) in the “staff “budget item for any reason.

Beneficiary organisation

The Persons in Charge of the Organisation, with which the research is conducted and which is, as a rule, the beneficiary of the funding for contributions to specific research of the researcher (Centre Manager/Director and Administrative Manager) shall sign the acceptance of this Regulation, of FISM's Code of Ethics and of the annexes requiring a specific signature, undertaking to issue any warranties required by FISM against money transfers, and to permit access to the facility.

The Organisation may be based in any country. Applicants must comply with the provisions of this Regulation and annexes thereto, which are an integral and substantial part thereof, as well as, in any event, with the Italian Law and the exclusive jurisdiction of the Italian Court of Genoa.

In case of multicentre research projects, the project coordination manager, the managers, including administrative managers, of each centre, and the costs relevant to each of them are to be indicated.

In filing the application, the person presenting it vouches for the acceptance of the project by the various centres or operational units.

In no event funds for research projects may be granted to pharmaceutical companies or people, organisations or facilities operating in connection with/on behalf of the same.

FUNDING

Amount of funding

Requests for funding cannot exceed 30,000 Euro for pilot projects, 100,000 Euro for annual projects, 250,000 Euro for two-year projects and 400,000 Euro for three-year projects. Requests exceeding such limits will not be considered and will be inadmissible.

Requests for project's staff cannot exceed 30,000 Euro.

For Multicentric studies the aforementioned limit of € 30,000/year for project's staff has to be considered per participating centre.

Availability of other funding sources

Upon the application and throughout the period covered by FISM's funding, a researcher shall have a duty to indicate whether other funds are being used for the same or for related research projects, stating their source, amount and duration. Researchers shall also declare whether other applications have been filed for the same or for related research projects and, as soon as it is known, the relevant result. Such information, to be promptly given to FISM throughout the period of development of the research project, is essential, insofar as FISM's funding may also take the nature of co-financing. Failure to give communication, or late communication of any other existing funding for the same project shall amount to serious non-compliance, and FISM reserves in such cases to take revocation measures under the provisions of this Regulation.

Beneficiary of previous FISM funding

If a researcher obtained funds from FISM, they shall enclose a report stating the use of such previous funding, and a report regarding the results achieved on completing the research, failing which, they will not have access to the new funding requested.

Notice

In the event that the project has been approved, both the researcher in charge and the Organisation, with which the research projects are to be conducted, will be notified by e-mail, followed then by a paper copy, of the duration and amount of the contribution granted and will receive an approved budget with a detail of admitted costs.

Researchers are requested to take into account the comments (if present) and suggestions given by the referees and by the Scientific Council members during the development of their research project and when drawing up their scientific report.

Period

Usually, research projects should start after the approval of the project as stated in the general rules. In particular circumstances, stated upon filing the application, the applicant may submit a request to start earlier, from the moment of publication of the call. FISM will assess such request taking into account the relevance and characteristics of any activities already carried out.

Allocation of funds

Funds will be allocated as follows:

- for pilot projects or other projects of one year duration: 50% at the beginning, 30% after the approval by FISM of the progress report on the activity of the first six months and 20% after the approval by FISM of the final economic and scientific report;
- for two-year projects: 40% at the beginning, 40% after the approval by FISM of the progress economic and scientific report on the activity of the first year and 20% after the approval by FISM of the final economic and scientific report;
- for three-year projects: 30% at the beginning, 30% after the approval by FISM of the progress economic and scientific report on the activity of the first year, 25% after the approval by FISM of the progress economic and scientific report on the activity of the second year, and 15% after approval of the final economic and scientific report.

For the assessment of the progress reports and final reports, FISM may avail of ad-hoc Committees and make on-site verifications in accordance with the provisions of the general rules.

In case of complexity or delays occurred during the implementation of the project, verified by FISM through the scientific or economic reporting or the auditing and monitoring visit through the forms of access granted to it as above, FISM may define various procedures and dates for the payment of the residual amounts, in more instalments and with lower advances, without prejudice to the general rules on suspension or revocation of the grants, where appropriate.

In the event that the final scientific and economic report is not approved by FISM, the latter may demand that the Beneficiary Organisation repay any sum previously paid by FISM in order to guarantee the continuity of the Project.

Unspent funds

Even though the expense estimates are realistic, it is possible that part of the contributions remain unused at the end of the research. Such funds shall be returned to the Foundation on a mere request, promptly and however within and not later than 30 days from the said request, to allow the latter using them for funding other research projects.

Invariability of the amounts granted

The funds granted are fixed and unchangeable. Nevertheless, during the research period, additional funds may be requested in absolutely exceptional cases, duly proven with regard to the objectives and expected results, or due to the need to deal with unforeseen and unforeseeable situations. In order to be assessed by the Foundation, such requests must include a justification, supported by documents, of the needs underlying it. In any event, the Foundation shall have no obligation to accept such additional funding applications.

Transfer of the contribution

Transferring a contribution from one Organisation to another one further to the transfer of the researcher in charge is not permitted, as a rule, as the key elements of the project cannot be freely changed. In entirely exceptional cases, on a justified and well-reasoned request, a transfer may be possible, after the prior approval of the Foundation, given in writing by registered letter or certified email. Concurrently with the transfer application, a new application is to be filed, with a cost budget, which is also to be approved by FISM. Moreover, the Organisation, with which the funding relationship is interrupted, shall submit to the Foundation a detailed report of the costs and return all and any unspent amounts to the same Foundation before the transfer takes place. No funding

interruption will take place if the grant transfer application is received by the Foundation at least 90 days before the date, on which the transfer is to take place, always provided that the application is accepted.

Multi-centre research

In case of involvement of more than one centres in one project, grants will be allocated to the coordination centre, and possibly to each centre, based on the indications previously given in the application and specifically approved. Progress and final reports shall be gathered and drafted under the responsibility of the project coordinator, who shall send them to FISM within the stated deadlines.

FINANCIAL MANAGEMENT AND REPORTS

Financial management

The funds allocated will be transferred to the Organisation which is the funding beneficiary indicated in the application. Such Organisation is usually the Organisation with which the leading researcher operates. In particular cases, upon the submission of suitable documents, FISM's Board may examine requests for allocation of funds to an Organisation other than the one where the lead researcher operates, but however interested and involved in the research.

The funds allocated for research projects may be directly managed by FISM on an express written request of the lead researcher.

Economic-financial reports

The final report for all costs incurred for the project is to be submitted to the Foundation within 45 days of the end of the project. For multi-year projects, the economic – financial reports are to be submitted within 45 days after the end of each year.

For such purpose, FISM will supply the researchers, before the conclusion of the project, with the forms for submitting the accounting reports.

Scientific reports

A final report is required within 45 days of the project expiration date. A progress report is required within 45 days of the expiration of the first and second year of a three-year grant, within 45 days of the expiration of the first year of a two-year grant or within 45 days of the first 6 months of an annual grant. The progress report and the final report shall be compiled on line on proper forms which will be made available, and shall include:

- 1) the summary of the original project, as submitted in due time.
- 2) a summary of the research conducted;
- 3) a clear and concise illustration of the various steps of the research and of the results achieved, pointing out those, which the researcher considers to be important; in the absence of positive results, the work carried out, the difficulties encountered and the reasons of the negative outcome of the research should however be described.
- 4) a complete bibliography of posters, reports, articles, materials published after FISM's approval, or which are being published or prepared, referred to the funded project. The bibliography shall be indicated in a complete manner (all authors, year, front and end page, title) and must relate to the funded project or fellowship;
- 5) additional materials (pictures, .pdf files of the works, of drafts or of manuscripts) may be enclosed and will be part of the report, which the referees and the Scientific Committee will be allowed to consult.

- 6) a report on how the results of the research represent, or may represent if further developed, an actual benefit for people with MS, in particular in identifying better therapies (either curative or symptomatic) or an improvement of living conditions and quality of life.

Failure to send the reports within the above deadlines shall imply the suspension of the funding settlement and any unjustified amounts will be claimed back according to the general rules.

FUNDING FOR SPECIAL PROJECTS

DEFINITION AND CONTENTS

In specific cases, FISM can contribute to funding of “Special Projects”. Special Projects includes:

- proposals for wide-ranging projects concerning particularly important and innovative issues and involving the collaboration of various senior researchers, or various national and/or international centres/networks of excellence;
- proposal for the construction of a large equipment or a very expensive service that aims to provide an operational tool for a wide audience (scientists and/or people with multiple sclerosis),.

Those wishing to submit a proposal for a special project, they can do so at any time of the year, as the possible financing will be borne by dedicated funds.

Proponents of a special project will still have to register and submit the project via computer, using the form provided on the site www.aism.it, which should describe the project, the completion time, the utility, the users, the cost, the co-financing and the contribution requested from FISM.

A researcher shall not submit a funding application for a special project if they have already been funded for a project having the same or similar scope within annual call.

Special projects are subject to the general provisions laid down in this Regulation; if needed, greater and more detailed regulation should be defined at the beginning of the special project.

FUNDING FOR SPECIAL PROGRAMMES

Special programmes may be the object of special calls, endowed with funds devoted to research scopes which FISM considers as priorities for people with Multiple Sclerosis according to the strategic directions developed by the Foundation also in collaboration with foreign Associations and/or Foundations engaged in overcoming Multiple Sclerosis.

PARTICIPATION PROCEDURES

The special call will indicate the specific procedures for participating in the same.

ASSESSMENT CRITERIA

Special programmes will be assessed through a process similar to the one used for annual calls, possibly appointing ad-hoc Scientific Committees.

Special programs are subject to the general provisions laid down in this Regulation; if needed, greater and more detailed regulation should be defined at the beginning of the special project.

FUNDING FOR RESEARCH FELLOWSHIPS

DEFINITION, CONTENTS AND BENEFICIARIES

The Foundation encourages the recruitment of young researchers in the field of multiple sclerosis research through two fellowships, for an amount not exceeding 25% of the total call amount.

In the requests for funding of fellowships, recipients must indicate if their fellowship is associated with a research project presented in the same FISM Call. If the associated project is not funded, the fellowship cannot be assigned, but if the project is financed, the associated fellowship will be then evaluated for potential funding.

Research fellowships

They are intended for promising and motivated young people, when the training programme supported through the Foundation's grant increases their chance to carry out significant and independent research into Multiple Sclerosis or they may be accessed by graduates (with a master's or specialist degree) already able (as proven by their curriculum) to propose and carry out an autonomous research project or to autonomously conduct a well-defined part of a more broad-based research project of the mentor. Such fellowships may relate to applications for grants for scientific research, but applications must be autonomous, compiled on forms available on the website and not included within research funding applications. Such applications must contain a detailed training or research programme and shall be assessed on the basis of such programme, as well as of the mentor's research project (to be shortly summarised); preference will be given to the former. The Mentor shall submit and sign the training or research plan that s/he intends to develop for the researcher in question.

"Senior" research fellowships

These fellowships are reserved for graduates who propose an autonomous research programme, and whose curriculum clearly shows that they are able to formulate and carry out an autonomous research project. Apart from the research programme, therefore, the following curricular aspects will be considered:

1. PhD or Master's Degree
2. Seniority of degree or PhD.
3. Any periods of specialisation with qualified Italian/foreign Institutions.
4. Qualification in issues and techniques relating to the project.
5. Previous experience in the field of research into multiple sclerosis.
6. Scientific publications, with particular attention to the quality of the magazines where they are published, the position of the proponent's name among the authors, the issues dealt with.
7. Any invitations to international congresses.
8. Any special assignments or previous fellowships granted.
9. Any funding from national or international Agencies.

Citizenship

Italian citizenship is not a requirement, except for the case that the fellowship is utilised outside the Italian territory.

Institutions and Mentors

It is the responsibility of the applicant to reach agreements for their own training with Institutions and Mentors.

Duration of the Fellowship

Research fellowships have a maximum duration of two years.

Senior Research fellowships instead have a maximum term of three years with the possibility of renewal for a further period of two years, depending upon a request of extension to FISM and a positive assessment by FISM Scientific Committee.

Those who have been awarded a two-year research fellowship may request a senior research fellowship in a subsequent call. This way, FISM intends to incentive the continuity of research of young people for a period up to seven years.

Exclusions

Fellowships are not granted for clinical training aimed at completing mandatory internship or post-graduate specialisation, or for the performance of duties pertaining to a technical role. Fellowships cannot be used to remunerate those whose primary responsibility is teaching and/or routine work, although fellows are encouraged to devote a reasonable portion of their time (up to 10%) to such activities.

ASSESSMENT CRITERIA

For research fellowships, the fellow's curriculum and the proposed training plan shall be assessed, together with the research project, in accordance with the procedures indicated for research projects (see page 17).

Preferential titles

The assessment is based on the application submitted, complete in all parts, on the training curriculum and of any publications in the relevant field. The indication that, at the end of the training period, the fellow has the opportunity to continue working in a Research organisation and/or an Assistance and research organisation interested in issues relating to multiple sclerosis is also a preferential element.

Ineligibility

FISM's fellowships cannot be granted to assignees of other fellowships or regular pays (PhD students, specialisation students, research associates, etc.). No fellowships will be granted to employees of pharmaceutical companies.

FILING OF APPLICATIONS

Period

Applications for fellowships are to be submitted within the dates indicated by the call, on forms published on the website in accordance with the general rules.

FINANCING

Economic grant

Grants vary depending on the type of fellowship and the location, where the fellow carries out the research relating to FISM's fellowship. The maximum amounts are indicated by typology:

- Research fellowships:
the annual amount is Euro 24,000 for fellowships used in Italy, and 33,000-38,000 Euro (depending on the hosting country) for those used abroad.
- "Senior" research fellowships:
the annual amount is Euro 32,000 for fellowships used in Italy, and 40,000-45,000 Euro for those used abroad (depending on the hosting country).

Grants will be paid directly to the fellow, in monthly deferred instalments.

Travelling expenses

Funds may be exceptionally allowed to cover the cost for travelling only from Italy to other European and extra-European countries or vice-versa, and only for the beneficiary of the fellowship. The amount will be sufficient to cover return tourist class airfare or equivalent. Half of the funds allocated for travels, where granted, will be paid with the first contribution. The residual funds for travels will be paid with the last contribution of the fellowship.

The fellows are required to attend each year a Scientific Convention organized by FISM in May during the National Multiple Sclerosis Week and for this FISM request to plan the costs for such participation in the budget.

Allowances to the hosting Organisation

An allowance not exceeding € 2,000 per year may be given to help the host Organisation to pay off the costs of the fellow's activity as a lump sum, but only when such funds are requested in the original application and approved by the Foundation.

REPORTING

Financial reports

Reference is made to the general rules, insofar as applicable.

Scientific reports

A final report is required within 45 days of the fellowship expiration date. A progress report is required within 45 days of the expiry of the first year of the fellowship, if it is a two-year fellowship, and within 45 days of after 6 months if it is annual. Both the progress and the annual report are to be approved by the Mentor in case of training fellowships. Reports must be prepared and sent on proper forms available on line.

Funds will be suspended and the fellowship will be revoked, claiming back any amounts paid, if the progress report is not sent within 45 days following the expiration date. The last instalment of the fellowship will only be paid after receiving the final report. If the report does not arrive within 45 days of the expiry date, such instalment will not be paid.

“RITA LEVI MONTALCINI” CAREER FELLOWSHIP

DEFINITION AND CONTENTS

FISM intends, through the career scheme, to enhance the career of Italian scientists, selected and assessed exclusively on the basis of excellence and independence criteria. FISM intends by this funding to help bringing qualified Italian researchers back from abroad or transferring qualified researchers from an institution to another in Italy, by providing a three-year fellowship and three-year funding for an autonomous research project, also including, if it is the case, buying everything necessary to set up a new research activity.

This three-year fellowship cannot be awarded to people already working for the institution where they intend to carry out the fellowship activity.

BENEFICIARIES CONTENTS AND ASSESSMENT CRITERIA

These fellowships are reserved for researchers, already of international standing, who propose an independent research programme, and whose curriculum clearly shows their scientific maturity and expertise in the field of the proposed research. Apart from the research programme, which is to be original, wide-ranging and with future development prospects, therefore, the following curricular aspects will be considered:

1. Seniority of degree or PhD.
2. Periods of research carried out in qualified foreign Institutions.
3. Assessment of results achieved with previous fellowship, funding, or research projects funded by FISM.
4. Qualification in issues and techniques relating to the project.
5. Previous experience in the field of research into multiple sclerosis.
6. Scientific publications, with particular attention to the quality of the magazines where they are published, the position of the proponent's name among the authors, the issues dealt with.
7. Invitations to international congresses.
8. Special assignments obtained.
9. Previous positions in the laboratories where they worked.
10. Previous funding from national or international Agencies.

This three-year fellowship cannot be renewed. At the end of the Rita Levi Montalcini (RLM) fellowship, FISM may consider, in agreement with the Institution that hosted the fellow, the opportunity to fund a further research programme. This programme will be considered only if the hosting Institution does not have the possibility to finance the candidate.

FINANCING

The fellowship should not exceed the initial salary of an associate professor (40-50,000 Euro before taxation) and the research award shall not exceed 110,000 Euro for the first year and 80,000 Euro for each of the following two years. The 2nd and 3rd year financing will only be given after an assessment by FISM of the activity actually carried out and, therefore, of the scientific results achieved at that moment.

The hosting institution shall give assurances on the space and facilities (equipment, staff etc.) available and on the independence granted to the researcher.

REPORTING

Financial reports

Reference is made to the general rules, insofar as applicable.

Scientific reports

A final report is required within 45 days of the career fellowship expiration date. A progress report is required within 45 days of the expiry of the first and the second year of the fellowship. The reports are to be prepared and sent on proper forms available online.

Funds will be suspended and the fellowship will be revoked, claiming back any amounts paid, if the progress report is not sent within 45 days following the expiration date. The last instalment of the fellowship will only be paid after receiving the final report. If the report does not arrive within 45 days of the expiry date, such instalment will not be paid.

INSTRUCTIONS FOR THE PREPARATION OF FINANCING APPLICATIONS

GENERAL

How to use the software

- Registered users only are allowed to use the software for filling in forms.
- **The registered user has to be the applicant of the project.**
- If you wish to stop filling in the form and resume it later on, click **“save and close”**.
- The number of characters to be used to type your answers to the form questions is limited and cannot be exceeded. The number of characters includes spaces. Each paragraph mark is two characters. These spaces are large and do not need to be fully used.
- After filling in the form, please first validate your application by using the Validation Summary, then save and close the application by clicking on the **“Submit the application”** button.
- If you wish to print the form, click **“PDF of the application (Print)”** and print the PDF file that has been saved.
- If the form is not sent, please check that all compulsory fields have been filled in. If users think they do not have to fill in all compulsory fields (e.g. those fields concerning budget), please type “0” in the corresponding box.

How to fill in the form

- Application forms must be filled in English.
- Application forms must be fully filled in; if they are not, they will be excluded from the assessment process.
- Users are asked to be clear in order to ease the assessment work carried out by referees and the Scientific Committee of the Italian MS Foundation. Please use technical jargon, acronyms and abbreviations as little as possible, so to make it easier for people who are not experts in those fields to read the forms.
- Application forms ought to be text files. Should research projects be proposed, additional files may be attached (e.g. images, tables or charts, procedure details etc.); however this is to be done only if deemed necessary. Referees will rather choose concise and clear projects, which contain all details needed to assess the project.
- **ATTENTION.** Upon submit an application form, you are asked to print, accept and sign the FISM (Italian MS Foundation) regulations and those terms and conditions concerning the privacy laws (FISM rules). The page has then to be scanned and attached to the application form to be sent with it. If you are applying for training or research fellowships, please scan your adviser's and the applicant's letters (this is an optional choice). As for Rita Levi-Montalcini career fellowships, what is needed is attaching the scanned letter of the Director of the host Institute.

RESEARCH PROJECTS

Title of research project (maximum 200 characters)

The title of the Research proposal must provide the necessary information concerning the proposal. It must be short and easily understandable, even to inspectors who are not experts in the field of the project. For technical reasons, please do not use capitals when writing down the title of your research proposal.

Duration and type of project

Please add the envisaged duration of the project. If this is a pilot project, explain (maximum 1000 characters) why this project can be listed as such (a very innovative project; a risky project, which is worth of approving; the expected results for further extending it).

Proposal type

Please specify if this is a new project, the extension of an earlier FISM-financed project, or a project that was proposed in a previous call for proposals, but had not been funded. In such a case (revised project), please explain criticism to the project and what has been done to modify and improve it (maximum 5000 characters).

ATTENTION: do not list as "new projects", those projects that had already been proposed in past call for proposals and were not funded. As a matter of fact, such procedure might entail the exclusion of the proposal from the assessment process in the future. For the sake of clarity, if a project is proposed again and has not been revised, it is still a "revised project" and the applicant is to explain why they have not taken into consideration the inspectors' comments and remarks.

Personnel involved in the research project.

Please list all the members of the research team that are very much involved in the project.

External collaboration.

Should external collaboration be needed (e.g. suppliers of special components or materials, such as transgenic mice, samples of biological materials etc. or technical consultants or experts), please indicate their names, surnames and the institute or company they work for. Explain why these collaborations are needed, their added value and the specific role that each collaborator will play in the project.

ATTENTION: you MUST attach the scanned letters signed by these collaborators, in which they say they know the project and they are aware of their roles.

For multicentric studies only

As for multi-centric studies, what is needed is communicating the necessary pieces of information concerning the Centre managers or Operational Unit managers, each centre's staff involved into the carrying out of the project and activities and corresponding papers (bibliography must be detailed, as already mentioned) written by the manager in charge of each unit participating into the project.

Research field

Please specify the field of expertise the project is referring to. If this is a multi-centric project, specify the main field of expertise in the box at the end of the application form. These pieces of information are mandatory for both statistics and pointing out the fields of expertise that must be known to referees.

Potential Referee

Enter names, affiliations and e-mail addresses of four referees (2 Italian and 2 foreign), who have not conflicts of interest and can evaluate the submitted project.

Summary of the project (maximum 3000 characters)

Please briefly and clearly describe the hypotheses and goals of the project. The abstract is part of the proposal. It must be fully understandable and summarize the full project. Goals, the rationale, the expectations, and the phases of the project need to be summarized in the corresponding boxes, both in Italian and English. General statements must be avoided (e.g. MS affects the CNS and is characterised by...); inspectors must clearly and precisely understand what the project is about. The project abstract must be always added to the progress reports; it is thus possible to monitor its compliance with the original project.

Lay summary (maximum 2000 characters)

The research project must be summarized by using very simple language that can be understood by laymen. Please write in Italian. If the project is financed, such a summary will be used as a piece of information to be published on the mass media.

Relevance for multiple sclerosis (maximum 1000 characters)

Please clearly state why the goals of the project are important to better understand the etiopathogenesis, the course, the diagnosis, the prognosis and the treatment of MS; do not add general statements.

Proximity to find new pathogenic mechanism (max 1000 characters)

Please state, the possible short, medium and/or long term impact of the research's results on people with MS. In particular, indicate time and research's plan necessary to the characterization of new pathogenic mechanisms;

Proximity to cure (max 1000 characters)

Please state, the possible short, medium and/or long term impact of the research's results on people with MS. In particular, indicate time and research's plan necessary to develop therapies for MS

State of the art (maximum 8000 characters)

Please consider the current knowledge on these issues and what gap is the project supposed to fill in.

The scientific rationale and main goals of the proposed project (maximum 10000 characters).

State the goals that the project wants to achieve and the hypotheses that need verifying. Please clearly state the specific goals of the proposed research project and add a persuasive and clear description of the scientific, technical and economic consequences of such a project. The project's goals must be implementable and innovative if compared to the current knowledge. Please specify the final goals. Should projects be two- or three-year projects, please specify the mid-project goals, after the first and second years.

Preliminary results (if any) that have already been achieved (maximum 10000 characters).

Preliminary results concerning the project's subject matters are of the essence to envisage the possible success of the research project. Such preliminary results are achieved by the applicant and do not refer to data that can be found in medical literature.

Research programme and method (maximum 16000 characters).

Precisely and realistically describe the research programme and the techniques to be used to achieve the project goals. Add the methods of analysis and interpretation of results. Describe any new method that is being used and what advantages it does entail if compared to the existing methods. Those methods that have not yet been described in medical literature must be explained as to allow other researchers to implement them.

The proposed project must be implemented in 1, 2 or 3 years, as envisaged, in compliance with the type of project. Please be careful not to propose a very large project, since it might not be possible to develop it within the envisaged time.

Point out the difficulties and limits that may result from the proposed techniques and the possible alternatives that will be used to achieve the project goals. Please describe the statistical details that are to be used.

As for more basic studies concerning cells or tissues (human or non-human tissues), state the origin of materials (you may add the acceptance letter of the supplier), the collection and preservation methods of human tissues, and specify if they have been already collected; why they are used and their advantages if compared to other materials.

As for those projects using animals, please specify their species, stock, age, gender, and why that species has been chosen. State the number of animals and the minimum size of the needed specimen. Describe the methods used to minimize animals' suffering during caging and experimental phases, as per EU Law no. 86/609, accepted by Italy by means of the L.D. no. 116 /1992. All the information requested as per art. 8bis of this general regulation must be provided.

As for those projects studying diseases based on animal models: the adequacy of models chosen for the proposed projects must be verified.

As for clinical studies wanting to correlate clinical researches - old or new MRI techniques are also included - to disability or other clinical parameters, such as fatigue, relapses etc. the following must be listed:

1. Preliminary results concerning the variability of the proposed outcomes and measurements among people or related to only one individual.
2. Sample size must be calculated (patients and examinations): it must be large enough to obtain statistically valid data.
3. Exclusion and inclusion criteria to be applied to the patients taking part into the project.
4. Proposed techniques: their pros, effectiveness and suitability.

As for those studies monitoring the effectiveness of medications and drugs, by means of any technique:

- The side effects of such medications and drugs must be clearly stated (interactions with other meds and drugs must be listed as well).
- Please clearly explain how physicians may foresee and manage such side effects and how they may affect the number of patients involved; drop-outs must be taken into consideration.

As for those researches using non conventional MRI, please explain why you chose such techniques and why they are beneficial if compared to the more convenient traditional techniques.

As for the other clinical researches - rehab, therapy and marker assessments etc. are included - the inclusion criteria, the statistical assessment of the number of patients and the drop-out assessment must be clearly stated.

What must be done is a reasonable assessment of the duration of the study, including the time needed to involve patients into the study, and the statistical methods that are going to be used to interpret data must be described.

Multi-centric studies

Please describe each centre's role and specific contribution as far as the achievement of the overall goals of the project is concerned (maximum 8000 characters), as well as the coordinator's role (maximum 2,000 characters); please specify how the project is to be managed; how the activities of each centre are to be monitored by the coordinator; how the development, methods and analysis of the project are regularly controlled, and how results are to be integrated.

Please note that "multi-centric" study does not mean a group of independent studies that are being carried out in a number of centres, but one single study to which more centres contribute.

Bibliography (maximum 8000 characters)

Bibliography items MUST DETAIL all names of the authors, the titles of papers and books or magazines and journals, as well as the volume number, page numbers and year of publication. Please write an essential, updated and coherent bibliography.

Project responsible's curriculum vitae and publication

Please attach to the application the curriculum and the list of papers written by the Project Manager. Bibliography items MUST DETAIL all names of the authors, the titles of papers and books or magazines or journals, as well as the volume number, page numbers and year of publication.

More funds

Provide the needed information on available funds or funds that have been requested.

Please specify those available amounts stemming from other sources, together with the funding agency.

Budget

The description of envisaged expenses must be accurate and related to the carrying out of the project. A general description or general expenses that cannot be precisely described will not be accepted, e.g. what cannot be done is specifying a specific sum for consumables without detailing individual items; moreover do not include amounts related to collaborators' salaries without specifying their qualification, roles, mission duration and whatever is necessary to correctly assess expenses.

You may apply for funds for the following budget items:

Staff

The Project Manager is allowed to employ collaborators or sign collaboration contracts (through their institute), thus employing ad hoc collaborators - even part-time collaborators - that have been chosen for their expertise or as sheer workforce. The employment relationship can be established with graduates or people who did not get a degree and must concern the project's research activities (e.g. cleaning staff, delivery men, hospital porters etc.). Please clearly indicate the amount of money needed to establish such an employment relationship and those tasks expected from collaborators and workers; you do not have to communicate their names or send their CVs, since these

collaborators are chosen exclusively by the institution receiving the money, and not by the Italian MS Federation.

This employment relationship cannot be described as a FISM "fellowship". Details concerning those being paid and the tasks performed must be explained upon reporting or receiving the payment request from the Italian MS Federation.

If consultancy services or contracts need to be paid € 18,000/year or more, no more fellowships will be awarded for that project. No payment over € 30,000/year is allowed for this kind of projects.

PLEASE NOTE that if your project envisages collaboration with foreign laboratories needing to hire local staff to carry out this research, the upper limit value might be increased (it needs to be approved by the Scientific Committee and the governing body of the Italian MS Federation) to be in line with the laws in force in that given foreign country.

PLEASE NOTE that for Multicentric studies: the limit of € 30,000/year has to be considered per participating center.

Risk insurance premiums and more insurance policies

The MS Foundation cannot be held responsible for any risks and/or accidents that may happen during the carrying out of the research activities. The body carrying out research activities must take out the needed insurance policies. Funds to be used to pay premiums related to risks or more insurance policies taken out for staff being paid thanks to the research contribution, may be included, however this is to be done only after the approval of the Italian MS Federation. No premium payment will be allowed for insuring equipment or supplies that have been purchased by using (or not) the granted funds.

Patient costs

Funds requested for health and welfare services dedicated to patients during the research activity, might be granted only if an explanation is added to the application; in such a way, what is shown is that such costs are needed for the proposed research and that the usual fund sources are either unavailable or inadequate. The same goes for any insurance policy that must be taken out for patients. The research body is to pay a number of services and they cannot be included among those services for which the contribution was requested.

Tools and instruments

The scientific tools and instruments that have been bought by using the granted funds are owned by the Foundation and thus it falls in the availability of the Foundation at the end of the project. The receiving body owns these tools and instruments, only if explicitly agreed in writing. The costs for installing the purchased tools and instruments are not covered by the granted funds, unless this is requested in the application and explicitly and specifically approved by the cost estimate of the granted contribution. The receiving body must take care of the maintenance of the purchased tools and monitor the correct working of tools and instruments for the entire duration of the project.

Expenses due to tools and instruments must be limited and must not exceed € 30,000, unless exceptions are accepted and agreed upon by the Foundation. Purchase of laptop computers, instead of desktop computers, must be clearly explained. When the project is closed, the instruments can be redeemed by the host Entity, as well as the Foundation reserves the option of donating the equipment to the host Entity and/or the researcher.

Consumables

This must be specified; generic definitions are not allowed. Consumable stocks may include any type of consumable supplies for laboratories, including the purchase and care of guinea pigs.

Research travels & Conferences

Expenses needed for domestic or overseas travels and participation into conferences relating to the research plan can be granted only if requested in the application. If these costs are paid out of the contribution, they will have to abide by the rules of the receiving body or the Foundation, should FISM be in charge of their management. Costs related to travels and conferences must be explicitly referred to the research project and should be kept to a minimum. Please note that the expenses to take part into the progress and final report meetings organised by FISM on an annual basis, must be envisaged over the entire duration of the project.

Other expenses (not more than 10% of total budget) (maximum 1000 characters)

-Allowed Expenses: publication and reprinting expenses, shipments of samples and animals. If software is required, specify what you need for the proposed research.

Expenses for the purchase of books and magazines are allowed in exceptional cases and only if they have been approved in the estimate of the granted contribution.

The following expenses are allowed only if indirect costs are not required (overhead) and only if in line with the approved research: stationery (paper, etc...), computer consumables (toners, CDs ...), instrument maintenance and repair, correspondence.

-Expenses that are not allowed: fax and telephone bills, except for those projects involving many telephone calls to patients (e.g. a number of epidemiological studies).

Indirect costs (overhead)

The receiving body – thanks to its legal representative -, who signed the application, is allowed to keep up to 5% of the sum requested by the lead researcher from the granted fund (indirect costs). The amount and reason of such indirect costs must be explained in the application, failure to do so may result in your application being rejected.

Indirect costs are not accepted if connected to funds requested or used for:

- a) Use of hospital beds;
- b) Purchase of, changes to or installation of equipment
- c) Structural changes to laboratories, benches, plants etc.

As for contributions to foreign institutes and bodies, indirect costs will not be accepted unless a special explanation is given. Indirect costs higher than 5% will be considered only in exceptional cases; please clearly and precisely detail and explain the reasons of these indirect costs in your application, they will be assessed by the Scientific Committee and the FISM governing body and must be specifically approved .

Final Regulations

Expenses that are not included in the cost estimate attached to the application will not be accepted, unless they have been approved in writing by the Foundation following its specific request.

At the close of the project, the Foundation will ask for the reimbursement of all expenses that were not previously envisaged, and after the submission of the administrative account.

The Foundation cannot be held responsible for those costs exceeding the contribution.

RESEARCH FELLOWSHIPS AND "SENIOR" RESEARCH FELLOWSHIPS

Please note that the instructions provided herein are similar to the instructions related to the research projects or training fellowships (PLEASE READ THEM AND ABIDE BY THOSE RULES). However, there are some differences, e.g. as far as the parts dedicated to the different sections. Please read carefully these instructions.

Proposal type

Specify if this is a new research fellowship, or a fellowship that was already submitted in the past, but it had not been funded. If so (revised fellowship), please summarize criticism against the project and the improvements and corrections that were made to the project (maximum 5000 characters).

Fellowship associated to a Project presented in the same FISM Call

Specify if the fellowship is associated to a project presented in the same FISM Call; if yes, indicate the title and the PI of the project.

Letter of acceptance of the candidate

This letter is optional. If it is written and submitted, please scan it and attach it to the application form.

Letter of acceptance of the mentor

The mentor is required to approve the proposed training and the person who proposes it. The scanned letter must be attached to the application form.

Abstract (maximum 3000 characters)

Please clearly and briefly describe the goals of the training. The abstract is part of the Proposal. It must be fully understandable and summarize the full project. Summarize the goals, reasons and training phases, both in English and Italian, in the corresponding boxes.

Lay summary (maximum 2000 characters)

The research project must be summarized by using very simple language that can be understood by laymen. Please write in Italian. If the project is financed, such a summary will be used as a piece of information to be published on the mass media.

Relevance for multiple sclerosis (maximum 1000 characters)

Please clearly indicate why the goals of training are important to better understand the MS etiopathogenesis, progress, diagnosis or treatment.

State of the Art (maximum 6000 characters)

Assess the current knowledge of the subject and the gap that the project is expected to fill.

Scientific rationale and main objectives of the proposal (maximum 6000 characters)

State the goals that the project wants to achieve and the hypotheses that need verifying. Please clearly state the specific goals of the proposed research project and add a persuasive and clear description of the scientific, technical and economic consequences of such a project. The project's goals must be implementable and innovative if compared to the current knowledge.

Please specify the final goals and – as far as the two-year fellowships are concerned – the goals to be achieved after the first year.

Preliminary results (if any) which have already been achieved (maximum 4000 characters)

Preliminary results concerning the project's subject matters are of the essence to envisage the possible success of the research project. Such preliminary results are achieved by the applicant and do not refer to data that can be found in medical literature.

Research Plan and Methods (maximum 14000 characters)

Precisely and realistically describe the research programme and the techniques to be used to achieve the project goals. Add the methods of analysis and interpretation of results. Describe any new method that is being used and what advantages it does entail if compared to the existing methods. Point out the difficulties and limits that may result from the proposed techniques and the possible alternatives that will be used to achieve the project goals. Please describe the statistical details that are to be used.

As for those projects using animals, please specify the minimum number of animals needed to achieve statistically significant results, their species, stock, age, gender. Please specify how animals will be treated during caging and experimental phases.

Please indicate the source and method of collection and storage of human material, specifying whether the material has already been collected.

As for clinical trials, please specify what follows:

- a) The study type (please say if it is a blind study);
- b) Data related to the people involved (number of patients, inclusion criteria etc.)
- c) Clinical procedures and their frequency;
- d) Limitations, difficulties, alternative procedures;
- e) Medication doses and drug administration;
- f) Safety, potential risks, how to deal with problems;
- g) Processing and interpreting data, statistical methods;
- h) The realistic planning of time, with a special reference to the time needed to recruit patients.

Bibliography (maximum 6000 characters)

Bibliography items MUST DETAIL all names of the authors, the titles of papers and books or magazines, as well as the volume number, page numbers and year of publication. Please write an essential, updated and coherent bibliography.

IMPORTANT NOTE (maximum 2000 characters).

The applicant is required to say if the proposed project is an independent project or mentor-supported project. In such a case, they are requested to clearly state which part of the project they will be in charge of.

Funds available for the training programme (maximum 500 characters)

When awarding training fellowships, FISM wants to make sure that the mentor has the necessary funds for the training programme to be carried out. Please specify the available funds (their sources and amounts) in this section; please specify if and to what extent the carrying out of the grant recipient's project is based on successful funds applications for research projects submitted to FISM or other institutions.

Grant recipients' Curricula - past research activities (maximum 4000 characters)

Describe the past research activities carried out with universities or other institutions (courses, internships, laboratory work, and clinical activity). Please specify the foreign languages known by grant recipients and the level of knowledge in this section.

RITA LEVI MONTALCINI CAREER FELLOWSHIPS

To fill in this application form, please refer to the instructions related to research projects (see Instructions - section B). Please note what follows:

Request for funds

Please specify the overall fund request on an annual basis; please be aware that the fellowship cannot exceed € 50,000 gross per year, whereas requests related to other expenses cannot exceed € 110,000 in the first year and € 80,000 in the second and third year. Therefore, the overall funds request for three years cannot exceed € 420,000.

Letter from the Manager of the host institute

In this letter, please specify what follows (please scan it and attach it to the application form):

- 1 The assessment of the applicant is needed, as well as why they might be accepted;
- 2 Please describe rooms, laboratories, equipment, staff and everything else that might be used by and available to guest researchers during the carrying out of the research activities.
- 3 The independence of the candidate researcher - as far as the research programme is concerned – must be officially guaranteed.
- 4 Any benefit or advantage that the host institute may enjoy from hosting the candidate researcher.
- 5 Any possibility of being hired by the host institute after the fellowship has come to an end and after assessing the outcomes that have been achieved in the past three years.
- 6 Your availability at being subjected to one or more inspections by FISIM officials in order to verify the initial conditions and the project development.

INFORMATION PURSUANT TO ART. 13, GDPR 679/2016

Italian Multiple Sclerosis Foundation - FISM Onlus with offices at no. 40 Via Operai, Genoa, as Data Controller (hereinafter, "**Data Controller**"), pursuant to art. 13 EU Regulation n. 2016/679 (hereinafter, "**GDPR**"), provides the following information regarding the processing of personal data.

1. Purpose and subject of treatment

FISM guarantees that it will process personal data in a lawful and correct manner, it will gather and record them for defined, explicit and lawful purposes and will use them in line with such purposes. FISM shall make sure that such data are correct, updated, relevant, complete and not in excess for the purposes for which they have been gathered and processed.

Personal data - such as name, surname, telephone number, e-mail etc. - will be processed by FISM for the following purposes:

- scientific and administrative management of research project/ fellowship;
- obligations provided for by laws, regulations, community legislation or orders of authorities.

The legal bases of treatment can be identified, alternatively:

- in the execution of obligations coming from a contract pursuant to art. 6.1, lett. b) GDPR;
- in the fulfillment of obligations required by law pursuant to art. 6.1, lett. c) GDPR.

2. Method of treatment

The following treatments might be performed on personal data: collection, registration, organization, structuring, storage, adaptation or modification, extraction, consultation, use, comparison or interconnection, limitation, cancellation or destruction. The data may be processed by FISM electronically or in paper form suitable for guaranteeing security and confidentiality.

3.Storage time

The personal data will be stored for the period necessary with regard to the purposes indicated in this statement and in any case for a period of time not more than 10 years starting from the application.

4. Data Communication

Within the limits relevant to the processing purposes indicated above, data might be transmitted to suppliers (e.g. insurance companies, work consultancy studies, etc.) that perform activities on behalf of FISM, in their quality of data processor. Without the need for express consent (pursuant to Article 6 letter b) and c) GDPR), Data Controller may communicate data to judicial authorities as well as to those public and private entities, to whom communication is mandatory by law or for the fulfillment of the aforementioned purposes. data will never be disseminated or disclosed to unauthorized third parties.

5. Data transfer

Personal data will be stored on servers located within the European Union. Data will not be transferred to non-EU countries or in any case not subject to the GDPR regulations.

6. Nature of the provision of data and consequences of the refusal

The provision of data is mandatory and, therefore, any refusal to supply them in whole or in part can give rise to the impossibility for FISM to evaluate the application for research project / fellowship.

7. Rights of data subject

Data subject could exercise at any time the rights referred to in articles. 15-22 of the GDPR.

In this regard, Data Subject have the right to:

- request the updating, rectification, integration, cancellation, transformation into anonymous form, blocking of data processed in violation of the law, including those no longer necessary for the pursuit of the purposes for which they were collected;
- have information about the logic, the methods and the purposes of the processing;
- receive data in a structured format, commonly used and readable by automatic device;
- revoke any consent given in relation to the processing of your data at any time and object in whole or in part to the use of documents ;
- propose a complaint to the Authority, as well as to exercise the other rights recognized by the current legislation.

8. Method of exercising rights

At any time Data Subject can exercise the rights mentioned above sending an e-mail to FISM Office at fism@aism.it or to FISM Data Protection Officer at dpofism@aism.it .

9. Data Controller and Data Protection Officer

FISM Onlus
Via Operai 40, 16149 Genoa
phone: +39 010.27131
Fax: +39 010.2713205
e-mail: fism@aism.it

FISM Data Protection Official is Liguria Digitale, based in Genoa Science and Technology Park, Via Melen 77, 16152