Global Ophthalmology Awards Program from Bayer

Terms and Conditions

PP-EYL-GB-0420
November 2019

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AWARD TERMS AND CONDITIONS

Term

This Agreement comes into force upon signature of the parties and continues until all reports have been received by Bayer. The term of the project under this Agreement commences upon receipt of the first payment by Institution and continues for 12 months, unless stated otherwise in the application ("Research Term").

Change in the Award Recipient's Status

Awards under the Program ("Awards") are made to the Institution for use by the Award Recipient for the awarded Research project only. If there are any significant changes in an Award Recipient's circumstances, the Award Recipient must contact the program administrator that has been nominated by Bayer ("Program Administrator") to describe these changes and explain how they might affect the use of awarded funds.

The transfer of an Award to another institution for the pursuit of the awarded Research project by the Award Recipient will be at the sole discretion of Bayer.

Authorized Expenses

- Salary and fringe benefits
- Equipment and supplies necessary to fulfill the project's aims
- Travel expenses directly related to the implementation of the project
- Costs associated with the publication of the research

Unauthorized Expenses

- Salaries, travel and/or housing related to sabbaticals
- Purchase or rental of office equipment
- Fees for tuition
- Membership dues, congress/meeting registrations, subscriptions, books or journals

Funds and Financial Reports

The Institution is required to submit a statement stating that the respective Award amount has been received. In the event that unexpended funds remain at the end of the Research Term, these funds must be returned to Bayer. A final financial report is due 60 days after the end of the Research Term reconciling the proposed budget with the actual expenditure.

Progress and Final Reports

A Progress report for the award must be submitted to the Program Administrator at the end of the Research period; if the Research period exceeds 12 months, an interim report needs to be submitted at 12 months. Final reports are due 60 days after the end of the Research Term. Pro forma progress and final reports will be emailed to awardees at least one month before these deadlines.

Disbursement of funds

Projects up to 1 year will receive funding in two installments. The first installment, consisting of 75% of the Award will be disbursed upon signature of this Agreement. The second installment consisting of the remaining 25% of the Award minus any unused funds will be disbursed after all required documents have been received

including the final progress report. Projects exceeding 1 year will receive a first instalment consisting of 50% of the Award upon signature of the Agreement, a second installment consisting of 25% of the Award upon receipt of the interim 12-month report and a final installment consisting of the remaining 25% of the Award minus any unused funds after receipt of the final report.

Termination of Support

Bayer reserves the right to terminate support of a funded project in case both Bayer and Award Recipient consider continuation of the respective project as no longer reasonable.

GOAP Award ceremony

It is expected from the awardee to be present in order to receive the award in person at the GOAP Award Ceremony. BAYER will book and pay for flights (economy class airfare), train travel and hotel accommodation in connection with the Award Recipient's attendance at the GOAP Award Ceremony. In addition, the Award Recipient shall be reimbursed by Bayer for other reasonable travel expenses actually incurred by Award Recipient in connection with the attendance of the GOAP Award Ceremony, subject to the receipt of invoices or receipts. Costs for meals and drinks are not considered travel expenses.

Recombinant Molecules, Animal, and Human Subjects

Award Recipients requesting an award to carry out research with recombinant molecules and/or animal or human subjects must obtain approval from the appropriate institutional or government authorities, e.g. an Institutional Review Board. If an Institute does not require special permission for using recombinant molecules, then this must be communicated to the Program Administrator. Bayer can provide assistance with this process if requested by the Award Recipient.

If the Research program involves the use of recombinant molecules, animals or the participation of human subjects, the Award Recipient has to send to the Program Administrator copies of appropriate permissions before any Award funds will be disbursed.

The Institution has responsibility for ensuring that the rights of any human subjects are upheld and that animals are cared for in a humane manner.

Clinical Trials

When clinical trials are required for clinical investigation, the project must meet certain Bayer international standards for clinical studies (which will be provided to the Award Recipient) and conform to all local safety reporting regulations.

Patient safety is the primary concern in any clinical study, so Bayer will not release funds for clinical trials until both the company and the investigators agree on the safety and suitability of the trial. In addition, relevant patient safety data must be supplied to the appropriate Bayer safety officer.

Publications

Bayer encourages Award Recipients to publish work carried out under the Program; this includes abstract submissions to congresses. Award Recipients must acknowledge the receipt of funding from Bayer in publications and abstracts describing research conducted with Awards made under the Program. Award

Recipients are required to communicate to the Program administration the references of any Peer-reviewed publication or oral/poster congress presentation of outcomes of the research project occurring within 3 years from the end of the Research period.

Inventions and Patents

Award Recipients supported by the Program may generate inventions that should be patented. The Award Recipient and/or other researchers and/or the Institution will own the patent according to arrangements they have made with each other.

Because it is important to Bayer as well as to Award Recipients that inventions are patented properly, Bayer encourages investigators to protect their inventions. For researchers that are not familiar with the patent process, and do not have access to an IP department in their institutions, Bayer can offer advice, in a manner that will not compromise ownership, to ensure that adequate patent protection is obtained. However, Bayer can neither prepare the patent application for the investigator nor fund the patent application process. In Bayer's view, any patent remains the property of the investigator and/or the Institution, and it is the responsibility of one or both to patent inventions of merit.

The Award Recipient is responsible for ensuring that intellectual property is protected by assuring confidentiality until appropriate patent applications can be filed and by notifying the Program Administrator of potential inventions in time to permit proper evaluation and action.

If the Institution chooses not to file any patent application arising from work performed under an Award from the Program, Bayer may seek the option to file such a patent application on the invention, subject to an agreement on the commercialization rights (see paragraph below). It will be the responsibility of the Award Recipient to assist in the preparation of such patent applications and to preserve their confidentiality. In this case, Bayer will pay the cost of patent preparation and filing and the respective inventions will be assigned to Bayer.

Patent applications cannot be filed overnight, and advance planning is needed prior to any publications. Bayer will have a minimum of 30 days and a maximum of 60 days to evaluate an invention for patentability before the Award Recipient is free to publish the information. In this case, "publication" includes any oral presentation and electronic information transfer in addition to the publication of manuscripts and abstracts. If Bayer decides that the invention should be patented, the Award Recipient may not publish anything until the appropriate patent applications have been filed. This is in the best interests of the Award Recipient, the Institution, and Bayer.

If the Award Recipient has received or plans to receive funding from other agencies or companies that may interfere with agreement to these terms and conditions, it is the responsibility of the Award Recipient to inform the Program Administrator as soon as possible.

Commercialization Rights

Institution understands the value of the Award and hereby grants to Bayer a non-exclusive, worldwide, royalty-free and sub-licensable license to use the results (including, but not limited to, patented inventions, technical data, materials and know-how) generated under the Award ("Results") for commercial exploitation.

Institution further grants to Bayer the right of first negotiation to obtain an exclusive, worldwide and sub-licensable license to use the Results for commercial exploitation.

Compliance with Laws and Industry Guidelines

(a) Bayer, Institution and Award Recipient each agree that they shall comply with all applicable federal, state and local laws and regulations in performance of its respective obligations pursuant to this Agreement, including, without limitation, laws related to fraud, abuse, privacy, discrimination, disabilities, samples, confidentiality, false claims and prohibition of kickbacks. Without limiting the generality of the foregoing, each party to this Agreement certifies that such party shall not violate the US Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) or comparable laws in other jurisdictions with respect to the performance of this Agreement.

(b) In the case that the Award Recipient is a member of a committee that sets formularies or develops clinical guidelines, the Award Recipient shall disclose to such committee the existence and nature of his or her relationship to Bayer and follow any procedures set forth by the committee in connection therewith; this requirement shall survive expiration or termination of this Agreement for two (2) years.

Pharmacovigilance

(a) Award Recipient agrees to provide to Bayer written reports of all Adverse Events (AE) and Product Technical Complaints (PTC) (each as defined below) regarding Bayer product(s) and/or services which are the subject of this Agreement that come to their attention by fax to +49-30-468-994441 or E-mail to GPV.CaseProcessing@bayer.com within one (1) business day from receipt of such information.

(b) For purposes of this Agreement, (i) an “Adverse Event (AE)” means any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment; and (ii) a “Product Technical Complaint (PTC)” means any report received from a third party (written, electronic or verbal communication) about a potential or alleged failure of a product in its quality (including the identity, durability, reliability, safety, efficacy or performance) or suspect counterfeit which may or may not represent a potential risk to the customer.