International Waldenstrom Macroglobulinemia Foundation

1449 S Michigan Ave STE 13329
Chicago, IL 60605
T : 941-927-4963
www.iwmf.com
Email: GrantAdmin@iwmf.com

International Waldenstrom Macroglobulinemia Foundation | Bliss Family

Request for Proposal
Bliss Family Fund to Advance Cellular Therapies for WM

On behalf of the Bliss Family (BLISS) and International Waldenstrom Macroglobulinemia Foundation (IWMF), we are pleased to announce the ***Bliss Family Fund to Advance Cellular Therapies for WM*** – a Request for Proposal (RFP).

ABOUT US

The International Waldenstrom Macroglobulinemia Foundation (IWMF) is a nonprofit 501(c)(3) organization standing at the forefront of a global mission to transform Waldenstrom Macroglobulinemia (WM)from an incurable cancer into a disease where a cure becomes a reality. IWMF defines "cure" not as remission, but as the achievement of sustained, treatment-free survival. Complete responses in Waldenstrom Macroglobulinemia (WM) remain very rare, and even with the best novel combination therapies to date, recurrent disease relapses are expected. IWMF is committed to identifying and supporting new insights, approaches, and therapeutics that ultimately will achieve a WM cure.

As the world's leading patient-centered organization dedicated exclusively to WM, IWMF leverages its unrivaled network, Scientific Advisory Committee expertise, and global commitment to drive groundbreaking research, fund innovative therapeutic discoveries, advance novel clinical trials, and foster collaborations to reshape the future for all affected by this rare disease.

Bliss Family (BLISS)
Tim and Ginny Bliss have pledged $3 million to IWMF, the largest single gift in the Foundation's history, to jumpstart research into Cellular Therapy. As a patient since 2017, Tim is on a mission to accelerate the development and clinical application of cellular therapies. This historic gift sets a new standard for what's possible in WM research, opening the door to innovative treatments and, ultimately, better lives for patients everywhere.

PROGRAM BACKGROUND: CELLULAR THERAPY GRANTS

Over the past decade, patients with WM have benefited from the novel agents initially developed for other hematologic malignancies, including chemoimmunotherapies, covalent and non-covalent BTK inhibitors, BCL2 antagonists, and other targeted therapies. These advances have improved outcomes for WM patients across multiple clinical settings and expanded the range of available treatment options. Second-generation BTK inhibitors are now established as safe and effective therapies in WM, and newer agents, including non-covalent BTK inhibitors and BTK degraders, have shown promising activity in relapsed and refractory WM, including in patients previously exposed to covalent BTK inhibitors.

Nevertheless, despite improved clinical outcomes for WM patients, important clinical challenges remain. Complete response rates remain uncommon with currently available therapies, resistance or progression after BTK inhibitor-based therapy remains a significant problem, durable fixed-duration treatment strategies have not yet been established, and the optimal management of biologically high-risk or multiply relapsed disease remains uncertain. In addition, as WM is generally characterized by prolonged disease control rather than eradication, there remains a need for therapies capable of producing deeper, more durable responses and, ideally, treatment-free remission. Molecular markers of durable efficacy, including MRD-negativity or other biomarkers predictive of long-term benefit, may also become increasingly important in future WM clinical trials.

Cellular immunotherapies and related immune-redirection strategies have transformed the treatment landscape for multiple myeloma and several B-cell malignancies and now represent compelling areas for investigation in WM. Multiple platforms have shown major clinical activity in related diseases, including autologous CAR-T therapies, allogeneic cell therapies, bispecific, and other engineered immune-redirection strategies. Targets of interest in WM include, but are not limited to, CD19, CD20, BCMA, and other antigens with clear biologic relevance to the disease. Yet, important translational uncertainties remain regarding the feasibility of candidate cellular therapy targets in WM, including protein-level expression across the malignant B-cell and plasma-cell compartments, changes in target expression with disease evolution or treatment relapse, and the potential impact of soluble antigens or related proteins on cellular therapy activity. Additionally, while current consensus guidelines recommend observation rather than treatment for asymptomatic WM patients, earlier intervention with cellular therapies may be appropriate for clinical investigation in high-risk patients given evidence of a more intact immune microenvironment in earlier disease course of WM.

PROGRAM DESCRIPTION

Under this Grant program, BLISS and the IWMF seek to support independent investigators affiliated with academic institutions in conducting investigator-initiated trials (IITs) of cellular immunotherapies and related immune-redirection strategies with potential to significantly advance the treatment of WM. Importantly, the BLISS/IWMF are seeking distinctly novel advances and highly innovative approaches. Applications are invited for clinical studies evaluating novel cellular or immune-engaging therapeutic approaches for WM, including but not limited to autologous or allogeneic cell therapies, CAR-T or CAR-NK platforms, bispecific and trispecific immune engagers, dual-target or next-generation engineered cellular approaches, rational immune-based combination therapies, or other highly innovative immunotherapeutic strategies with strong scientific and clinical rationale for WM.

Applicant studies should be designed to pursue clinically meaningful benefit for WM patients, including deeper and more durable remissions, complete responses, MRD-negativity, improved disease control, and/or biologic or clinical proof-of-concept sufficient to justify larger studies, if successful. Additional clinical studies of T-cell therapeutic strategies that are specifically designed to overcome WM-associated immune dysfunction, T-cell exhaustion, immune paresis and to address the WM immune microenvironment and features that may limit cellular therapy activity in WM patients are also of great interest. These may include rational combinations, sequencing approaches or earlier disease intervention in high-risk populations, designed to optimize cellular therapy outcomes for WM patients.

Successful studies are expected to demonstrate proof-of-concept of clinical benefit in a limited number of patients. Successful study results should provide validation for larger clinical studies in the future that lead to novel therapy inclusion in NCCN Guidelines, FDA approval, or other comparable regulatory approvals (and likely require co-funding beyond the means of the BLISS/IWMF).

Applicants should provide a detailed explanation of the proposed rationale, prior clinical or translational data supporting the thesis, and a clear rationale for the overall duration and projected schedule for milestone-based payments throughout the Grant period. The BLISS/IWMF also welcomes proposals that incorporate correlative studies, where appropriate, to strengthen interpretation of clinical findings and inform future therapeutic development in WM.

RESEARCH FOCUS

BLISS and IWMF's research funding is focused on advancing clinical translational research breakthroughs that deepen the understanding of WM biology and advance novel clinical approaches. BLISS and IWMF seek applications for clinical research studies that will have a meaningful impact on WM patients within the next 3-5 years. Therefore, the proposed studies should demonstrate clear clinical relevance with the potential to improve patient-centered outcomes, inform evidence-based clinical decision making, or address gaps in current therapeutic insights and approaches. Applications lacking a well-defined link to advancing patient outcomes or translating clinical research findings into meaningful therapeutic advances will be considered non-responsive.

REVIEW CRITERIA

Rationale:
The scientific and clinical rationale is based upon a body of high-quality, relevant data and presents a compelling justification for the proposed therapeutic strategy in WM, including the selected target(s), platform, patient population, and clinical setting, as applicable.

Plan/Impact:
The project plan includes a well-designed clinical trial capable of generating meaningful clinical insight for WM. The potential impact of the study on advancing treatment for WM patients, informing future development of cellular immunotherapies, and generating data sufficient to justify larger follow-on studies is meaningful. Proposed project milestones are appropriate in relation to the research plan.

Clinical Relevance:
The proposal clearly addresses an important unmet clinical need in WM and has a plausible path to generating meaningful patient benefit, whether through improved disease control, deeper remission, reduction of complications, or other clinically relevant outcomes. Importantly, clinical risk-benefit for candidate patients is clearly defined and data driven.

Feasibility:
The proposed clinical trial is feasible and achievable within the project timeline. Adequate resources, expertise, and operational readiness are proposed and available. Please consider the following:

- Qualifications of the PI and/or additional investigator(s).
- Provisions for the protection of clinical trial participants.
- Availability and quality of resources and institutional environment.
- Access to the intended patient population and patient samples (where applicable).
- Readiness of the clinical and operational infrastructure needed to conduct the study.
- The overall manufacturing, product supply and delivery plan, and its robustness and feasibility to meet study needs for cell-based or biologic products (where applicable).
- Contingency plans for unanticipated clinical, manufacturing or supply challenges.
- A demonstrated and clear path to market access for corporate-owned assets.
- If applicable, committed additional funding from the applicant's institution and/or the
- sponsor that enhances the proposal in its goal to benefit WM patients.

Clarity:
The proposal demonstrates clarity of thought and presentation of the plan.

Grant applications that require access to investigational new drugs or approved drugs should have previously secured agreement from the manufacturing sponsor for access to study drug supply. The Grant funds should not be used to pay for or offset the cost of the drug.

FUNDING AVAILABLE
BLISS and the IWMF will provide a grant up to $1,000,000 USD in funding of the research. All aspects of the grant will be managed by the IWMF. Indirect costs are limited to 20% of the total Grant Award value. For institutions that choose not to use the full amount of available indirect funds for indirect costs, the Grant allows these funds to be applied toward the approved budget for direct costs.

Once awarded, in order to facilitate study/trial startup costs, 20% of the total grant is provided as startup funding. A final payment of $20,000 USD is held until the grant closeout report is submitted and approved by the IWMF. A detailed funding schedule will be a part of the award package.

ELIGIBILITY
Applications may be submitted by academic, nonprofit entities that engage in oncology clinical research. Non-US institutions are welcome to apply.

The sponsoring organization must have a track record in scientific leadership, collaboration, and demonstrate depth and breadth in its research. The organization must ensure support for the proposed research project. Appropriate institutional commitment to the program includes

the provision of adequate staff, facilities, and resources that can contribute to the planning process and implementation of the project. The sponsoring organization must ensure to provide protected time to the Principal Investigator.

Principal Investigators (PIs)

- Must have a doctoral degree (MD, PhD, MD/PhD, DO, DVM, or equivalent doctoral degree)
- Must be a full-time employee of sponsoring institution with an independent research or academic position

HOW TO APPLY

Applications can be submitted at www.iwmf.com/research/applying-research-grant in the Cellular Therapy Grants Initiative. Applications should clearly describe the proposed therapeutic platform, relevant target(s), clinical rationale in WM, and, where applicable, the source of study product, sponsor/manufacturer support, and any anticipated manufacturing or delivery dependencies. The project description, significance, aims, timelines and milestones, and scientific approach should follow the application format. Additional pages should include references, biographical sketches, detailed budget with budget justification, list of other projects, and appendices as necessary.

This is a rolling grant program. Applications will be accepted year-round, aggregating submissions four times yearly for review and awarding grants. Deadlines for the current cycle will appear on our website.

INAUGURAL KEY DATES

RFP Opens	September 9, 2026
RFP Closes	November 9, 2026
Award Notification	Mid-late January 2027
Grant Term	Two – Four years

DIRECT COSTS (PERMISSIBLE)

Permissible direct costs include the following with the specified limitations:

- Personnel expenses include salary, wage, or stipend with fringe benefits. In total, no more than 40% of the direct costs may be requested for the salary and fringe benefit expenses of professional staff with a postgraduate degree (i.e., MD, PhD, MD/PhD, DO, DVM or equivalent doctoral degree) regardless of function or role. This restriction does not apply to technical staff (lab assistants, nurses, etc.).
- Supplies and materials requests should be itemized by category.
- Equipment purchase requests must identify each item of equipment with an acquisition cost of more than $4,000.

INDIRECT COSTS (PERMISSIBLE)

Permissible indirect costs (often referred to as Institutional Overhead, IDC, M&A, G&A, or pooled
costs) are those costs incurred for common or joint objectives that cannot be readily identified with a particular project (general maintenance, utilities, library, etc.).

- Indirect costs are limited to 20% of the total grant award value. For sponsoring institutions that do not need to use all the indirect funds allocated for indirect costs, the remaining

funds can be applied to the project's direct costs, or the applicant may elect to only request their true indirect costs.
- Journal publication costs are permitted.

IMPERMISSIBLE COSTS
Impermissible costs include membership dues, tuition, books, journals, and travel costs.

PEER REVIEW OF APPLICATIONS
Research proposals are reviewed by an independent committee composed of selected members of the IWMF Research Strategy Committee, the Cellular Therapy Scientific Advisory Committee (CT-SAC), and other experts in the field.

This independent committee may in turn respond to the research proposal applicant(s) with questions and/or request clarification regarding certain aspects of the proposal itself. The proposals are ranked using the review criteria described in this RFP and informed by NIH-style standards of scientific review.

AWARD PROCESS
The IWMF CT-SAC will make recommendations to the IWMF Board of Trustees for the final approval of the grants. Notifications for the inaugural grant will go out mid- to late-January 2027.