

General Guidelines for the DDTP Scholarship and Fellowship Competition

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1. APPLICATION PROCESS

1.1. PROGRAM OBJECTIVES

The long term objective of the multidisciplinary Drug Development Training Program (DDTP) is to prepare independent young scientists and clinician-scientists from a range of disciplines for the challenges of modern drug development. Our specific aims are:

- to create an integrated training program at the nexus between drug design, medicinal chemistry, biochemistry, animal model development, pharmacology, pharmacokinetics, toxicology, screening technology, drug formulation, clinical trials, drug evaluation, materials engineering, intellectual property development, regulatory affairs and commercialization.
- to train students in the interdisciplinary *modus operandi* required to design and develop new screening and delivery technologies and novel therapeutics.
- to specifically target known bottlenecks in drug design and development for study through collaborative academic-industry teaching and “hands-on” practical experience.

1.2. APPLICATION DEADLINE

Applications sent by email must be received by 11:59 PM on the day of the specified deadline. Applications sent by mail must be sent by courier only and must be postmarked the day of the deadline.

Incomplete and late applications will not be considered except under extenuating circumstances beyond the applicant’s control (e.g., death in the applicant’s immediate family, weather conditions leading to university closures, jury duty, etc.). To request an extension of deadlines, the applicant (or the supervisor) must submit a written request to the DDTP research grant administrator.

1.3. APPLICATION PROCESS

1.3.1. APPLICATION DOCUMENTS

Applicants must provide the following documents either in printed form or as an electronic file in PDF format:

- Studentship form (Graduate students only)

- Fellowship form (Post-doctoral fellows only)
 - Supervisor form
 - Proof of acceptance in a McGill Graduate program (for MSc and PhD candidates only) or proof of registration in a McGill program
 - 1 letter of reference (from someone other than the supervisor or co-supervisor).
 - Official transcripts of all university-level studies
 - Accepted and in press publications (for all articles that have not yet appeared in journals, correspondence related to the submission must be provided)
 - Check list
- Any additional documents provided but not required will be disregarded in the selection process.
 - All printed documents must be sent by registered courier to:

McGill CIHR Drug Development Training Program
 Royal Victoria Hospital, Room M3.10
 687 Pine Avenue West
 Montreal, QC H3A 1A1
 - Applications in electronic format must be sent to trainingindrugdev@mcgill.ca

1.3.2. FORMAT REQUIREMENTS

Forms must be completed in Times New Roman or Arial fonts with a character size no smaller than 11 pt. All texts must fit within the provided text boxes and must be single-spaced. Failure to respect formatting rules may lead to automatic rejection of the application.

All electronic documents must be sent in PDF format.

1.3.3. ACKNOWLEDGEMENT OF RECEIPT

Upon receipt of the application, an acknowledgement of receipt will be sent by e-mail to the applicant.

1.4. APPLICANT ELIGIBILITY

1.4.1. REGISTRATION

All applicants must be officially registered as a graduate student or post-doctoral fellow at McGill University to receive funding.

1.4.2. CITIZENSHIP OF APPLICANTS

The competition is open to Canadian citizens, permanent residents and foreign citizens provided that they meet the requirements set by Citizenship and Immigration Canada.

1.4.3. ELIGIBILITY REQUIREMENTS FOR GRADUATE STUDENTS

Graduate Students (Master's and PhD's) can receive a DDTP scholarship for a total of 4 years during their graduate studies (Master and PhD) when the following eligibility criteria are met:

1.4.3.1 ELIGIBILITY REQUIREMENTS FOR MASTER'S STUDENTS

- First applications from Master's students must be received during or prior to their first year of study.
- Master's students can only apply for renewal during year 1 of a MSc program.
- Students applying prior to the beginning of their first year of study must be officially accepted in the Master's program at McGill.
- Master's students are eligible to receive funding for a maximum of 2 years.

1.4.3.2. ELIGIBILITY REQUIREMENTS FOR PHD STUDENTS

- Candidates in this category are eligible to submit a first application prior to or within their first 3 years of the PhD program.

- To be eligible to apply, prior to starting their first year, students in this category must be officially accepted in the PhD program.
- Students within their 5th year of PhD cannot receive funding from the DDTP and are not eligible to apply.

1.4.4. ELIGIBILITY REQUIREMENTS FOR POST-DOCTORAL FELLOWS

- Post-doctoral fellows are eligible to apply only within the first 2 years of being granted a PhD degree. When calculating the eligibility period of 2 years, the date of issuance of the PhD degree indicated on the diploma is taken into consideration as opposed to the date of the PhD defense.
- The award is renewable only once.
- Post-doctoral fellows having received their PhD at McGill are not eligible for funding if they remain in the laboratory where they pursued their PhD studies.

1.4.5. INTERRUPTION OF STUDIES

Interruption of a program for 6 months to 1 year due to medical leave or maternity and/or parental leave will be taken into account in the evaluation of eligibility.

1.5. DRUG DISCOVERY AND DEVELOPMENT RELEVANCE

The mission of the McGill CIHR Drug Development Training Program (DDTP) is to train students in all aspects of drug discovery and development. While all students from the laboratories of DDTP mentors meeting eligibility requirements can apply, the relevance of their assigned project(s) to the field of drug discovery and development is a *sine qua none* for their selection as DDTP awardees. Likewise the relevance of a given conference/meeting to drug discovery and development is the primary requirement for the DDTP travel award competition.

In each competition, priority will be given to students working on projects or seeking to attend meetings that have direct relevance to drug discovery and development. Thus, the onus is on the applicant and his/her supervisor to make a case for the relevance of his/her project to the DDTP. The current guideline describes eligible areas of research deemed relevant to the DDTP competitions.

1.5.1. RESEARCH PROJECT RELEVANCE

Relevance is considered within 11 categories:

- Drug design and synthesis
- Process chemistry
- Target identification and validation
- Toxicology
- Pharmacokinetics and metabolism
- Development of tools for drug discovery
- Drug formulation and delivery systems
- Bio-engineering
- Development of animal models
- Drug related clinical research
- Combination therapy

Drug design and synthesis

Under this category, molecular modeling or rational drug design, total synthesis of a bioactive agent, structure modification for enhancing bioactivity, stability or water solubility are considered relevant. In cases where the project is limited to the synthesis of a bioactive drug, an effort to collaborate with another investigator with the appropriate expertise for biological testing is encouraged.

Process chemistry

Research on any methodology development toward efficient synthesis of a drug or a class of drugs is relevant. This includes (but is not restricted to) the design of expedient, green or cost-efficient synthesis of drugs and the design of scalable synthesis. This does not include total synthesis of natural products unless the proposed synthesis is adaptable to large scale production of drugs.

Target identification and validation

Under this category, work on specific proteins (e.g. receptors, enzymes, transporters, etc) are considered relevant only if evidence of a potential therapeutic benefit for the treatment of a given disease is described. Target-directed proteomics, chemical proteomics projects, and signal transduction studies are deemed relevant.

Toxicology

Research projects on aspects of toxicology that are related to drug safety or drug effect on normal cells or tissues are considered relevant. Environmental toxicology is not relevant unless it is related to process chemistry.

Pharmacokinetics and metabolism

Under this category, any project on pharmacokinetics of a clinical drug *in vitro* and *in vivo* are considered relevant. Likewise, projects in drug metabolism *in vitro* and *in vivo* are acceptable.

Development of tools for drug discovery

Any method or assay development project that has the potential to accelerate drug discovery is eligible. Under this category, *in silico* analysis and molecular modeling are considered relevant.

Drug formulation and delivery systems

Nanotechnology directed at drug delivery, design and development of inhibitors of drug efflux pumps or any transporters are eligible. Any project dealing with controlled release of a drug with the purpose of enhancing bioavailability is deemed relevant.

Bioengineering

This category includes the design and engineering of new materials for drug delivery like new polymers, nanotubes, DNA cages, patches etc. The word delivery has to be understood from a pharmacokinetic standpoint.

Development of animal models

Projects on the development of new animal models, or improvement of an existing model designed to study a pathological pathway or to evaluate the toxicology or efficacy of a new drug, are considered relevant. Likewise, animal models to be used tools for imaging or pharmacokinetic studies fall in this category.

Drug related clinical research

In this category, clinical studies designed to determine the pharmacokinetics, the mechanism of action of a drug in human tissues and clinical pathology studies related to drug effects are considered relevant.

Combination therapy

Projects studying the combined effect of drugs (e.g. drug combinations for cancer treatment, AIDS tri-therapy etc.) or combination of a drug with interventional treatments (e.g. radiation + drug, photo-activated chemotherapy) are considered relevant. For interventional treatments (e.g. radiation, phototherapy), eligibility will be restricted to projects in which the drugs used in the intervention are the main focus of the application.

1.5.2. ELIGIBLE CONFERENCES FOR DDTP TRAVEL AWARDS

The DDTP travel award is to encourage trainees to go to conferences where they will learn about drug discovery and development. Both the relevance of the conference and the abstract to drug discovery and development will be assessed.

The applicants must demonstrate the relevance of the event to their project by providing the necessary information (e.g. links to event website, participating researchers, etc).

1.5.3. RELEVANCE STATEMENT IN THE APPLICATION FORM

In all cases, the onus is on the student and supervisor to emphasize the relevance of their projects to drug discovery and development. It is the student's responsibility to select the appropriate relevance category on the form and to justify their choice in the appropriate box.

2. REVIEW PROCESS

2.1. STATEMENT REGARDING PRIVACY AND CONFIDENTIALITY

All information provided by applicants during the application process is strictly confidential.

Reviewers shall not reproduce confidential information in any form. Following the review process, application material provided in digital form must be deleted. Reviewers must destroy the printed documents or return them to the DDTP office. In the event that the printed documents are not returned to the DDTP, the reviewer shall confirm that all relevant information has been destroyed.

2.2. FUNDING SCOPE

2.2.1. BUDGET

The total budget available for scholarships and fellowships will be announced to the review panel for each individual competition.

2.2.2. FUNDING LEVELS AND DURATION

Annual funding amounts and duration of funding for each academic level are as follows:

- Master's students: \$10,000 per year.
- PhD students: \$10,000 per year.
- Post-doctoral fellows: \$20,000 per year.

2.3. REVIEW PROCESS

Applications are reviewed and assessed by the members of the Scholarship and Fellowship committee. Members of the committee are recruited based on their level of scientific expertise and knowledge of the drug discovery and drug development process.

Prior to assignment of applications for review, panel members are provided a list of all applicants in the competition and are requested to declare any conflict of interest* regarding any of the applicants.

Reviewers are not assigned applications for which they have declared a conflict of interest.

External reviewers are only assigned applications when the applicant's supervisor gives consent for an external review. The identity of external reviewers will not be disclosed to the applicant or to the supervisor.

Applications within the same category are assigned to the same number of reviewers to maintain a fair review process.

Review panel members are sent the applications to be reviewed in digital form. Their responsibility is to provide score sheets for each application assigned by the deadline given by the DDTP Research Grant Administrator.

Scores assigned by each reviewer are used to rank the candidates. Applications that receive equal or approximately equal scores are discussed at length at the review panel meeting.

*** Definition of Conflict of Interest:**

A conflict of interest is defined as any situation where the reviewer's personal interest, opinion or past or existing relationship with the applicant might influence his or her judgment. The most common situations of conflict of interest are the following: being a former supervisor of the applicant, having a personal relationship with the applicant, having collaborated on a grant application or scientific paper.

2.4. APPLICATION EVALUATION CRITERIA

When evaluating applications, the following criteria are considered: academic record, awards and scholarships, research progress, proposed project, and statements of support.

The level of clarity and quality of presentation of the application will significantly influence its evaluation. The preparation of a DDTP application should be given the same attention to detail as that of a scientific paper.

2.5. MARKING GUIDELINES

2.5.1. EVALUATION OF GPA

When evaluating GPA, only the GPA for the last two years of study and the general GPA trend during the duration of university studies will be evaluated.

To facilitate the evaluation of GPA for students from foreign countries, grades will be calculated on the basis of current McGill conversion tables provided by Admission Services.

2.5.2. PROJECT RELEVANCE

Project relevance to the drug discovery and development field will first be assessed by the program co-director before being sent to the reviewers and discussed in the panel meeting if required.

2.5.3. STANDARDIZATION OF RESULTS

Scores given by each reviewer are standardized using a commonly accepted statistical method.

2.5.4. BIASES

Reviewers must evaluate all applications fairly and without prejudice. Discrimination or biases based on age, religion, gender, ethnicity, country of origin, sexual orientation, personal or professional relationship, or any other factors are not acceptable in the review process.

2.6. REVIEW PANEL MEETING – RULES AND PROCEDURES

Prior to the meeting, applications that receive approximately the same score will be flagged for panel discussion. However, any particular concerns raised by the reviewers on any application will be discussed during the panel meeting. Revised scores will be assigned following panel discussion. During the panel meeting, review panel members in conflict of interest with particular applications will be requested to leave the room. The panel will vote to approve the final ranking obtained for each category.

2.6.1. RANKING AND FUNDING RANGE

Applicants will be ranked by the review panel according to normalized scores. Based on the average quality of the applications in each competition, the panel will vote on a minimum fundable score.

2.6.2. DECISIONS OF DDTP ARE FINAL

Ranking by the DDTP scholarship and fellowship committee is final. This ranking will also be used to assign new grantees in case of declined awards.

2.7. COMPETITION RESULTS ANNOUNCEMENT

Funding decisions are first disclosed individually to each applicant by written notice and subsequently announced to the public on the DDTP website.

DDTP does not disclose applicant scores or assignment of reviewers.

2.8. ACCEPTANCE OR DECLINE OF AWARDS

Award recipients shall confirm by e-mail whether they accept or decline awards within 3 weeks of receiving the announcement. However, the applicant must notify the DDTP immediately upon receiving other awards at anytime during the funding period.

2.9. REASSIGNMENT OF DECLINED AWARDS

Awards declined before receipt of the first installment of the stipend are automatically awarded to the next ranked candidate in the same category. In the event the next ranked candidate in the same category did not receive a fundable score, the award will be held for the next fundable candidates in another award category e.g. PhD, Master's, Post-doctoral. In the event that no other candidates receive fundable scores, funding will be automatically assigned to the budget of the next competition.

Awards declined after receipt of the first payment installment are not reassigned. The balance of the award will be automatically assigned to the budget of the next competition.

2.10. FUNDING DISBURSEMENT

Awards are disbursed based on the McGill bi-weekly payroll schedule and are deposited directly to the trainee's bank account. Student appointments are created and transmitted through Minerva. The appointment is created for the period of January 1st to December 31st for the fall competition and July 1st to June 30th for the spring competition.

2.11. CONDITIONS OF FUNDING

Funding can be terminated should one of the following requirements not be fulfilled:

a. End of Term Report

All trainees have to complete and submit the End of Term report when required.

b. Notification of change of status with respect to other awards or if leaving McGill.

Trainees are responsible for notifying the DDTP office should any change arise in their project such as a change of research project, laboratory or supervisor, registration status, of matching funding etc. Once notification is given to the DDTP, the panel will be informed of the change and will determine whether to continue or discontinue funding.

c. Workshop Attendance

Trainees are required to attend all workshops and courses as recommended by their Academic Advisor.

Should a DDTP trainee not attend one of the DDTP event (workshop, symposium or retreat) for which attendance is mandatory without authorization from the DDTP office, the trainee will receive a first warning and lose their eligibility to apply for a DDTP travel award. After a second absence, funding from the DDTP will be terminated.

d. Matching Funding

Equivalent matching fund must be guaranteed by the supervisor.

2.12. TEMPORARY LEAVES

Under special circumstances, a temporary leave of absence may be granted. The DDTP follows the same policies as the CIHR for family medical, maternity and/or parental, medical, relocation, and other leaves. CIHR policies are outlined at <http://www.cihr-irsc.gc.ca/e/22631.html#2-B1> .