CELL THERAPY TRAINING COURSE

a partnership between ASTCT & ISCT

Application Instructions & Criteria

The International Society for Cell and Gene Therapy (ISCT) and the American Society for Transplantation and Cellular Therapy (ASTCT) are proud to present the fourth biennial ISCT - ASTCT Cell Therapy Training Course from Monday, October 23, 2023 to Friday, October 27, 2023 hosted at the University of Pennsylvania in Philadelphia, PA, USA.

Applications open October 26, 2022 and will be accepted until January 31, 2023.

Tuition, travel, housing, and meal expenses will be paid for up to 12 scholars to attend the course. Participants will be competitively selected. Preference will be given to fellows and faculty with no more than two years of BMT and Cellular Therapy experience following training or a faculty appointment. See "Eligibility and Application" for more information.

Objectives and Curriculum

The ISCT and ASTCT Boards of Directors created the course to help address the need for in depth training in the development and translation of cellular therapies. Learners will cover all aspects of translation from pre-clinical research to cell manufacturing and clinical trials in cellular therapy, including regulatory components.

The course is designed to help scholars develop and refine the translational studies for and/or conduct of a cellular therapy clinical trial. The components of this course include:

1) An initial proposal for a cellular therapy product or trial by the scholar presented at the beginning of the course, to be refined in small group discussion with faculty, and presented as a final version at the end of the course
2) Didactic lectures
3) Visits to GMP facilities for cell products
4) Breakout sessions on select topics with case-based examples
5) Informal discussions and networking with Faculty on Career development and mentorship

The course aims to cover:

Development of Investigational New Drug [IND] – Including collation of pre-clinical data, preparation of chemistry, manufacturing, and controls (CMC) documents such as SOPs & worksheets, development of release criteria, establishment of quality indicators, validation of procedures, training of staff, and pre-clinical Pharm/Tox studies. Emphasis on Toxicology/Tumorigenicity study design and interpretation.

Translating Concept into a GMP Product – Translational research design and execution. Full scale engineering runs and final process qualification, developing QA and QC programs.

Development of Manufacturing and Testing Procedures to Provide Clinical Products and the Accompanying Documentation for the Trial Including – cGMP infrastructure, inventory management, environmental monitoring, cleaning & changeover, production monitoring, coordination of product testing, competency & proficiency testing, SOP creation, review & revision, performing audits, review quality indicators, developing stability testing.

Product Release and Follow-up – Assembling batch/manufacturing records, collate test results, issuing certificate of analysis, perform audits, controlled GMP storage, release for administration, product follow-up and recall.

Protocol Development – Inclusion of required and correlative studies.

Infusion Cell Therapy Products – Pre-infusion conditioning, monitoring infusion reactions, patient follow-up.

Clinical Trial Design – Including research subject eligibility and recruitment, biostatistics, clinical trial conduct, regulatory approvals, monitoring adverse effects, long-term follow-up (correlative studies), research ethics.

Team Science – Approaches to forming and sustaining a multi-disciplinary translational research team. Collaboration between laboratory and clinic, communication, strategies for pursuing and developing a successful career in cell therapy.

Viral Vector Development and Characterization

2023 Planning Committee Faculty

Co-Chairs:

Bruce Levine, PhD
Barbara and Edward Netter Professor
In Cancer Gene Therapy
University of Pennsylvania
Philadelphia, PA, United States

Marcela Maus, MD, PhD
Paula O'Keefe Associate Professor of Medicine
Harvard Medical School
Director, Cellular Immunotherapy Program
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Planning Committee:

Emily Hopewell, PhD
Assistant Professor of Clinical Medical
and Molecular Genetics
Director Cell and Gene Therapy Manufacturing
Indiana University School of Medicine
Indianapolis, IN, United States

Nirali Shah, MD
NIH Distinguished Scholar
Head of the Hematological Malignancies Section,
Pediatric Oncology Branch
National Cancer Institute
Bethesda, MD, United States

Andrew Fesnak, MD
Assistant Professor of Clinical Pathology and
Laboratory Medicine
Perelman School of Medicine
Director, Cell Manufacturing and Development
Clinical Cell and Vaccine Production Facility
University of Pennsylvania
Philadelphia, PA, United States

Olalekan Oluwole, MBBS, MD
Assistant Professor of Medicine
Hematology/Oncology
Vanderbilt University
Nashville, TN, United States

The Course Faculty will be established investigators from both local and non-local institutions. Faculty members will participate over multiple days to share expertise and mentor the Course Scholars.

Eligibility and Application
This program is open to all geographic regions. Geographical scholar representation will be six from North America (USA/Canada/Mexico) and six international scholars outside of North America.

An applicant must be a Fellow-in-Training or have a Junior Faculty* position and ***must be an ISCT and/or ASTCT member and sponsored by an ISCT and/or ASTCT member***. To join ISCT and/or ASTCT, please visit www.isctglobal.org and/or www.astct.org.

**Junior Faculty is defined as two years or less teaching in the BMT and Cellular Therapy field. Other applicants may be considered based on perceived need and potential benefits from the course.*

Previously unselected applicants are eligible and encouraged to apply for the 2023 Course.

Previous ISCT-ASTCT Cell Therapy Training Course Scholars and previous ASTCT Clinical Research Training Course Scholars are not eligible for the 2023 Course.

To apply, please submit the following (4) items:

1) A 1-2 page letter of application (maximum 1,000 words, Arial, font size 10). The letter should provide the applicant's background, training, interest in cellular therapy and clinical research, and career goals. Particular attention and weighting will be placed on the applicant's reasons for attending the course.
2) A detailed proposal for a translational research project in cell therapy to be further refined at the course. The candidates should have a cell therapy product that they plan to translate to the clinic. The proposal outline should be a total of 5 pages (excluding references) which includes: project title, specific aims, hypothesis, significance, innovation and brief research plan. Applicants must also provide the name of a mentor from their own institution with whom to work in implementation of the project after the course.
3) A current curriculum vitae (CV), preferably in the NIH Biographical Sketch format.
4) A 1 page letter of recommendation from the applicant's mentor. This should include a description of the resources (facilities, infrastructure and funding) available to the candidate to complete the proposed clinical investigation.

Complete Application Form

Applicant selection will be based on criteria including, but not limited to:

1) Applicant training, productivity and experience as indicated in the curriculum vitae, letter of application and letter of recommendation.
2) Proposed project significance, feasibility, and likelihood of completion, with due consideration to the quality of mentor supervision available and the resources (facilities infrastructure and funding) available to support the project in the future.
3) Commitment to a career in clinical translational research as outlined in the letter of application.
4) All other considerations being equal, regional representation.

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Scholarship Application Selection Criteria

Primary scoring will be based on three categories: Applicant, Project, and Support. Each category will be scored from 1 (Exceptional) to 9 (Poor) as outlined in the table below. When assigning scores, please consider the following questions:

The Applicant (Aggregate score from 1-9)
Training: How well suited is the applicant to the project? Is there evidence of appropriate experience and training?

Accomplishments: As much as can be determined for individuals in an early stage of their career, have they demonstrated an ongoing record of practical competence or accomplishments that have advanced their field?

Career Prospects: Are they likely to continue their career in the field of cellular therapy?

The Project (Aggregate score from 1-9)
Importance: Does the project address a clinically important problem? If the aims of the project are achieved, how will technology or clinical practice be improved? How will successful completion of the project change the methods, technologies, treatments?

How novel is the project in its concept, technology or clinical application? Does the project challenge clinical practice paradigms? Alternatively, does it represent a useful refinement or improvement over current methodologies?

Likelihood of successful completion: Is the proposal well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

Letter of support (Aggregate score from 1-9)
Environment: Is there evidence that the laboratory environment in which the work will be done is favorable to a successful completion of the project?

Mentorship: Is there adequate mentorship?

Institutional support: What is the probability that institutional support will be maintained over the period of the project?

Overall Enthusiasm (Score from 1-9)
Applicant Impact Factor: Overall, does the applicant demonstrate the ability to successfully utilize the teachings of this course to positively impact and advance the field of cell therapy? Would this course provide unfulfilled training the applicant does not already have access to through their institution/mentors?

Project Impact Factor: Will the applicant's participation in this course play a critical role in the translation of their proposed product?

Rationale for Scoring Summary:

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses
Minor Weakness: An easily addressable weakness that does not substantially lessen impact **Moderate Weakness:** A weakness that lessens impact **Major Weakness:** A weakness that severely limits impact		

Second Tier of Selection:
In the case of multiple suitable applicants, selection may be influenced by:

- *Diversity of project topic*
- *Representation of diverse institutions*
- *Diversity of scholars – MD, PhD, Quality of home institute, M/F ratio*