
**PROJECT AGREEMENT**

**BY AND BETWEEN**

**THE CRITICAL PATH INSTITUTE**

**AND**

[INSTITUTION FULL NAME]

This Project Agreement ("Agreement") is entered into by and between CRITICAL PATH INSTITUTE ("C-Path"), a non-profit 501(c)(3) organization with a business address at 1840 E River Road, #100, Tucson, Arizona 85718, and [INSTITUTION FULL NAME], with an address of [INSTITUTION FULL ADDRESS] ("INSTITUTION"). C-Path and INSTITUTION are individually a "Party," and collectively, the "Parties."

**RECITALS:**

WHEREAS, C-Path wishes to enter into this Agreement with INSTITUTION for INSTITUTION to perform the work described herein and INSTITUTION has the capability to complete the work.

**AGREEMENT**

NOW, THEREFORE, for and in consideration of the mutual covenants, conditions and undertakings herein set forth, the parties agree as follows:

1. Statement of Work. In connection with the project, INSTITUTION agrees to perform certain work (hereinafter "Work") as described in the Statement of Work in Exhibit A entitled, "_____." All Work shall be performed in accordance with the TRxA Operational Policies and Procedures incorporated by reference into this Agreement through Exhibit C.

2. Period of Performance. The project period under this Agreement is intended to commence on _____, 20__, and continue until _____, 20__. The Period of Performance may be extended by mutual agreement of the parties, in writing.

3. Cost and Payment. In support of INSTITUTION's development of [Name of therapeutic molecule(s)] ("THERAPEUTIC MOLECULE"), C-Path shall provide the funding as described below, and in return for such funding, INSTITUTION shall pay C-Path the percentage of GROSS INCOME to the INSTITUTION as described in Section 5.1.

3.1 Funding. C-Path agrees to fund the identification and/or further development of the THERAPEUTIC MOLECULE(S), the maximum amount not to exceed **$**_____ (See Exhibit B). Grant payments shall be milestone driven based on the Statement of Work (Exhibit A), with the last payment issued after TRxA's receipt of the final project report (See Exhibit C – Reporting).

3.2 Payment. Payments shall be made by C-Path to INSTITUTION in accordance with the payment schedule provided as Exhibit B, with expense reports provided quarterly (See Exhibit C – Reporting). In the event reported grant expenditures are less than 50% of the total amount issued to date and/or agreed milestones in the Statement of Work are not achieved, TRxA reserves the right to hold subsequent payments until grant funds are spent down and/or deliverables achieved.

It is the responsibility of the INSTITUTION to submit an invoice for grant payments. Each invoice will state the portion of work for which funding is being requested, and must be submitted within three (3) months of the scheduled payment as defined in Exhibits A and B.

**INSTITUTION will send invoices by email to:**

Accounts Payable (**accountspayable@c-path.org**)

Critical Path Institute
Attn: Accounts Payable
1840 E. River Road, #100
Tucson, AZ 85718

Payment of final invoice shall be contingent upon satisfactory completion and submission of a final report to C-Path describing the Work.

4. Responsibility

4.1 Responsibility on behalf of INSTITUTION. The person with primary responsibility for the Work provided by INSTITUTION will be _____.

4.2 Primary contact for C-Path. Project management support will be provided by Michelle Morgan, mmorgan@c-path.org.

5. Consideration.

5.1 Definitions.

**"THERAPEUTIC MOLECULE(S)"** means any product, service or process that is made, developed, processed, refined, improved upon, and licensed, sold, or transferred that was conceived in sufficient detail to allow another to practice the invention during the performance of the Work as outlined in Exhibit A.

**"GROSS INCOME"** means all amounts received by INSTITUTION on any and all licensing, sale, transfer or other commercial utilization sales, however characterized, by INSTITUTION of the THERAPEUTIC MOLECULE(S) to a LICENSEE.

**"LICENSEE(S)"** means any person or entity to whom INSTITUTION grants or licenses all or any portion of its the rights in THERAPEUTIC MOLECULE(S).

5.2 **Recordkeeping and Audit.** INSTITUTION will keep, and will require its LICENSEEs to keep, true and accurate records containing data reasonably required for the computation and verification of payments due under this Agreement. C-Path may, during the Term of this Agreement, appoint an auditor for the purposes of verifying compliance with the terms under this Agreement. C-Path must provide INSTITUTION with reasonable advance notice of its desire for such audit. Furthermore, such audit will be carried out during INSTITUTION'S business hours and without unreasonably interfering with INSTITUTION'S business and operations. Audits will be conducted no more than once per year and the term and scope of the audit will be mutually agreed upon prior to audit.

**5.3 Periodic Reporting of Income.** INSTITUTION will provide to C-Path a written report (the "REPORT"), detailing the GROSS INCOME received to date. The REPORT must be provided semiannually beginning the first calendar year after initiation of the award, applying to each period ending June 30 and December 31 and reported to C-Path no later than 30 days thereafter.

**5.4 Consideration to C-Path and Payment Terms.** INSTITUTION will pay to C-Path an amount equal to five percent [5%] of GROSS INCOME if the total cumulative funding provided by TRxA to develop the THERAPEUTIC MOLECULE is less than $500,000.00. INSTITUTION will pay to C-Path an amount equal to seven and a half percent (7.5%) of GROSS INCOME if the total cumulative funding provided by TRxA to develop THERAPEUTIC MOLECULE is equal to or larger than $500,000.00 and less than $1,000,000.00. INSTITUTION will pay to C-Path an amount equal to ten percent [10%] of GROSS INCOME if the total cumulative funding provided by TRxA to develop THERAPEUTIC MOLECULE is equal to or exceeds $1,000,000.00. INSTITUTION is responsible for all past and future patent costs incurred in connection with the THERAPEUTIC MOLECULE (S), regardless of when incurred.

All payments will be made to Critical Path Institute in United States dollars, net 30 days from the due date of the REPORT, unless otherwise specified above. All overdue amounts will be subject to a charge of interest compounded monthly until payment, at a rate the greater of (i) one and half percent (1.5%), or the highest rate allowed by law).

Payments will be made electronically via ACH or wire transfer on a semiannual basis in accordance with the following or any other instructions as may be specified by C-Path.

**5.5 Additional Reporting Requirements.** In addition to the reports described in Section 5.4, INSTITUTION will provide progress reports to C-Path as follows:

a. Monthly Updates: INSTITUTION will be required to participate in monthly teleconferences with C-Path to provide progress reports (via slides and discussion) that summarize achievements since the prior reporting period, how TRxA funds have been used, any financial risks to the project, any other foreseeable risks and mitigation strategies, and information about any plans for scientific publications and/or IP protection resulting from the Work.
b. Interim Report: At the mid-point of the Work, a written scientific summary of progress to date, including status of the budget, study results, and any challenges encountered, shall be submitted.
c. Final Report: A final written report summarizing completed and open activities and detailing any unused funds is to be submitted within 30 calendar days of the conclusion of the Work.

6. Confidentiality. For purposes of this Agreement, each Party shall be considered the "Receiving Party" with respect to the other Party's Confidential Information. Any such Confidential Information disclosed by a Disclosing Party shall be identified by such Disclosing Party (i) in the case of oral Confidential Information, verbally at the time of disclosure, and subsequently in writing, and (ii) in the case of written Confidential Information, in writing at the time of disclosure. Notwithstanding the foregoing, the failure to mark, or reduce such information to writing shall not preclude such information from being considered "Confidential Information" hereunder if a person knowledgeable in the field would reasonably conclude that such information is confidential based on the nature and circumstances of the disclosure.

During the term of this Agreement and for a five (5) year period after its expiration or termination, the Receiving Party agrees to maintain all Confidential Information in confidence and not to disclose Confidential Information to any third party. The Receiving Party shall use the Confidential Information only for the purpose of the Project in accordance with this Agreement, and for no other purpose. The Receiving Party shall be responsible for informing its employees, officers and other representatives who may have access to the other Party's Confidential Information of the confidential nature thereof and the Receiving Party's obligations under this Agreement. The Receiving Party will take reasonable steps to ensure that its employees and officers and other representatives will comply with the terms and conditions of this Agreement.

The Receiving Party will not have obligations of non-disclosure and non-use with respect to any portion of the Disclosing Party's Confidential Information which the Receiving Party can establish (i) was publicly known and made generally available in the public domain prior to the time of disclosure; (ii) becomes publicly known and made generally available after disclosure through no action or inaction of Receiving Party; (iii) is in the possession of Receiving Party, without confidentiality restrictions, at the time of disclosure by the Disclosing Party as shown by Receiving Party's files and records immediately prior to the time of disclosure; or (iv) is independently

developed by the Receiving Party without reference to or reliance upon the Disclosing Party's Confidential Information, as evidenced by the Receiving Party's written records.

In the event Receiving Party is required to disclose Confidential Information as required by law, regulation, or court order, such disclosure shall not be a breach of this Agreement provided that the Receiving Party (i) discloses only that portion of Confidential Information as required to be disclosed; and (ii) provides the Disclosing Party with written notice thereof prior to disclosure, to the extent it is legally able, so that the Disclosing Party may seek a protective order.

7. Public Relations: Neither party will publicize the collaboration between the two organizations or use each other's name, trademark, or variations of same in any press release or other conference, government or public presentation without written approval of the other.

8. Relationship of Parties. In assuming and performing the obligations of this Agreement, INSTITUTION and C-Path are each acting as independent parties working together in support of the project governed by this Agreement and neither shall be considered or represent itself as an agent or employee of the other. Neither party will use the name or any trademark of the other in any advertising, sales promotion or other publicity matter without the prior written approval of the other.

9. Indemnification. INSTITUTION shall defend, indemnify, and hold C-Path, its officers, employees, and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys' fees), or claims for injury or damages arising out of the performance of this Agreement, except to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of C-Path, its officers, employees, or agents.

C-Path shall defend, indemnify, and hold INSTITUTION, its officers, employees, and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys' fees), or claims for injury or damages arising out of the performance of this Agreement, except to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of INSTITUTION, its officers, employees, or agents.

10. Termination. This Agreement shall continue for as long as INSTITUTION continues to receive income for the THERAPEUTIC MOLECULE. Upon a breach of this Agreement by INSTITUTION, C-Path may terminate this Agreement effective on thirty (30) days written notice to INSTITUTION. Such termination will become automatically effective upon expiration of the thirty-day period unless INSTITUTION cures the breach before the period expires. Termination shall not relieve either party of any obligation or liability accrued hereunder prior to termination, or rescind or give rise to any right to rescind any payments made prior to the time of termination.

11. Subcontracts. INSTITUTION will not subcontract any portion of the Work or substantive project effort not outlined in Exhibits A and B without the prior written approval of C-Path. INSTITUTION will enter into separate agreements with contract research organizations ("CROs") or other institutions and pay them directly for services provided as indicated in

EXHIBIT B. Costs incurred for service providers (e.g., CROs) will not be eligible for the inclusion or application of indirect costs.

12. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Arizona, without regard to its conflicts of laws principles.

13. Miscellaneous.

13.1 Assignment. Neither party shall assign nor transfer any interest in this Agreement nor assign any claims for money due or to become due under this Agreement without the prior written consent of the other party.

13.2 Entire Agreement. This Agreement, with its attachments, constitutes the entire agreement between the parties regarding the subject matter hereof and supersedes any other written or oral understanding of the parties. This Agreement may not be modified except by written instrument executed by both parties and signed by the authorizing authority representing each party.

13.3 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties, their successors and permitted assigns.

13.4 Notices. Except as provided in Section 3 hereof with regard to payment of invoices, any notice, reports or other communication required or permitted to be given to either party hereto shall be in writing and shall be deemed to have been properly given and effective: (a) on the date of delivery if delivered in person during recipient's normal business hours; or (b) on the date of delivery if delivered by courier, express mail service or first-class mail, registered or certified, return receipt requested. Such notice shall be sent or delivered to the respective addresses given below or to such other address as either party shall designate by written notice given to the other party as follows:

In the case of INSTITUTION:

**Scientific**

[INSERT MAILING ADDRESS]
ATTN: _____

**Contractual**

[INSERT MAILING ADDRESS]
ATTN: _____

In the case of C-Path:

**Scientific**

The Critical Path Institute
1840 E River Road, #100
Tucson, AZ 85718
ATTN: Mark Drew, PhD

**Contractual**

The Critical Path Institute
1840 E River Road, #100
Tucson, AZ 85718
ATTN: Kristen L. Swingle, President and COO

15. Execution by Counterpart. This Agreement may be executed separately or independently in any number of counterparts, each and all of which together shall be deemed to have been executed simultaneously and for all purposes to be one Agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives effective as of the day and year first written above.

| The Critical Path Institute | **[INSTITUTION FULL NAME]** |
|---|---|
| By: _____ | By: _____ |
| Name: Kristen L. Swingle | Name: [SIGNER NAME] |
| Title: President and Chief Operating Officer | Title: [SIGNER TITLE] |
| Date: _____ | Date: _____ |

[Additional signature(s) on next page]

Read and acknowledged by principal investigator(s): _____

Name: [PI FULL NAME]

Title: [PI TITLE]

Date: _____

_____

Name: [PI FULL NAME]

Title: [PI TITLE]

Date: _____

**Exhibit A**
[Insert Statement of Work]

**Exhibit B**
[Insert Payment Schedule and Budget]

**Exhibit C**

## TRxA Operational Policies and Procedures

This document describes policies and procedures that inform TRxA grant operations with respect to, among others, decision making, publications, grant and patent applications and the adjudication process(es); recognizing that the formal legal agreement is the ultimate governing document.

### Scientific decision making and planning of experiments

Scientific direction of the project is governed by the university's Principal Investigator(s) (PI(s)) together with TRxA personnel (Executive Director and the Director of Drug Discovery and Development). This project team will decide on the order of experiments, based on the team members' expertise and input from external consultants, as appropriate. The team will also define target values for the lead molecule(s) and define go/no-go decision-making points in the project. TRxA reserves the right to either stop funding the project if progress has not been sufficiently made, or, alternatively, increase the amount of funding available for the project if warranted.

### Intellectual property protection and publication of results

**Decision making around protection of IP**
Care should be taken to not jeopardize the intellectual property (IP) being developed, with support from TRxA, by publishing prior to appropriate protection being in place. Such protection should be sufficient to garner and maintain the interest of biotech and pharma for potential licensing of the IP (ideally worldwide protection, or at minimum the US and EU). The project team will try to achieve consensus on the best IP strategy. However, since IP is owned by the academic institution, their respective tech transfer and/or licensing office is ultimately responsible for making these patent protection decisions. TRxA reserves the right to stop funding the project if protection is not adequate for ultimate commercialization efforts.

**Protection of IP vs publication**
TRxA recognizes the need for publishing in the academic environment for promotion and tenure considerations. With that said, it is requested that adequate efforts are made to delay publication if the project team deems this in the best interest of the project's future licensing opportunities and thus the ability to bring the new medical product towards patient care. Options should be explored to avoid using graduate students or other trainees on the project,

who are especially vulnerable to the need to publish to finalize their training. Instead, it is recommended that professional technicians be utilized to execute the work, should publication restrictions be anticipated. With respect to the PI's performance metrics, it should be explored to what extent patent applications can be counted towards promotion and tenure decisions, to further support the delay of publication while not negatively impacting the PI's career development.

**Timing of publication**
Patent applications become public 18 months after the priority date. Therefore, should the project team deem it in the best interest of the commercial prospects of the project to postpone publication, this can only be delayed to a maximum of 15 months after the priority date. This allows the remaining 3 months for manuscript submission, review and potential revisions, to allow simultaneous publication of the patent application with the manuscript, and not give potential competitors more lead time than necessary.

**Notification of publication and recognition language**
(Plans for) submission and publication of manuscripts will be tracked in the monthly project team meetings while the project is actively being supported by TRxA. Should manuscript submission and/or publication happen post active TRxA funding, TRxA will need to be notified of publications during follow up reporting, which will be at minimum on an annual basis.

In publications, to recognize TRxA support, please include the following language: "This publication was supported by Critical Path Institute's Translational Therapeutics Accelerator (TRxA)."

## Commercialization

The goal of TRxA's support is to improve the likelihood of commercialization of academic drug discovery projects, whether through licensing with an established industry partner, or through venture-backed company formation. The responsibility and decision making for these commercialization efforts ultimately lie with the university's tech transfer office (TTO) and/or licensing office, with TRxA only serving in an advisory role.

## Conflict Resolution

It is anticipated that most differences of opinion on scientific direction, IP protection, or timing of publication can be resolved within the project team by building consensus, keeping in mind the ultimate goal of getting new therapies to patients. Neutral, external consultants can be engaged to provide additional expert advice, to complement the project team's experience. These consultants can be engaged by any party associated with the funded project. However, should consensus be elusive to achieve, the issue can be escalated to an adjudicating committee, composed of leadership from the university and Critical Path Institute. The project team will agree on the final composition of this body and could include individuals such as the Dean of the PI's School or the Vice President of Research at the university, the head of the TTO, the Chief Science Officer of Critical Path Institute and a representative of the Frederick Gardner Cottrell Foundation, which funds TRxA; external consultants could also be included. It is recommended to have a small, odd number of individuals comprising this committee, such as a minimum of three or a maximum of five individuals.

## Reporting

The project team will meet monthly via Zoom, Microsoft Teams or a similar platform, to provide a status update and ensure alignment on next steps for the coming weeks. TRxA will provide a template agenda for these meetings to streamline information sharing. Expenditure reports shall be provided quarterly, as well as prior to requesting milestone payments, and shall include a breakdown of expenditures of any sub awardees.

A written report is required at the 6-month mark and should be submitted within 30 days of this date; this will be reviewed by TRxA's Scientific Advisory Committee, who will provide feedback on progress and direction. This report is expected to contain both technical and financial information.

A final report will be required within 30 days of the end of the grant period. Similar to the 6-month report, this submission is expected to contain both technical and financial information. The Scientific Advisory Committee will once again review this report and also provide a recommendation to TRxA's Programmatic Review Board (PRB) for continuation of funding beyond the initial grant period. The PRB will make the final decision on the opportunity to continue funding, depending on progress but also availability of funds in the TRxA portfolio. Exact requirements and process for continuation of funding will be shared towards the end of the project period.

Templates will be provided for all required reports.