PFICell Yearbook 2026

A Cell & Gene Therapy Reference

Templates and Regulations

HEAD QUARTER

Profound Future focused
Innovative Cell & gene therapy

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President Speech

Dear Colleagues, Researchers, and Innovators, It is with great enthusiasm that I introduce the **PFICELL Yearbook 2026**, a prestigious initiative aimed at recognizing and showcasing the most impactful advancements in cell and gene therapy. We are excited to announce that the infrastructure, categories, registration system, and submission guidelines are now fully in place, and we are ready to begin the process of selecting 100 high-impact articles across 10 specialized categories. Our goal is to create a comprehensive resource for the global scientific community, featuring systematic, meta-analytic reviews and literature reviews that push the boundaries of innovation. Through a transparent and rigorous process, we aim to ensure that only the highest-quality research is selected for inclusion.

Managerial Structure

The **PFICELL Yearbook 2026** is governed by a well-defined framework to ensure the highest standards of quality:

- **Senior Management:** Provides strategic oversight, ensuring alignment with PFICELL's mission.
- **The Yearbook Secretariat:** Manages submissions, communications, and operational details.
- **Editorial Board:** Finalizes the selection of articles, ensuring consistency and scientific rigor.
- **Arbitrators (Peer Reviewers):** A distinguished panel of experts who evaluate the submissions based on scientific merit and clinical relevance.

The Process of Forming the Yearbook

The process of selecting and publishing the **PFICELL Yearbook 2026** follows these key steps:

1.Registration on the Platform:
Researchers and reviewers must register on the **PFICELL** platform to participate in the process. Authors are invited to submit up to five titles; however, they may submit no more than two soft topics per topics, with only one article per title.g-edge research in cell and gene therapy.

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1.Registration on the Platform:
Researchers and reviewers must **register on the PFICELL platform** to participate in the process. Authors are invited to submit up to five titles; however, they may submit no more than two titles per category, with only one article per title.

2.Paper Submission:
Authors submit their work directly on the platform. We encourage thoughtful selection to ensure the submissions align with the yearbook's scope.

3.Peer Review:
Submitted papers undergo peer review by arbitrators who evaluate their scientific impact, clinical relevance, and methodological rigor.

4.Finalization by Editorial Board:
After review, the Editorial Board ensures the selected papers meet editorial and scientific standards before approval.

5.Approval and Selection for the Yearbook:
After approval, the **100 best articles** are selected for inclusion in the yearbook, which will represent cutting-edge research in cell and gene therapy.

6.Publication and Digital Archiving:
The yearbook will be published and made available to the global scientific community, and all articles will be stored in a **digital databank** for future reference.

A Call to Action

We now invite researchers and reviewers to register and submit their work. This is a unique opportunity to contribute to the advancement of precision medicine and help shape the future of cell and gene therapy.
With the frameworks and guidelines now in place, we look forward to your participation. Together, let us elevate scientific excellence and drive innovative progress in the field.

Good Luck
Dr. Fathi
President of Pficell Academia
Associate Professor of Clinical
Cell Therapy at Pficell

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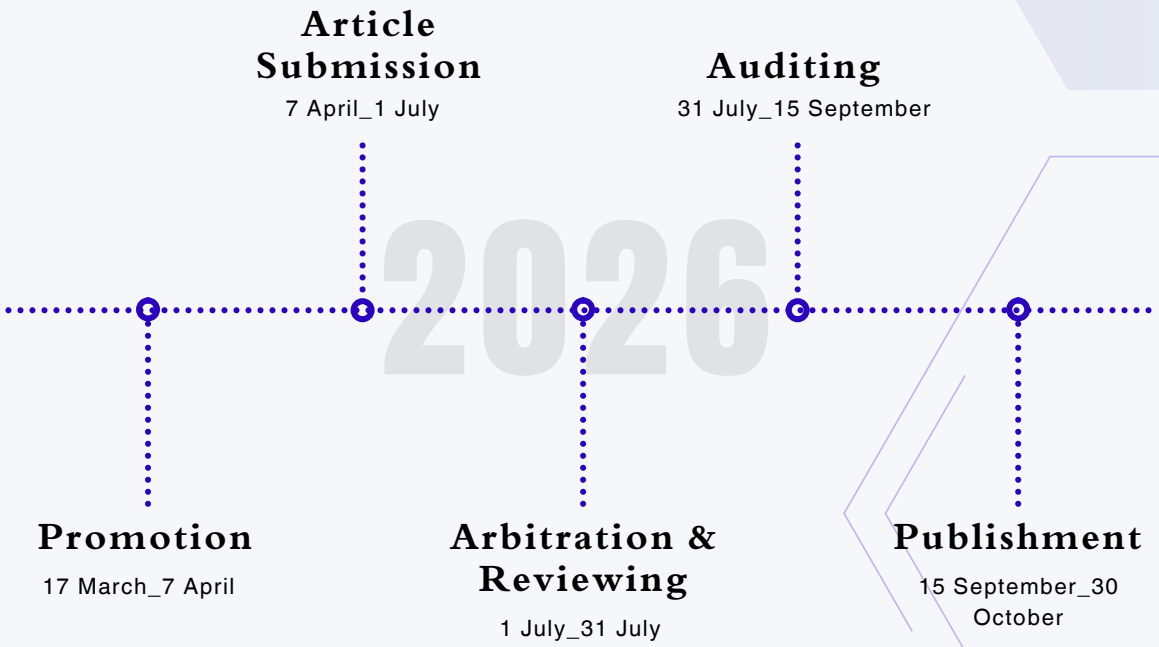
TIME SCHEDULING



Promotion: Introducing the book to all Health and Academic centers, institutions and companies of research and development, research and clinical services in the field of cell and gene therapy, with the aim of attracting the support of top professors and researchers and providing reliable scientific resources.

Article Submission: Registering authors in the system, selecting topics and subtopics of Yearbook 2026, and compiling articles related to the selected topics.

Arbitration and review of Article: Review and Appraisal evaluating articles by expert and professional referees, and Scoring, and feedback to Authors.

Auditing: Auditing articles and based on the referees' their comments, and the revisions made, and final approval of articles for

publication in the book or the articles system. Publishing: Publishing the book and publishing articles in the Pficell articles system.

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Introduction to Pficell

Pficell (Profound Future focused on Cell and gene therapy) is a research and development Canadian institute and Corporation, located in Canada with a global perspective. Its activities began years ago with a future-focused approach, involving guidance, planning, investment, and support for both small and large-scale studies across North America and five continents. The result of these clinical trials has been the attainment of unparalleled technical knowledge and cutting-edge technologies in the fields of cell therapy and gene therapy, which are being utilized and will continue to be employed to serve the global community and guide society **towards sustainable health solutions.**

Ongoing Activities

One of the Pficell notable and ongoing activities is its support for approved clinical trials by the Supreme Council of the organization, relying on experienced regional researchers and prominent scientists in the field of cell and gene therapy. It is evident that the technical knowledge, biological development protocols, clinical skills, and other essential requirements for conducting these studies are provided by Pficell. Currently, more than ten clinical trials are underway in Asia, Europe, and South America, supported by Pficell.

Data Science and Clinical Trials

Our invaluable data science bank and clinical trials are built on a strong foundation of research investment and a commitment to excellence. We prioritize the collection of up-to-date data, ensuring that our findings reflect the latest advancements in the field. Our approach incorporates best practices and evidence-based methodologies, including systematic reviews, meta-analyses, and FDA Approved Clinical Trials which provide comprehensive insights and a robust understanding of therapy effectiveness.

Collaboration with Medical Centers

Additionally, we collaborate with some of the most renowned medical centers, leveraging their expertise and resources to enhance the quality and reliability of our research outcomes. This strategic focus on rigorous research, evidence aggregations, and collaboration with leading institutions empowers us to drive innovation and deliver impactful therapeutic solutions.

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Our Commitment

At Pficell, our colleagues form a close-knit community, united by our commitment to integrity and transparency. Every registered and accepted basic or clinical trial conducted by Pficell represents a collective obligation to uphold the highest standards of excellence in research and collaboration.

- We utilize a comprehensive array of indices and applications to assess the compatibility of our trials with established protocols and standard criteria, ensuring the safety and accuracy of our methodologies and results. However, our most essential asset in striving for excellence remains trust.

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Introduction to the Yearbook 2026

The **PFICELL Yearbook 2026 in Cell and Gene Therapy** is a prestigious publication dedicated to highlighting groundbreaking research, innovative systematic reviews, and meta-analytic studies in the rapidly evolving field of cell and gene therapy. This yearbook serves as a platform for registered members of our academic community to share their knowledge and contribute to the global scientific discourse.

For the 2026 edition, we are inviting submissions under 10 key categories, each designed to address the most pressing challenges, advancements, and future directions in cell and gene therapy:

1. Cell and Gene Therapies
2. Innovations in Cellular Research
3. Artificial Intelligence in Life Sciences
4. Regenerative Medicine
5. Cell Development and Manufacturing
6. 3D and 4D Culture Technologies
7. Advanced Cell and Gene Therapies
8. Sustainability and Ethics in Research
9. Future Perspectives
10. Young Scientists and Outreach

Note: You can read the subtopics of each topic in the attachment.

Each category will feature 10 exceptional articles, culminating in a total of 100 insightful contributions. We particularly encourage systematic and meta-analytic reviews that offer deep insights and critical evaluations, shaping the future of our field.

To recognize outstanding contributions, we are awarding one research grant per category, supporting the authors of the most impactful papers. The selection process will be conducted by a distinguished panel of experts, ensuring that only the most innovative and high-quality research is included in the final publication.

The PFICELL Yearbook 2026 will not only serve as a repository of knowledge but will also provide an elegant and professional presentation for each featured article, reinforcing the significance of your work. This is a unique opportunity to have your research acknowledged on an international stage and contribute to the collective advancement of cell and gene therapy.

Join us in shaping the future—your research could be the next breakthrough that transforms the field.

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Scope and Objectives of the Yearbook

The **PFICELL Yearbook 2026** is designed to serve as a comprehensive reference for professionals, researchers, and scholars in the field of cell and gene therapy. By compiling high-quality systematic and meta-analytic reviews, as well as cutting-edge research articles, and Literature Reviews Cell and Gene Therapy management and leadership the yearbook aims to provide valuable insights into emerging technologies, clinical advancements, ethical considerations, and future prospects.

Scope

The PFICELL Yearbook 2026 will cover a broad range of topics within cell and gene therapy, making it an essential resource for:

- Academic Institutions & Research Centers – as a teaching and research reference for students, educators, and investigators in biotechnology, regenerative medicine, and gene therapy programs.
- Hospitals & Clinical Departments – supporting clinicians and medical researchers involved in translational medicine, personalized therapies, and clinical trial design.
- Biotechnology & Industry – providing innovative perspectives on cell manufacturing, and regulatory considerations.
- Regulatory and Ethical Committees – serving as a guideline reference for ethical, safety, and regulatory standards in experimental and approved therapies.
- Government and Policy Makers – offering evidence-based insights for shaping policies and funding decisions in regenerative medicine and genetic engineering.

Objectives

The primary objectives of the PFICELL Yearbook 2026 are:

1.To Provide a Reliable Scientific Reference

- Establishing the yearbook as a trusted source of knowledge for cell and gene therapy professionals worldwide.

2.To Highlight Innovations and Research Excellence

- Showcasing pioneering research from leading scientists, institutions, and young innovators.

3.To Encourage Collaboration and Knowledge Exchange

- Fostering multidisciplinary collaboration between researchers, clinicians, and industry leaders.

4.To Set Standards for Systematic and Meta-Analytic Reviews

- Promoting high-quality, evidence-based research to guide future studies.

5.To Support Emerging Scientists and Novel Ideas

- Providing a platform for young scientists to gain recognition and funding for their contributions.

6.To Influence Policy, Regulatory and Ethical Standards

- Assisting in the development of global best practices for safety, ethics, and regulatory compliance in cell and gene therapy.

7.To Inspire Future Research Directions

- Identifying key challenges and opportunities in regenerative medicine, genetic editing, and cell therapy applications.

By fulfilling these objectives, the PFICELL Yearbook 2026 will not only be a repository of knowledge but also a catalyst for innovation, shaping the future of cell and gene therapy research, education, and application.

Ethical and Scientific Standards

The PFICELL Yearbook 2026 upholds the highest ethical and scientific integrity in the publication of research related to cell and gene therapy. We adhere to international guidelines to ensure that all contributions maintain scientific rigor, transparency, reproducibility, and ethical responsibility.

1. Ethical Standards in Research and Publication

1.1 Human and Animal Research Ethics

- All studies involving human participants must comply with the Declaration of Helsinki and obtain approval from an Institutional Review Board (IRB) or Ethics Committee.
- Studies involving animal research must follow the 3Rs Principle (Replacement, Reduction, and Refinement) and receive ethical clearance from a recognized Institutional Animal Care and Use Committee (IACUC).
- Informed consent must be obtained from all human subjects or their legal representatives.

1.2 Data Integrity and Reproducibility

- All submitted research must be original, reproducible, and supported by verifiable data.
- Authors are encouraged to share raw data in publicly accessible repositories when possible.
- Fabrication, falsification, or selective reporting of data is strictly prohibited.

1.3 Authorship and Contributions

- Authors must meet ICMJE (International Committee of Medical Journal Editors) authorship criteria, ensuring that only those who have significantly contributed to the research are credited.
- Ghostwriting, honorary authorship, and undisclosed contributions from third parties are not permitted.
- A clear conflict-of-interest statement must be disclosed by all authors.

1.4 Plagiarism and Duplicate Publication

- Plagiarism, self-plagiarism, and duplicate publication are strictly prohibited. All submissions will undergo plagiarism screening using advanced detection software.
- Proper citations must be provided for all references, figures, and datasets.

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2. Scientific Standards and Methodological Rigor

2.1 Systematic and Meta-Analytic Reviews

- Articles must adhere to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for systematic reviews and meta-analyses.

2.2 Clinical Trials and Translational Research

- Studies involving clinical trials must be registered in recognized registries (e.g., ClinicalTrials.gov, WHO ICTRP).
- Clinical research should follow CONSORT (Consolidated Standards of Reporting Trials) guidelines.

2.3 Data Reporting and Statistical Standards

- Statistical analysis should follow best practices, including power calculations, confidence intervals, and effect size reporting.
- Bioinformatics and computational studies must ensure algorithm transparency and data availability.

2.4 Transparency in Funding and Conflicts of Interest

- All sources of funding, institutional affiliations, and potential conflicts of interest must be disclosed.
- Industry-sponsored research must follow Good Publication Practice (GPP) guidelines.

2.5 Cell and Gene therapy management and leadership papers

- Review articles in the field of management and leadership of cell and gene therapy need to be based on credible and reliable scientific sources and reports from reputable, standard and world-class centers.
- Review articles in this field should provide appropriate guidance in the field of structuring and explaining strategies and direction of management and leadership of organizations, institutions and companies active in the field.

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3. Arbitrator review and Editorial Integrity

3.1 Double-Blind Arbitrator review Process

- The PFICELL Yearbook 2026 follows a double-blind Arbitrator review to ensure impartial evaluation.
- Reviewers must adhere to COPE (Committee on Publication Ethics) guidelines for ethical reviewing.

3.2 Editorial Decision-Making and Appeals

- Decisions will be based on scientific merit, originality, and ethical soundness.
- Authors have the right to appeal editorial decisions through a transparent process.

By adhering to these ethical and scientific standards, the PFICELL Yearbook 2026 aims to maintain credibility, integrity, and excellence, ensuring that all published research contributes meaningfully to the advancement of cell and gene therapy.

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Guidelines for Authors

The PFICELL Yearbook 2026 invites researchers, clinicians, and industry experts to submit high-quality manuscripts that contribute to the advancement of cell and gene therapy. We particularly encourage systematic and meta-analytic reviews and literature reviews in management and leadership of cell and gene enterprise, as well as innovative research articles that align with our mission to showcase groundbreaking scientific progress.

1. General Submission Guidelines

- Eligibility: Submissions are open to all researchers, with priority given to registered members of the PFICELL academic community.
- Language: All manuscripts must be written in English and conform to professional academic standards.
- Originality: Submissions must be original, unpublished work that has not been submitted elsewhere.
- Ethical Compliance: Research involving human or animal subjects must include appropriate ethics approval and informed consent documentation.
- Plagiarism Policy: All manuscripts will be screened for plagiarism, and any detected misconduct will result in rejection.
- Conflict of Interest: Authors must disclose all funding sources and any potential conflicts of interest.

2. Manuscript Categories and Formatting Requirements

Submissions must fit within one of the 10 core categories of the PFICELL Yearbook 2026:

1. Cell and Gene Therapies
2. Innovations in Cellular Research
3. Artificial Intelligence in Life Sciences
4. Regenerative Medicine
5. Cell Development and Manufacturing
6. 3D and 4D Culture Technologies
7. Advanced Cell and Gene Therapies
8. Sustainability and Ethics in Research
9. Perspectives
10. Young Scientists and Outreach

Each category will include 10 selected articles, totaling 100 published contributions. The following manuscript types are accepted:

2.1 Systematic and Meta-Analytic Reviews (Preferred)

- Comprehensive literature analyses following PRISMA guidelines.
- Must include a clearly defined research question, methodology, inclusion criteria, and statistical analysis.
- Meta-analyses should provide a quantitative synthesis of existing studies.

2.2 Original Research Articles

- Must present new experimental, translational, or clinical findings.
- Includes hypothesis, methodology, results, and discussion.
- Clinical trials must be registered (e.g., ClinicalTrials.gov).

2.3 Case Reports and Case Series

- Must describe novel or rare clinical cases with high relevance to cell and gene therapy.
- Includes clinical presentation, diagnostic approach, treatment, and outcomes.

2.4 Technical and Methodological Advances

- Reports on new techniques, protocols, or laboratory methodologies in the field.
- Requires validation data and comparison with existing methods.

2.5 Short Communications and Commentaries

- Includes rapid research updates, expert opinions, and critical analyses of emerging topics.
- Limited to 1,500 words with a maximum of 2 figures/tables.

2.6 Position Papers and Consensus Guidelines

- Expert group recommendations on best practices, regulatory concerns, and future directions.
- Should be endorsed by a recognized scientific or clinical body.

3. Manuscript Preparation and Structure

All submissions must follow this standard structure:

3.1 Title Page

- Title (concise and descriptive)
- Author names and affiliations
- Corresponding author contact details
- Conflict of interest and funding statement

3.2 Abstract

- Structured format (Background, Methods, Results, Conclusion)
- Maximum 250 words

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3.3 Keywords

- 4–6 relevant keywords

3.4 Main Text

- Introduction: Clearly state the research question, background, and objectives.
- Methods: Detailed explanation of study design, protocols, and statistical analysis.
- Results: Objective presentation of findings (without interpretation).
- Discussion: Interpretation of results, comparison with existing literature, limitations, and future implications.
- Conclusion: Summary of key findings and their significance.

3.5 References

- Follow Vancouver citation style.
- Minimum 30 references for systematic reviews.

3.6 Figures and Tables

- Must be high-resolution and cited in the text.
- Include a legend for each figure/table.

4. Submission and Review Process

4.1 Submission Portal

- Manuscripts must be submitted through the PFICELL online platform.
- Ensure all files (manuscript, figures, tables, supplementary data) are included.

4.2 Arbitrator Review Process

- Double-blind Arbitrator review for fairness and objectivity.
- Reviewers will evaluate based on scientific merit, originality, and relevance.
- Typical review timeframe: 4–6 weeks.

4.4 Publication and Recognition

- Accepted articles will be featured in the PFICELL Yearbook 2026.
- One article per category will receive a grant award for outstanding contribution.

5. Copyright and Open Access Policy

- Authors retain intellectual property rights but must grant PFICELL Institute a publication license.
- The yearbook follows an open-access model for members, ensuring global visibility for all member contributions with preserving Pficell Copy Rights and authorities.
- By following these guidelines, authors will contribute to a high-impact, widely respected scientific reference that advances the field of cell and gene therapy.

Guidelines for Arbitrator reviewers

The PFICELL Yearbook 2026 maintains a rigorous and transparent Arbitrator review process to ensure the highest standards of scientific integrity and scholarly excellence. Arbitrator reviewers play a critical role in evaluating submitted manuscripts for quality, originality, and ethical compliance.

1. Role and Responsibilities of Arbitrator reviewers

As a PFICELL Yearbook 2026 Arbitrator reviewer, you are expected to:

- Provide Constructive Feedback: Offer clear, detailed, and unbiased assessments to help authors improve their manuscripts.
- Evaluate Scientific Merit: Assess the originality, methodology, data accuracy, and logical coherence of the manuscript.
- Maintain Confidentiality: Do not share, discuss, or use any part of the manuscript for personal research or professional advantage.
- Identify Ethical Concerns: Report any signs of plagiarism, data manipulation, conflicts of interest, or ethical breaches.
- Adhere to Deadlines: Submit timely reviews to maintain an efficient publication schedule.

2. Arbitrator review Process

2.1 Manuscript Assignment

- Reviewers are selected based on expertise in the manuscript's subject area.
- Upon receiving an invitation, reviewers must confirm their availability and lack of conflicts of interest.

2.2 Double-Blind Review

Reviewers will assess the manuscript based on the following aspects:

	Subject	Co efficiency	Scaling	Scoring
1)	Structure	3	5: Perfect organization, clear sections, and coherent flow.	5
			4: Well-organized but minor structural issues.	4
			3: Adequate structure with noticeable issues.	3
			2: Poorly organized, lacks coherence.	2
			1: No discernible structure.	1
2)	Integrity	3	5: Perfect adherence to ethical and scientific standards.	5
			4: High integrity with minor issues.	4
			3: Adequate adherence, some ethical/scientific concerns.	3
			2: Significant breaches of integrity.	2
			1: Lacks integrity, major ethical violations.	1
3)	Literature and fluency of the text	4	5: Perfect, comprehensive review, and excellent fluency.	5
			4: High-quality literature review and good fluency.	4
			3: Adequate coverage, some language or fluency issues.	3
			2: Limited literature review, poor fluency.	2
			1: Lacks literature support and fluency.	1

	Subject	Co efficiency	Scaling	Scoring
4)	Strategy of search	3	5: Full coverage, appropriate, relevant, and structured.	5
			4: Extensive and relevant search strategy, minor gaps.	4
			3: Adequate strategy, noticeable gaps in coverage.	3
			2: Poor strategy, limited relevance.	2
			1: No structured strategy.	1
5)	Content Validity	4	5: Full content validity, accurate and relevant.	5
			4: High validity with minor inaccuracies.	4
			3: Adequate validity, some content inaccuracies.	3
			2: Limited validity, major inaccuracies.	2
			1: Lacks validity, misleading content.	1
6)	Conclusion Validity	4	5: Perfect logical and methodological construction.	5
			4: Strong construction with minor issues.	4
			3: Adequate construction, noticeable flaws.	3
			2: Poor construction, significant flaws.	2
			1: Illogical or unsupported construction.	1

	Subject	Co efficiency	Scaling	Scoring
7)	Construction Validity	2	5: Perfectly relevant, recent, and credible references.	5
			4: High-quality references with minor gaps.	4
			3: Adequate references, some outdated or irrelevant sources.	3
			2: Limited relevance or credibility of references.	2
			1: Lacks valid references.	1
8)	Reference Validity	3	5: Perfectly relevant, recent, and credible references.	5
			4: High-quality references with minor gaps.	4
			3: Adequate references, some outdated or irrelevant sources.	3
			2: Limited relevance or credibility of references.	2
			1: Lacks valid references.	1
9)	Applicability	4	Completely applicable and ready to use	5
			High applicable and near to market	4
			Need to some development	3
			Need to more study to use	2
			Not applicable	1

	Subject	Co efficiency	Scaling	Scoring
10)	Future Focused and innovation	5	5: Fully global, innovative, and future-focused.	5
			4: One of the main innovations.	4
			3: Rapid follower in innovation.	3
			2: Limited innovation.	2
			1: Retrospective, no innovation.	1

2.4 Providing Reviewer Comments

- Use professional and constructive language when critiquing the manuscript.
- Clearly highlight strengths and suggest areas for improvement.
- If rejecting the manuscript, provide a detailed explanation for the decision.

Example of Reviewer Comments:

Constructive Comment:

"The manuscript presents an innovative approach to gene therapy; however, additional statistical validation is required to support the conclusions. Including a control group in future studies could enhance reliability."

Unhelpful Comment:

"The study is weak and should not be published."

2.5 Recommendation Decision

After review, select one of the following recommendations:

1. **Accept** – Publish with minor or no revisions.
2. **Minor Revisions** – Acceptable after addressing specific comments.
3. **Major Revisions** – Requires substantial improvements before reconsideration.
4. **Reject** – Manuscript does not meet publication standards.

3. Ethical Responsibilities of Reviewers

3.1 Confidentiality and Data Protection

- Do not disclose, copy, or discuss the manuscript with others.
- Do not use any unpublished data for personal or professional gain.

3.2 Conflict of Interest Disclosure

- If you have any personal, financial, or professional conflicts of interest with the authors or research topic, decline the review.

3.3 Fair and Unbiased Review

- Evaluate the manuscript based on scientific quality, not personal biases.
- Avoid discrimination based on geography, institution, or author identity.

4. Reviewer Recognition and Incentives

- Arbitrator reviewers will receive official recognition in the PFICELL Yearbook 2026.
- Top reviewers may be nominated for awards and invited to contribute to future editorial activities.

By following these guidelines, reviewers help ensure that the PFICELL Yearbook 2026 maintains its commitment to scientific excellence, transparency, and integrity.

Ethical, Legal, and Regulatory Frameworks

The PFICELL Yearbook 2026 upholds the highest ethical, legal, and regulatory standards in cell and gene therapy research, ensuring that all published works comply with international guidelines for safety, efficacy, and responsible scientific conduct. This section outlines the fundamental principles governing research ethics, legal requirements, and regulatory frameworks that must be followed by authors submitting to the yearbook.

1. Ethical Frameworks in Cell and Gene Therapy

1.1 Data Integrity, Transparency, and Scientific Misconduct

- All submitted data must be accurate, verifiable, and reproducible.
- Plagiarism, data fabrication, falsification, and selective reporting are strictly prohibited.
- Authors must disclose all potential conflicts of interest, funding sources, and affiliations.

1.2 Privacy and Confidentiality in Genetic Research

- Patient genetic data must be handled with strict confidentiality and comply with privacy regulations such as GDPR (General Data Protection Regulation) and HIPAA (Health Insurance Portability and Accountability Act).
- Researchers must de-identify patient information when sharing genomic datasets.

2. Legal Frameworks and Compliance

2.1 International Regulations Governing Cell and Gene Therapy

- All clinical studies must comply with guidelines from regulatory authorities such as:
  - FDA (U.S. Food and Drug Administration) – Cell and gene therapy regulations under the Center for Biologics Evaluation and Research (CBER).
  - Health Canada- Cell and gene therapy regulations and guidelines.
  - EMA (European Medicines Agency) – Advanced Therapy Medicinal Products (ATMPs) regulatory framework.
  - WHO (World Health Organization) – Global guidelines on ethical gene-editing and clinical trial governance.
  - ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) – Standards for drug development and safety.

2.2 Clinical Trials and Good Clinical Practice (GCP)

- All experimental therapies involving human subjects must be registered in recognized clinical trial databases (e.g., ClinicalTrials.gov, WHO ICTRP).
- Trials must follow Good Clinical Practice (GCP) guidelines, ensuring patient safety and rigorous data collection.
- Informed consent and patient safety monitoring are mandatory at all trial stages.

2.3 Intellectual Property and Patent Considerations

- Researchers must respect intellectual property rights related to gene-editing technologies (e.g., CRISPR, CAR-T therapy).
- Patents must comply with the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) under the World Trade Organization (WTO).
- Open-access genomic data sharing must align with policies from NIH, EMBL-EBI, and other genomic databases.

3. Regulatory Considerations for Cell and Gene Therapy

3.1 Manufacturing and Quality Control of Cell-Based Products

- Research involving cell manufacturing and gene-editing technologies must comply with Good Manufacturing Practice (GMP) guidelines.
- Standardized procedures must be followed for:
  - Cell sourcing and donor eligibility.
  - Genetic modification and vector production.
  - Product validation and safety testing.

3.2 Biosafety and Risk Assessment in Gene Editing

- Genome-editing research (CRISPR, TALEN, ZFN) must adhere to biosafety level (BSL) regulations.
- Studies must evaluate off-target effects, unintended mutations, and long-term genetic stability.
- Germline modifications are strictly prohibited in many jurisdictions due to ethical concerns.

3.3 Commercialization and Market Authorization

- Gene and cell-based therapies must undergo regulatory approval before commercialization.
- Regulatory pathways include:
  - FDA Biologics License Application (BLA) for cell and gene therapy products.
  - EMA Marketing Authorization for Advanced Therapy Medicinal Products (ATMPs).
  - Japan's Fast-Track Approval System for regenerative medicine.

4. Emerging Ethical and Legal Challenges

4.1 Human Germline Editing and Designer Babies

- The ethical debate on human embryo editing and genetic enhancement remains highly controversial.
- Current global consensus prohibits germline editing for reproductive purposes, but discussions on therapeutic applications continue.

4.2 Equity and Accessibility of Gene Therapies

- Many advanced cell and gene therapies have high costs, limiting accessibility for low-income populations.
- Ethical frameworks must ensure fair distribution of innovative treatments.

4.3 AI and Big Data in Personalized Medicine

- AI-driven genomic analysis and predictive medicine raise concerns about algorithm bias and data privacy.
- Regulatory policies must evolve to govern AI applications in gene therapy decision-making.

5. Conclusion

The PFICELL Yearbook 2026 ensures that all published research meets the highest ethical, legal, and regulatory standards in cell and gene therapy. By complying with international guidelines, we foster responsible innovation, patient safety, and scientific integrity, ensuring that cell and gene therapies are safe, effective, and ethically sound

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Submission, Review, and Publication Process

The PFICELL Yearbook 2026 follows a structured process to ensure fair, high-quality, and transparent Arbitrator reviewed publications. The process includes manuscript submission, expert review, revisions, and final publication.

1. Membership and Author Registration

All authors must be registered members of PFICELL Academia to submit manuscripts.

- Membership registration is available on www.pficell.ca.
- Authors must provide their full name, affiliation, and ORCID ID.
- For Students, would be better to submit:
  - Their academic email address.
  - Contact details of their supervisor(s) or professor(s) from the past five years.

Reviewers do not have any selection limitations and can review submissions from any category.

2. Submission Guidelines

- Authors may select up to five (5) subtitles but not more than two (2) subtitles per category.
- Manuscripts must be formatted according to PFICELL Yearbook 2026 guidelines (structured abstracts, citations in Vancouver style, and standard word limits).
- Submissions must include:
  - Title and abstract (max 300 words).
  - Keywords (3-5 relevant terms).
  - Main text (structured format for original research, systematic/meta-analytic reviews, case reports).
  - Figures, tables, and references.
  - Ethical approval statements, if applicable.

3. Review Process

The PFICELL Yearbook 2026 follows a double-blind Arbitrator review process to ensure objectivity and transparency.

1.Initial Screening (Editorial Office Review)

- Manuscripts undergo a plagiarism check and an initial assessment for completeness and compliance with submission guidelines.
- Submissions failing to meet basic requirements are returned to authors for revision.

1.Arbitrator review (2-3 Expert Reviewers Assigned)

- Manuscripts are assigned to expert reviewers based on subject matter expertise.
- Reviewers evaluate submissions based on scientific merit, originality, clarity, and ethical integrity.
- Students' submissions undergo an additional review stage by a senior scientist or professor.

2.Decision and Author Revisions

Reviewers provide feedback with one of the following recommendations:

Accept – Ready for publication with minimal or no revisions.
Minor Revisions – Requires small improvements before acceptance.
Major Revisions – Needs significant modifications; must be resubmitted for review.
Reject – Not suitable for publication in its current form.

- Authors receive reviewer comments and must submit revised manuscripts within two weeks for minor revisions and four weeks for major revisions.

3.Final Editorial Decision

- After revisions, the editorial team reviews changes and makes a final decision.
- Accepted manuscripts undergo proofreading and formatting for publication.

4. Publication and Author Recognition

- Accepted articles are officially published in the PFICELL Yearbook 2026.
- Selected top articles receive grant awards in each category.
- Authors and reviewers receive official certificates of contribution.

This structured process ensures that only high-quality and impactful research is included in the PFICELL Yearbook 2026.

References and Resources

The PFICELL Yearbook 2026 encourages authors and reviewers to rely on high-quality, Arbitrator -reviewed sources and established guidelines to ensure scientific accuracy, transparency, and credibility. This section outlines the key references and resources for cell and gene therapy research, ethical standards, regulatory compliance, and citation requirements.

1. Recommended Reference Sources

1.1 Scientific Journals and Publications

Authors are encouraged to cite recent and relevant literature from high-impact journals, including but not limited to:

- Nature Biotechnology
- Cell Stem Cell
- Molecular Therapy
- The New England Journal of Medicine (NEJM)
- Journal of Gene Medicine
- Stem Cells Translational Medicine

1.2 Regulatory and Ethical Guidelines

- Declaration of Helsinki – Ethical principles for medical research involving human subjects.
- Good Clinical Practice (GCP) Guidelines – International standards for clinical trials.
- FDA Guidance on Human Cell and Gene Therapy Products – Regulations for cell and gene-based treatments.
- European Medicines Agency (EMA) Guidelines on ATMPs – Regulatory framework for advanced therapy medicinal products.
- International Society for Stem Cell Research (ISSCR) Guidelines – Ethical and research guidelines for stem cell therapy.

1.3 Cell and Gene Therapy Organizations

- Profound Future focused Innovative Cell & Gene Therapy (PFICell)
- International Society for Cell and Gene Therapy (ISCT)
- American Society of Gene & Cell Therapy (ASGCT)
- Cell Therapy Transplant Canada (CTTC)
- European Society of Gene and Cell Therapy (ESGCT)
- World Health Organization (WHO) – Global Standards for Genomic Research

2. Resources for Authors and Reviewers

2.1 Manuscript Preparation and Citation Style

- All references must be formatted in Vancouver style (author-number system).
- Authors should use reference management tools such as:
  - EndNote
  - Mendeley
  - Zotero

2.2 Research Data and Open-Access Databases

To support reproducibility and data transparency, authors are encouraged to cite data from reputable databases:

- PubMed (NCBI) – Biomedical literature.
- ClinicalTrials.gov – Registry of ongoing and completed clinical trials.
- The Cancer Genome Atlas (TCGA) – Genomic data for cancer research.
- GenBank (NCBI) – Genetic sequence database.
- European Bioinformatics Institute (EMBL-EBI) – Bioinformatics research tools.

2.3 AI and Computational Resources

For authors working on AI applications in cell and gene therapy, the following platforms offer valuable datasets and computational tools:

- The Human Cell Atlas – Mapping all human cell types.
- Deep Mind Alpha Fold – AI-driven protein structure predictions.
- Gene Ontology Consortium – Bioinformatics resource for gene function classification.

3. Accessing PFICELL Resources

Members of PFICELL Academia can access exclusive resources, including:

- Full-text articles and systematic reviews via www.pficell.ca.
- Templates for manuscript submissions and ethical approval forms.
- Webinars and workshops on advanced cell and gene therapy topics.

By utilizing these references and resources, authors and reviewers can ensure that their contributions to the PFICELL Yearbook 2026 are based on rigorous scientific evidence and the highest ethical standards.

Glossary of Key Terms

A glossary of key terms is an essential tool for authors, reviewers, and readers to understand the specialized vocabulary used in cell and gene therapy. Below are some of the most frequently used terms in the field, along with their definitions.

A

- Adoptive Cell Therapy: A type of immunotherapy where T cells or other immune cells are removed from a patient, modified or expanded in a laboratory, and then returned to the patient to fight disease.
- Allele: A variant form of a gene found at a specific location on a chromosome.
- Allogeneic: Refers to cells, tissues, or organs transplanted between genetically different individuals of the same species.

B

- Biologics: Products derived from living organisms, such as vaccines, gene therapies, and monoclonal antibodies, used for therapeutic purposes.
- Biosafety: Measures and protocols designed to protect researchers, patients, and the environment from the potential risks of biological research, particularly gene therapy.

C

- CAR-T Therapy: Chimeric Antigen Receptor T-cell therapy, a form of immunotherapy that modifies T cells to target specific cancer cells.
- CRISPR-Cas9: A gene-editing technology that enables precise alterations to DNA by targeting specific genes for modification or correction.
- Cell Therapy: Treatment involving the administration of living cells to patients to repair or regenerate damaged tissues or organs.

D

- DNA Sequencing: The process of determining the exact sequence of nucleotides in a DNA molecule, essential for understanding genetic information.
- Donor Cells: Cells taken from a donor for use in therapies, such as stem cell transplants or gene editing.

E

- Ex Vivo: Procedures or experiments performed outside the living organism, usually in a laboratory setting (e.g., ex vivo gene therapy involves modifying cells outside the body before reintroducing them).
- Epigenetics: The study of changes in gene expression or cellular phenotype that do not involve alterations in the underlying DNA sequence.

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F

- Gene Editing: The process of making precise changes to the DNA sequence of a living organism using techniques like CRISPR or TALENs.
- Gene Therapy: A technique that modifies or replaces defective genes within a patient's cells to treat disease.
- Gamma-Delta (γδ) T cell: Gamma delta (γδ) T cells are the prototype of 'unconventional' T cells and represent a relatively small subset of T cells in peripheral blood. They are defined by expression of heterodimeric T-cell receptors (TCRs) composed of γ and δ chains

G

- Germline Editing: Genetic modifications made to the sperm, egg, or embryo that are inherited by future generations.
- GMP (Good Manufacturing Practice): A system that ensures products, including gene therapies, are consistently produced and controlled according to quality standards.

H

- Hematopoietic Stem Cells: Stem cells that give rise to all blood cells, often used in therapies for blood disorders or leukemia.
- HLA (Human Leukocyte Antigen): A group of molecules displayed on cell surfaces that play a critical role in immune system function and organ transplantation.

I

- Induced Pluripotent Stem Cells (iPSCs): Adult cells reprogrammed to revert to a pluripotent state, capable of differentiating into any cell type.
- Immunotherapy: Treatment that uses the body's immune system to fight diseases, often used in cancer treatment, including CAR-T therapy.

J

- Junctional Diversity: The variation in the DNA sequences that occurs during the formation of the T-cell receptor and B-cell receptor, contributing to immune system diversity.

K

- Knock-In: A genetic modification where a specific gene is inserted into a predetermined location in the genome.
- Knock-Out: A genetic modification where a gene is deliberately disrupted or inactivated to study its function.

L

- Lentivirus: A type of retrovirus used in gene therapy to deliver genetic material into cells.
- Ligase: An enzyme that facilitates the joining of two DNA strands, important in gene-editing and repair processes.

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M

- Monoclonal Antibodies: Antibodies that are identical because they are made from a single clone of cells, used in therapeutic applications to target specific antigens.
- Mesenchymal Stem Cells (MSCs): Multipotent stem cells that can differentiate into a variety of cell types, such as bone, cartilage, and fat cells.

N

- Nucleic Acid: DNA or RNA molecules that carry genetic information.
- NHS (National Health Service): In some regions, an organization responsible for providing healthcare services, often involved in clinical gene therapy trials.

O

- Oncolytic Virus: A virus that selectively infects and kills cancer cells, often engineered for therapeutic use in cancer treatment.
- Omics: A field of study that includes genomics, proteomics, metabolomics, and other related areas focused on the large-scale analysis of molecules that make up an organism.

P

- Plasmid: A small, circular DNA molecule used in gene therapy to carry foreign genetic material into cells.
- Progenitor Cells: Early descendants of stem cells that can differentiate into specific types of cells but are not as versatile as stem cells.

Q

- Quantitative PCR (qPCR): A laboratory technique used to amplify and simultaneously quantify a targeted DNA molecule.

R

- Regenerative Medicine: A branch of medicine focused on repairing or replacing damaged tissues and organs, often using stem cells or gene therapies.
- RNA Interference (RNAi): A biological process in which RNA molecules inhibit gene expression, often used in gene silencing therapies.

S

- Stem Cells: Undifferentiated cells with the potential to differentiate into a variety of specialized cell types.
- Systemic Therapy: A treatment that affects the entire body, such as gene therapy administered intravenously for genetic disorders.

T

- TALENs (Transcription Activator-Like Effector Nucleases): A gene-editing tool that uses customized proteins to target specific DNA sequences for modification.
- Tumor Microenvironment: The environment surrounding a tumor, including blood vessels, immune cells, and extracellular matrix, which can influence cancer progression and therapy outcomes.

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U

- Ubiquitination: A process that marks proteins for degradation, often used in regulating cellular processes, including gene expression.

V

- Vector: A vehicle used to deliver genetic material into cells, commonly viral vectors (e.g., adenovirus, lentivirus) or non-viral vectors (e.g., liposomes).
- Viability: The ability of cells to survive, divide, and function properly after exposure to therapeutic interventions.

W

- Western Blot: A laboratory technique used to detect specific proteins in a sample, often used to assess gene therapy outcomes.

X

- Xenograft: A transplant of tissue or organs between different species, often used in research models to study human disease.

Y

- Yeast Artificial Chromosome (YAC): A tool used in molecular biology to clone large DNA fragments, important for gene therapy research.

Z

- Zinc Finger Nucleases (ZFNs): A type of gene-editing tool that uses zinc finger proteins to target specific DNA sequences and create double-strand breaks for gene modification.

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Attachment : Topics and Soft topics

Head of the Author Team: Dr. Mohammad Reza Fathi, Professor of Cell and Gene Therapy at Pficell.This book from PFICELL is a collaborative effort created under the supervision and guidance of Professor Fathi.

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