The University of Maryland Baltimore Life Science Discovery (UM-BILD) Pilot Project Grant Program

Request for Proposals (RFP) for Cohort 2
LOIs due Sept. 13, 2024, Full Applications due December 15, 2024
Projects begin in April of 2025

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THE UM-BILD PILOT PROJECT GRANT PROGRAM – REQUEST FOR PROPOSALS

Deadlines:	Letter of Intent: Sept. 13, 2024, 5:00 PM (EST) Full application: Dec. 15, 2024, 11:59 pm EST *Late submissions **will not be** accepted.*
Eligibility:	Faculty and Staff from the University of Maryland, Baltimore (UMB), University of Maryland, Baltimore County (UMBC), Morgan State University, University of Maryland, College Park (UMCP – a UMB partner is required) or Faculty at other Baltimore City public universities.
Budget:	Up to $75,000 in direct costs (indirect costs not allowed) for a 12-month term.
Grant period:	Cohort 2: Awardees announced in March 2025. Projects start in April 2025.

The University of Maryland - Baltimore Life Science Discovery (UM-BILD) Accelerator is pleased to announce that we are accepting applications for the 2nd cohort of the UM-BILD Pilot Project Grant. Every year, UM-BILD Accelerator will provide approximately 12 proof-of-concept technology development grants to faculty innovators. These grants will be milestone-driven, development-focused programs that will serve to directly advance a life science technology to the next phase. The goal is to translate basic-science research projects into commercial products that will advance patient care, whether it be through new company formation or via movement towards licensing to a development partner. All types of products in the human health space (e.g. therapeutic, preventive, diagnostic, device, method, tool, software) are eligible. The research must have a direct application to an important unmet clinical need and the proposed solution, when commercialized, must have a benefit to patients and to community health. Projects with the potential to address healthcare disparities or otherwise benefit the people of Baltimore are particularly welcome. Early-stage technologies are suitable.

Successful Pilot Project applications will explain how the intended product will address an unmet medical need, outline the product's market potential, and include a product validation workplan. Projects must be completed within 12 months, with the ultimate goal of attracting follow-on funding from TEDCO, from a federal SBIR/STTR grant, from other non-dilutive sources, or through equity investment into a spinoff company.

Research teams should not already have secured funding for the proposed Specific Aims and/or milestones (no 'double dipping.') The focus should be on gathering data that advances the core hypothesis and addresses key translational risks.

For questions regarding application guidelines, please email the UM-BILD Admin Core at UM-BILD@umaryland.edu.

UM-BILD PROGRAM OVERVIEW

The University of Maryland Baltimore Life Science Discovery (UM-BILD) is a funding and mentoring resource for academic researchers led by the University of Maryland, Baltimore (UMB) with the School of Medicine being one of the anchor partners, and with University of Maryland Baltimore County (UMBC), Morgan State University (MSU), University of Maryland College Park (UMCP), Blackbird Labs, and TEDCO's Maryland Innovational Initiative (MII) as partners. Funded by the NIH through their Research, Evaluation and Commercialization Hubs (REACH) program, UM-BILD offers funding and industry-grade advising and support that will help improve applicants' projects.

RESOURCES

UM-BILD will provide commercialization-related education and training. A formal didactic learning opportunity - "Life Science Entrepreneurship" - seminar course, tied with a formal mentoring apprenticeship program, will help project teams to assess clinical needs, conduct market analysis, and prepare for regulatory requirements. Research teams may also make use of a range of UM-BILD Incubator services.

Each Pilot Project team will be assigned a Project Manager. This person will be a member of UM-BILD's Administrative Core (Admin Core) staff. He or she will collaborate with the Lead Principal Investigator (Lead PI) throughout the duration of the project. Project Managers will track progress on milestones according to the proposed timeline, and they will receive updates on spending. The Lead PI (or his or her designee) is required to meet monthly with their Project Manager.

In addition, each Pilot Project team (and UM-BILD MII Project team) will be matched with a Mentor. Each Mentor is a veteran of the biotechnology space, with experience in entrepreneurship and in private industry. Mentor activities can include making connections with experts on topics such as product development, contract manufacturing, regulation, reimbursement strategies, and writing commercialization grants such as SBIRs, STTRs, and MIIs.

The "Entrepreneurship in Life Science" Course focuses on understanding business planning for drugs, medical devices and digital health. It will emphasize the opportunities and challenges of startups in the Mid-Atlantic region. The course focuses on key concepts in early-stage commercialization. Prospective entrepreneurs are encouraged to learn about these topics as they consider whether to participate in the founding of a biotech startup based on the technology being explored in the UM-BILD Pilot Project grant. Content includes:

1) The makeup of a business plan
2) Managing long pre-revenue timelines
3) Licensing of I.P.
4) The nature of biotech drug and medical device risk, and of risks in other areas such as IT

5) Sources of funding, specifically early-stage financing which includes STTR and SBIR grants, State level programs, grants from foundations, angel and venture-based equity financing, and partnership-based funding with established pharma and device companies

6) Brick-and-mortar and virtual approaches to planning a biotech company

7) Accessing and augmenting management

8) Exit strategies

The course is designed for graduate students, post-doctoral trainees, and faculty (undergraduates are also welcome). All team members of current and former UM-BILD Pilot Project grants and UM-BILD MII Projects are welcome to participate. This will provide a boost to the local entrepreneurial ecosystem, not least by providing another means for training scientists with the potential to develop new technologies. The course will be offered in both in-person and virtual formats to maximize the reach to students. In the near future, we plan to launch a certificate program based on the course materials that will be offered as modules through the Smith School of Business.

In addition, for each team, one member will have the opportunity to complete an apprenticeship under an Entrepreneur-in-Residence or another established biotech innovator, so that the intern can gain visibility into in life science business development activities.

PILOT PROJECT GRANT APPLICATION PROCESS

Each year, the UM-BILD Accelerator will encompass approximately 12 projects (8 Pilot Project Grants and 4 UM-BILD MII Projects), with one cohort each year.

An application for the **UM-BILD Pilot Project Grant** begins with the submission of a Letter of Intent (LOI). LOIs will be reviewed, and applicants with the highest-rated ones will be invited to submit a Full Application.

Summary of the Application Process
A. Writing and Submission of Letters of Intent.
B. Evaluation of LOIs by UM-BILD's Internal Advisory Committee (IAC).
C. Invitation of the top-ranked LOIs to proceed to Full Applications.
D. Writing and Submission of Full Applications.
E. Evaluation of Full Applications by the External Review Board (ERB).
F. Selection of top-ranked Full Applications to be submitted to the NIH's Technical Guidance Committee (TGC).
G. Final selection of Cohort Pilot Projects by the IAC.
H. Notification of awardees and distribution of ERB and TGC feedback to applicants.

For 2024, the process for Cohort 1 of the **UM-BILD Pilot Project Grants** was: LOIs were due in March, full applications were due in May, awards were announced in August, and projects began in September .

Cohorts 2 (2025 start), 3 (2026 start), and 4 (2027 start) will run according to the following schedule: LOIs due in September, full applications due in December, awards announced in March, and projects begun in April.

In exceptional cases, an investigator may be invited to submit an LOI for a second year of funding to continue the development of an awarded Pilot Project. Such an invitation will be based on the project's success in achieving milestones during first-year award, and on the availability of funds to UM-BILD. A second-year LOI would compete on equal terms with the first-year LOIs in its cohort.

UM-BILD MII Project applications are not submitted directly to UM-BILD. Instead, these projects are selected by the UM-BILD IAC from among the active Technology Assessment MII projects that TEDCO has awarded via its usual processes, per the relevant RFA ([link](#)).

PILOT PROJECT GRANT LETTERS OF INTENT

A. Submission of a New Letter of Intent

All LOIs must be prepared according to the following guidelines and submitted via the UM-BILD REDCap portal, accessed via this "How to Apply" webpage ([link](#)). The September deadline for each cohort will be announced at least four weeks in advance. Please check our website regularly for updates for the current Call for LOIs, which will specify the submission deadline. Late submissions will not be accepted.

UM-BILD strongly recommends that teams considering the submission of an LOI begin by emailing UM-BILD@umaryland.edu for a pre-submission discussion. This will ensure alignment of the project with the funding criteria, and provide guidance on the pre-submission process.

The Specific Aims proposed in the LOI may overlap with those in an application to another funding source, as long as that source has not made a funding decision by the time that the LOI is submitted. However, if a project is funded by another source prior to the UM-BILD funding decision, the applicant is obliged to notify UM-BILD. As two sources of funding for a single specific aim is not permitted, the UM-BILD application would need to be withdrawn. The project with new Specific Aims can be re-written and re-submitted in a subsequent UM-BILD funding round.

By the LOI submission deadline, technologies must be disclosed to the Technology Transfer Office at the investigator's university, and assigned to the university, or subject to university ownership.

See the **UM-BILD PROGRAM GUIDELINES' Eligibility** section, below, for information on that important topic.

The LOI submission has two parts. First, the applicant must fill the online form and provide information on a series of topics:

- The project title
- The names of the P.I and of the Co-PI (if applicable; only one Co-PI is allowed)
- The type of technology (biologic drug, diagnostic assay, surgical device, etc.)

- The disease of interest
- The status of the underlying intellectual property and its disclosure to the applicant's university
- A Project Description (Abstract) limited to 3500 characters.

Second, the applicant uploads the LOI, as a formatted two-page document. A Word document template is provided in the Formatted Application Template section of the REDCap portal page, accessed from the "How to Apply" page of the UM-BILD website ([link](#)).

- Key aspects of the LOI's formatted document:
  - Two pages, with margins set at 0.5 inches all around
  - 11-point type, single spacing
  - A single image or figure can be included, with the font size of the figure legend set to 10 points or larger
  - Uploaded to the portal as a .PDF
- Page 1 contents:
  - The project title
  - The PI's name, university, and contact information
  - A copy of the Project Description, containing exactly the same information reported in the online form (limit 3500 characters) and including the following information:
    - A description of the technology
    - The status of the underlying I.P.
    - An explanation of the healthcare problem that the technology could help to solve. What would the product or service be? Who would be its customers?
    - A sketch of the current status of the project. For example, is the biochemical pathway identified? Have *in vivo* proof-of-concept experiments been run? Have you built an initial prototype? Is there clinical validation?
    - A brief outline of the key milestones and a budget for the proposed year-long project.
  - A Figure with a legend (optional; legend with ≤ 300 characters).
- Page 2 contents:
  - List of Team members. For each key Team Member, provide a one-paragraph biography.
  - A list of up to five References (optional).
  - <u>ONLY for resubmissions:</u> a Response to Reviewers (max 1,000 characters; ~150 words).

B. Resubmission of a Letter of Intent

A team whose LOI submission was not invited to submit a Full Application can resubmit a modified LOI to subsequent cohorts.

- Projects at the LOI stage that were not invited to submit a Full Application will have received written feedback summarizing the project's strengths and weaknesses, as identified by UM-BILD's IAC.
- Feedback is intended to guide teams in revising their proposals to improve competitiveness for future submissions. The resubmitted LOI should be revised to address the weaknesses noted by reviewers.
- The resubmitted LOI must include a "Response to Reviewers" section, which is to be placed on page 2 of the Formatted LOI PDF document. In this section (1,000 characters or ~150 words), applicants should summarize the reviewers' key concerns and explain how these have been addressed.

C: Triage of LOIs

The LOIs will be reviewed by the UM-BILD's Internal Advisory Committee (IAC) to consider the potential of the proposed projects, and how well they fit with UM-BILD's mission. The IAC includes reviewers with scientific, clinical, and entrepreneurship expertise, as well as reviewers with expertise in intellectual property protection, technology transfer, and commercialization.

All applicants who submit a LOI will be notified of the outcome. They will receive feedback from the UM-BILD IAC.

PILOT PROJECT GRANT FULL APPLICATIONS

A. Submission of a Full Application

Selected teams will be invited to complete Full Applications, which are based on the REACH Common Application (UM-BILD REDCap portal). About four weeks will separate the invitation date and the Full Application deadline.

The Full Application submission has two parts. First, the applicant must fill the online form covering five main points:
1. The technology under consideration.
2. The clinical problem that is being solved.
3. The competitive positioning of the proposed application in light of competing inventions, along with its market and risk assessment, and reimbursement strategy.
4. The potential for follow on funding, both private and public.
5. The key experiments that are proposed, and how they fit into the path towards a regulatory milestone.

B. Content of the Formatted Full Application

At the bottom of the REDCap portal page, provision is made for uploading the Full Application as a formatted document. A Word .docx template is provided in that section of the REDCap portal page.

The Formatted Full Application must include an Appendix, which will contain the applicable sections below. Where appropriate, a sample template for each is available for download from the UM-BILD website's "How To Apply" page (link). These files are:

1) <u>GANTT Chart</u> (Specific Aims) (link).
2) <u>Budget Worksheet</u> (link).
3) <u>Compliance Form</u> (link).
4) <u>Institutional Approval Letter</u> (link).
5) <u>Vertebrate Animal Research</u> (where appropriate; link).
6) <u>A Dual-PI Leadership Plan</u> (where appropriate).
7) <u>NIH-Formatted Biosketches</u> for each key team member; format outlined here.

A Dual-PI application must have a sole Lead PI. A single Co-PI is also permitted. In such cases, a brief (~ 150 word) Dual-PI Leadership Plan that describes their respective roles must be included in the Appendix of the Full Application. (See point C-2 of this NIH FAQ.) In these cases, the Lead PI will serve as the point of contact for communications.

The Formatted Full Application is uploaded to the REDCap portal as a single PDF file.

C. Coaching

Each team writing a new Full Application will be matched with a coach to assist in (1) sketching a product development plan, (2) setting project milestones, and (3) proposing a project budget. (Re-submissions will receive limited coaching on formatting of the Formatted Full Application.) Teams will have about one month to draft, edit, and submit their Full Application.

The PDF of the Full Application must be reviewed by the UM-BILD coach before submission.

D: Review of Full Applications

Full Applications will undergo review by the UM-BILD External Review Board (ERB), comprising industry and technology experts who are not employees of UMB or a UM-BILD partner university. These reviewers will evaluate proposals for feasibility and for commercial potential. Following the advice of the ERB, the IAC will select the highest-ranking proposals for submission to the NIH's Technology Guidance Committee (TGC).

The TGC is made up of NIH Program Officers, Entrepreneurs-in-Residence, and Intellectual Property specialists. Representatives from the FDA and CMS will weigh in on regulatory and reimbursement issues, where this is relevant to a project's commercialization pathway. Feedback from the TGC takes a narrative form. A key function of the TGC is to evaluate each proposal for its relevance to the core missions of the NIH's constituent Institutes and Centers. In rare cases, TGC reviewers may judge that no Institution or Center would be likely to endorse a proposed project. Such projects cannot be funded by UM-BILD or undertaken under its auspices.

The ERB's reviews and the TGC's comments will be the basis for the UM-BILD Internal Advisory Committee's final determination on which projects will be accepted into the UM-BILD Cohort.

Full Applications that are not selected for funding may submit an LOI in a future cohort. Note that in this case, only a single resubmission is allowed.

- Projects at the Full Application stage that were not selected for funding will receive extensive feedback from ERB reviewers (and in some cases, from TGC reviewers), highlighting key strengths and noting areas for improvement.

- The resubmitted LOI must include a "Response to Reviewers" section, which is to be placed on page 2 of the formatted LOI PDF document. In this section (1,000 characters or ~150 words), applicants should summarize the reviewers' key concerns and explain how these have been addressed.

- Teams whose previous Full Applications were declined and who re-submit a revised Full Application in a subsequent cohort are not eligible for additional support from a UM-BILD-assigned coach.

PILOT PROJECT GRANT ADMINISTRATION INFORMATION

Successful applicants will receive a letter that outlines the steps that must be taken prior to the initiation of the project. These will include:

- Return the signed notice of award, along with responses to the reviewers' comments and any other documents required by the UM-BILD Admin Core, by the requested deadline.

- Complete and return Page 1 and Page 2 of the PHS398 form.

- Provide the name and contact information of the Lead PI's Grants Manager.

- Review of the proposed use of Vertebrate Animals and of any potential Human Subjects Research. The UM-BILD Admin Core must be provided with the required documents, as highlighted in the **Institutional Regulatory Requirements/Approvals** section of the **UM-BILD PROGRAM GUIDELINES**, below.

- Schedule monthly meetings with the assigned UM-BILD Project Manager to discuss the award process and to review expectations on progress, spending, and reporting.

- A Mentor will be matched with each Pilot Project team. ry. He or she will meet monthly with the team (the Lead PI or designee) to share insights on aligning team initiatives with commercialization priorities. The Lead PI (or his or her designee) is responsible for setting up a monthly meeting schedule with the Mentor. For convenience, Project Manager meetings and Mentor meetings can be scheduled together.

- At the six-month point, the monthly meeting will take the form of the required Midterm Meeting. Both Project Manager and Mentor should attend. See **GUIDELINES FOR THE UM-BILD PILOT PROJECT MIDTERM MEETING**, below, for more detailed information*.*

UM-BILD MII PROJECTS

Although UM-BILD and TEDCO's MII program are separately administered and have different sources of funding, there is close alignment on objectives.

TEDCO accepts applications for Technology Assessment MII grants four times a year, on January 15, April 15, July 15, and October 15. These grants fund nine months of work.

Each year, UM-BILD's Internal Advisory Committee will review the about-to-begin and ongoing MII Technology Assessment grants with Primary Investigators from UM-BILD partner universities. Up to four of these projects' teams will be selected to join the Hub as *UM-BILD MII Projects*. While this status is not accompanied by a cash award, teams will be invited to participate in UM-BILD activities, including assignment of an industry mentor, participation in educational events, and attendance at seminars.

UM-BILD PROGRAM GUIDELINES

A. Eligibility

- Any Faculty or Staff member from one of the member universities of UM-BILD is eligible to apply as a Lead PI or Co-PI on a UM-BILD Pilot Grant. These institutions are the University of Maryland, Baltimore (UMB), the University of Maryland, Baltimore County (UMBC), and Morgan State University (MSU). Faculty/staff at other Baltimore City public universities are also eligible. Finally, faculty/staff from the University of Maryland, College Park (UMCP) may apply, so long as the project is based on intellectual property that is owned or co-owned by UMB, and the subject of an Inter-Institutional Agreement designating UMB as the Lead Party .

- An application must have a sole Lead PI. A single Co-PI is also permitted. In such cases, a brief (~ 150 word) Dual-PI Leadership Plan that describes their respective roles must be included with the full application. (See point C-2 of this NIH FAQ.) In these cases, the Lead PI will serve as the point of contact for communications.

- The Faculty or Staff appointment for a Lead PI or Co-PI must be for a 0.51 FTE or greater position.

- Other team roles do not share the eligibility limitations and the responsibilities of the Lead PI and Co-PI. Their duties and titles (e.g. Co-Investigator, advisor, collaborator) will vary from application to application. Per NIH guidelines, a Co-Investigator (Co-I) is involved with the Lead PI in the scientific development or execution of the project. Co-Is typically devote a specified percentage of time to the project. Co-PIs and Co-Is are considered 'senior/key personnel.'

- An investigator may serve as a Lead-PI *or* as a Co-PI on a maximum of one Pilot Project application per cohort. However, he or she may serve in other roles on any number of applications and ongoing projects.

- Lead PIs and Co-PIs are limited to one active UM-BILD application at a time.

- Lead PIs and Co-PIs with a previously funded UM-BILD project may apply as a Lead-PI or Co-PI for a new project only when the previous project is completed and there is no scientific overlap.

- In a limited number of cases, Lead PIs and Co-PIs with a previously funded UM-BILD Pilot Project may be invited to apply for Phase II of UM-BILD, contingent upon satisfactory completion of Phase I and the availability of funds.

- A Pilot Project Grant cannot be transferred to other institutions. The Lead PI and Co-PI must remain at the same institution for the entire duration of the award. If the Lead PI or Co-PI changes institutions, funding will end.
- Collaborative proposals are encouraged, but this is not a requirement.
- At the time the LOI is submitted, the intellectual property (I.P.) described in the proposal must be disclosed to the Technology Transfer Office at the PI's or Co-PI's university. Inventors must assign the intellectual property to the university. I.P. that is owned or co-owned by another party cannot form the basis of a UM-BILD Pilot Project. At the university's Technology Transfer Office's discretion, I.P. that is co-owned by another party but whose co-owners have executed an Inter-Institutional Agreement specifying that it will be wholly managed by the Office may be deemed eligible for UM-BILD Pilot Projects.
- Applicants may have created a company to pursue translation of their innovative technology, but there is no expectation that they would have done so. UM-BILD encourages applications at an early stage, prior to a decision to form such a company.
- On the day that the Pilot Project grant is awarded, a company may be *in negotiations* with the UM-BILD member university for the technology underlying the project, or it may have signed an *option* in this regard. However, technology that has been licensed is not a suitable basis for starting a Pilot Project grant. If a technology license is signed *during* the Pilot Project, that project may continue to completion.
- There is no limit to the number of applications that may be submitted from each university.
- A UM-BILD Pilot Project grant application does not need to be routed through the UM-BILD partner university's grants or external funding division. Instead, it is submitted directly to the UM-BILD web portal by the Lead PI (or his or her designee).
- Conditions that make a project *ineligible* for a UM-BILD Pilot Project Grant:
  - Undergraduates and graduate students are not eligible to lead a project as a Lead PI, Co-PI or Investigator. They are welcome as team members and may have other roles in the proposal. Students who are also inventors must assign their I.P. rights to the UM-BILD member university as a condition of participation.
  - Applications based on I.P. that is 1) encumbered by a third-party agreement (e.g. a sponsored research agreement) or 2) co-owned with a commercial third party are not eligible for UM-BILD Pilot Grant funding.
  - Applications based on I.P. where the UM-BILD member university has decided against pursuing a patent application (or another form of protection) are not eligible for UM-BILD funding.
  - NIH regulations do not permit UM-BILD or the other REACH Hubs to include employees of institutions located outside of the United States in Pilot Projects. Specific Aims or milestones may not depend on the work of collaborators at foreign universities or other institutions (such as CROs or CDMOs).

B. Institutional Regulatory Requirements/Approvals

- **General**
  - All required institutional registrations/approvals (e.g., Data Use Agreements, Biosafety registrations, Clinical Engineering clearance of devices, Radiation Safety registration, etc.) must be obtained prior to initiating any research activities for which the certification/registration/approval is required.
  - **Delays by the Investigators in submitting regulatory documents to the UM-BILD Admin Core can cause the initiation of a Pilot Project to be postponed. A postponement of 3 months or more from the stated start date would imperil UM-BILD funding for the project.**

- **Human Subjects Research (HSR)**
  - The one-page Pilot Project Compliance Form ([link](#)) is incorporated into the Appendix of the Formatted Full Application. It includes questions about the HSR status of the proposed Pilot Project.
  - Teams should use the [NIH decision tree](#) to determine if the NIH will consider their project to include Human Subjects Research. If so, the team must complete the [Human Subjects and Clinical Trials Information Form.](#)
  - An IRB Letter of Determination/Approval (or an analogous document) is not required at the time of the Pilot Project application submission. However, the IRB submission time-burden is likely to be significant, therefore, applicants are strongly encouraged to begin the Human Subjects Research (IRB) process as early as possible. All required regulatory approvals, and their supporting documents are required to be in place prior to the release of funds and the start of project activities.
  - For UMB: Review the [UMB IRB website](#) for required training of UMB and non-UMB team members engaged in research. MSU, UMBC and the other USM schools have comparable training requirements. Applicants from other institutions should contact their respective IRBs for information on other training requirements for research conducted at their institution.
  - If research activities are split across sites, consider the need for an IRB Reliance Agreement.
  - If the HSR activity is a clinical trial, teams must register the trial's protocol at [ClinicalTrials.gov](#).
  - During the review period, the Lead PI will be asked to provide the IRB-approved protocol as well as the IRB determination letter, including the Letter of Exemption (when applicable). Projects involving HSR conducted at collaborating institutions outside the UM-BILD hub or through a CRO must submit the IRB protocol approved by the institution where the work is to be performed. The IRB protocol should be valid for the duration of the Pilot Project.
  - Information on HSR activities will be forwarded to the NIH office responsible for the REACH hubs. Their approval (on completion of review) is needed before the Pilot Project can begin.

- **Vertebrate Animal Studies**
  - The one-page Pilot Project Compliance Form (link) is incorporated into the Appendix of the Formatted Full Application. It includes questions about the Vertebrate Animal studies included in the proposed Pilot Project.
  - Final IACUC approval and other supporting documents are not required at the time of the Pilot Project grant application submission. However, applicants are strongly encouraged to begin the submission process early. ALL required regulatory approvals and other supporting documents are required to be in place prior to the start of funding.
  - During the review period, the Lead PI will be asked to provide the Animal Care and Use Protocol (ACUP) approved by the IACUC under which the animal work is to be undertaken. This will typically be the UM-BILD partner university's IACUC. Projects involving animal work conducted at collaborating institutions outside the UM-BILD hub or through a CRO must submit the ACUP approved by the institution where the work is performed. This must be accompanied by a description of the procedures involving animals, using the NIH's template (link). The ACUPs should be valid for the duration of the Pilot Project. Analogous to HSR work (discussed above), information on animal studies will be forwarded to the NIH's office. Their approval (on completion of review) is needed before the Pilot Project can begin.

C. Funding Policies

- UM-BILD Pilot Project budgets must total no more than $75,000 in direct costs (indirect costs are not allowed).

- Funding for UM-BILD projects will be for one year, with September as the starting date for Cohort 1, and April as the starting date for subsequent cohorts.

- Required regulatory approvals and agreements, as well as other supporting documents, must be obtained prior to disbursement of funds. Applicants are strongly encouraged to begin the submission process early. Delays in submission of regulatory documents that delay the start of the project greater than 3 months from the stated funding period might result in loss of funding.

- Funds will be distributed in two disbursements: 50% at the start of the project period following the fulfillment of regulatory requirements, with the second 50% disbursement contingent upon satisfactory progress at the time of the 6-month meeting.

- Projects that do not meet predetermined milestones may be suspended or terminated upon the recommendation of UM-BILD's IAC.

- The Full Application must include a Budget, in the form of an Excel worksheet (link).

- In the event the Lead PI leaves his or her faculty position or is unable to continue leading the UM-BILD Pilot Project, responsibility and funding may be transferred to the Co-PI, if one is serving. Responsibility and funding may also be transferred to a qualified successor Lead PI at the UM-BILD member university. Funding cannot not be transferred to another institution.

D. Expenses

- Research supplies, recruitment and compensation of clinical study participants, are allowed.

- Salary and fringe support for faculty-level team members are allowed. Note that the Pilot Project grant is not intended to provide a large fraction of a faculty member's compensation.

- Salary and fringe support, including insurance, for technicians, research associates, graduate students, and coordinators are allowed. However, tuition fees are not permitted.

- Equipment costs (purchase or lease) are allowed, but these expenses are generally anticipated to account for under one-quarter of the budget.

- No set minimum effort (hours/week or % FTE) is required for this award. Team members' time commitments should align with the needs of the proposed project.

- Special consultative services from individuals may be budgeted.

- An outside organization may be compensated for providing a necessary service. Examples could include an academic core facility, CRO, or CMO). Such services must be provided by a domestic (cf. foreign) entity.

- **Unallowable Expenses:**
  - UM-BILD universities have agreed to forgo indirect costs. Thus, they should not be included in the budget.
  - A sub-award to an outside partnering organization is not allowed. As noted prior, service functions provided by a Core Facility, CRO or CMO are allowed.)
  - None of the following categories of expenses are allowed: administrative support, alterations/renovations of laboratory space, purchases of furniture, purchases of periodicals/books, tuition, refreshments, phone services, professional society membership dues, editorial services, publication fees, or travel expenses.

E. Reporting Requirements

- Failure to attend required meetings in a timely manner risks termination of funding.

- Monthly Updates
  - The Lead PI, Co-PI of a funded project or their designee are expected to schedule a 15 to 30-minute monthly meeting with the UM-BILD Project Manager on an ongoing basis.
  - Similarly, the Lead PI and/or Co-PI must schedule a 1 hour long monthly meeting with their UM-BILD Mentor.
  - These meetings may be scheduled together for convenience.

- Midterm Meeting
  - The 6-month meeting (counting from the official starting date) will focus on progress towards the milestones and on budget expenditures. It will take the form of a 45-minute meeting, where investigators will present slides reviewing the Gantt Chart that

was part of the original application (Aims, Milestones, and Timelines). Work to date, spending, and estimates of future progress will be discussed. See **"Guidelines for the UM-BILD Pilot Project Midterm Meeting"** section below.

- o UM-BILD Admin Core approval of the Midterm Meeting is a prerequisite for the release of the second 50% tranche of Pilot Project funds. If satisfactory progress is not demonstrated at the 6-month mark, the release of the second disbursement will be withheld until acceptable progress is achieved. This progress will need to be demonstrated in one of the upcoming monthly meetings with the Project Manager.

- Final Report
  - o A written Final Report is due within 30 days of the end of the award period.
- Semi-Annual Follow-up Notifications
  - o After completion of the project, teams agree to provide for the successive four years a brief semi-annual notification to support UM-BILD obligations for NIH program evaluation. Such notifications will track grant applications/awards, publications, and technological/intellectual property development/licensing. Notifications will also describe startup company formation resulting from the project, and any third-party funding events such as an equity raise. These Follow-up Notification may take the form of emails to UM-BILD@umaryland.edu .

F. Conflicts of Interest

- It is the responsibility of the awardee and all members of the study team to report all financial or fiduciary interests that present or might appear to present a conflict of interest (COI). This holds true at the time that the Full Application is submitted, during the review process, and throughout the project period. COIs and potential COIs must be reported to the UM-BILD Admin Core, and to the Conflict-of-Interest Officer of the Research Integrity Office of the member university (UMB, UMBC, or MSU).
- The presence of a COI does not automatically disqualify investigators from receiving a UM-BILD Pilot Project Grant. Its presence will trigger the review and management of this conflict by the COI Officer.
- The failure of a member of the study team to disclose all outside interests could result in a Pilot Project Grant's termination and the disallowance of all study costs.
- UMB's COI Policy information, including examples of what constitutes an outside interest, may be found here.
- UMBC's COI Policy information may be found here.
- Morgan State's COI Policy information may be found here.

PUBLICATIONS AND ACKNOWLEDGEMENT OF UM-BILD

Publications resulting from UM-BILD funded work must adhere to the NIH Public Access Policy. A NIH Manuscript Submission System ID can serve as provisional evidence of compliance for three months after a paper is published. Beyond that, a PMCID (PubMed Central Reference

Number) is necessary. (UMB teams can consider the Health Sciences and Human Services Library's open-access publishing fund, which is available to junior faculty.)

All publications, abstracts, poster presentations, grant/funding applications, intellectual/technological developments and licensing resulting from research supported by the UM-BILD Accelerator Program should cite UM-BILD as a contributing source of support. Please include the following citation:

"We acknowledge the support of The University of Maryland Baltimore Life Science Discovery (UM-BILD) Accelerator and the Research, Evaluation and Commercialization (REACH) Hub Award 1U01GM152511-01*."*

GUIDELINES FOR THE UM-BILD PILOT PROJECT MIDTERM MEETING

At the six-month mark, the monthly meeting with the UM-BILD Project Manager will take the form of a Midterm Meeting. The Lead PI, Co-PI (if applicable), and Mentor should attend; other team members are also welcome. The meeting may take place in person or via Zoom.

The most important thing is to explain the progress to date on the milestones stated in the Full Application, as laid out in the Gantt Chart. Based on this information, the Admin Core will decide whether to release the second 50% of funding. If progress has been delayed or certain goals have not been met, the team should use the Midterm Meeting as an opportunity to explain the circumstances and set forth a revised plan for the remainder of the project.

The Presentation:

The project team should prepare a 20-minute presentation, leaving the remaining time for discussion. You should cover the content outlined below in 10 to 13 PowerPoint slides (maximum of 15); please number them. Be sure to share the draft deck with your Mentor as you work on it.

The slide deck must be emailed two business days in advance of the meeting date to UM-BILD@umaryland.edu. If there are last-minute changes, they can be addressed during the meeting.

Required Slides:

- Overview of the project (1 or 2 slides). The UM-BILD team is already familiar with this, so these are reminders, *not* a comprehensive summary of the science.
- Gantt Chart pages from your original application (1 or 2 slides). These constitute a list of the milestones as they were proposed, along with their projected timing.
- Aims (1 slide each).
  - For each milestone, what has been accomplished? What is yet to be accomplished?
  - Have any changes been made? Are there unexpected issues or challenges?
- An Update on the Budget (1 slide). On one table (e.g. a screenshot of the relevant cells of a simple Excel worksheet), show the overall proposed budget from the original application, and spending-to-date by category.

- o Ask your Grant Administrator for a printout of spending-to-date. *It doesn't have to be exact, and it doesn't have to be up-to-the-minute.*
- o In one table (this can be a screenshot of the Budget worksheet), show the overall proposed budget from your original application, and spending-to-date by category.
- o Are there any unexpected spending issues or looming challenges?

Optional Slides:

- Updates on Intellectual Property issues (e.g. a new patent application filing) (1 slide).
- The Big Picture (1 slide). Your current views on the Product Concept, Customer Needs, Regulatory and Development Challenges, and the Market.

Once the Admin Core has found that you have satisfied the Midterm meeting requirement, the second 50% tranche of the grant's funding will be released.