

THE NATIONAL CANCER INSTITUTE'S CHEMICAL BIOLOGY CONSORTIUM PARTICIPANTS AGREEMENT

This Agreement is between the National Cancer Institute (“NCI”) and the Participant Institution (“Participant”) in the Chemical Biology Consortium (“CBC”). Collectively or individually, the NCI and Participant shall also be referred to as “Party” or “Parties.” The Parties rights and responsibilities in the use and protection of Confidential Information disclosed for the Purpose are outlined in this Agreement.

Participant:

Article 1. Introduction

The mission of the National Cancer Institute’s Chemical Biology Consortium is to increase the flow of early stage drug candidates into NCI’s drug development pipeline. By establishing an integrated network of chemical biologists and molecular oncologists from government, industry and academia, these CBC associate organizations and the NCI (collectively “Participants”) can further address the unmet needs in therapeutic oncology focusing on areas such as “undruggable” targets and under-represented malignancies. Through the CBC and the interactions among the various Participants, the NCI’s drug discovery and development pipeline can be enabled from target identification through proof-of-concept (POC) clinical trials. It is expected and understood that NCI will have the option to clinically develop successful compounds (NMEs) created by the CBC.

Article 2. Definitions

“**CBC Project**” or “**Project**” means target, agent, compound or class of compounds determined by the NEXT Senior Advisory Committee to be high priority.

“**Chemical Biology Consortium**” or “**CBC**” means the network organized by NCI comprised of government, industry and academic organizations addressing the unmet needs in therapeutic oncology focusing on areas such as “undruggable” targets and underrepresented malignancies.

“**Confidential Information**” means confidential scientific, business, financial information, or Identifiable Private Information provided that Confidential Information does not include:

- (a) information that is publicly known or that is available from public sources;
- (b) information that has been made available by its owner to others without a confidentiality obligation;
- (c) information that is already known by the receiving Party, or information that is independently created or compiled by the receiving Party without reference to or use of the provided information; or
- (d) information that relates to potential hazards or cautionary warnings associated with the production, handling, or use of the material.

“Confidential Information Provider” means any CBC Participant providing Confidential Information to the CBC under a CBC Participant Agreement for the CBC Project.

“Effective Date” means the date of the last signature of the Parties executing this Agreement.

“Good Faith Agreement” or “GFA” means an agreement entered into by Investigators pursuant to this Agreement.

“Government” means the Government of the United States of America.

“Investigator” means an individual who is an employee, contractor, agent, or staff member of the Participant assisting in the performance of research under this Agreement.

“Project Manager” or “PM” provides day-to-day direction, including organizing meetings, directing project workflow and ensuring CBC Data is entered into the CBC Database in a timely manner.

“Project Team,” “CBC Project Team” or “PT” means Investigators with interest and expertise assisting in the performance of the Project. The Project Team will consist of representative members of all Participants, as approved by NCI, who are participating in the CBC Project, including the Parties to this Agreement. The CBC Project Team will be managed by the NCI.

“Technology Transfer Committee” or “TT Committee” means a collaborative body whose composition and responsibilities include intellectual property and technology transfer.

Article 3. Participation

- 3.1 **Performance of CBC Activities.** The activities to be carried out under this Agreement will be performed by the Parties.
- 3.2 **Independent Contractors.** The relationship of Participants with one another and with NCI is that of independent contractors and not agents of each other or joint ventures or partners. Each Party will maintain sole and exclusive control over its personnel and operations.
- 3.3 **Participant Collaboration.** Participants are encouraged to enter into separate agreements with one another and with NCI to accomplish specific projects or tasks, the terms of which will be consistent with the obligations of this Agreement.
- 3.4 **Technology Transfer Committee.** The Parties agree to establish a Technology Transfer Committee (TT Committee) comprised of each Participant’s Technology Transfer

Representative (TTR), NCI Technology Transfer Project Manager (NCI TTPM) and NCI to discuss topics related to intellectual property and technology transfer.

- 3.4.1 Participants will assign a Technology Transfer Representative (TTR), identified on the Signature Page, to contribute to the TT Committee on the Participants behalf.
- 3.4.2 The TT Committee will meet on an Ad Hoc basis to develop guidelines, discuss intellectual property development and support the CBC initiative in commercial development.
- 3.4.3 Guidance will become effective only upon two-thirds majority agreement by the TT Committee.

Article 4. Obligations

- 4.1 **Investigators.** Individuals will be selected by the Participant to serve as members of a Project Team. Investigator shall continue to remain employed by their respective Participant, if any Investigator ceases to be employed by the Participant, they will provide timely written notice, such Investigator will be removed from the CBC Program.
 - 4.1.1 All Investigators must have a completed GFA (Appendix A) on file with the NCI prior to engaging in any activities with the CBC Program including but not limited to receiving confidential information and access to the CBC Database.
 - 4.1.2 All Investigators are bound by the confidentiality provisions at least as restrictive as those provided in this Agreement.
 - 4.1.3 All Investigators will use reasonable effort to ensure the protection of their CBC Database credentials and will not disclose or otherwise make available said credentials to any other person or entity.
- 4.2 **Funding.** There is no funding under this Agreement.

Article 5. Intellectual Property

- 5.1 **Ownership of Subject Inventions.** The producing Party will retain sole ownership of and title to all inventions made solely by its Investigators. Inventions produced jointly by Investigators of multiple Participants will be owned jointly by the producing Participants.
- 5.2 **Invention Reporting.** Parties will report all Inventions generated under a CBC Project to the NCI and all members of the CBC Project Team in sufficient detail to determine inventorship, which will be determined in accordance with U.S. Patent Law. Additional information is available in “CBC Invention Reporting Guidance” (Appendix B).

Article 6. Rights of Access and Use of Data

- 6.1 **Data Sharing.** Participant acknowledges that the basic research mission of NIH includes sharing with third parties for further research those research resources made in whole or in part with NIH funding. Consistent with this mission and the tenets articulated in “Sharing of Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts,” available at https://grants.nih.gov/grants/intell-property_64FR72090.pdf, Participants will share data and resources within the CBC community. Participants shall not share or communicate data with any third party other than the CBC community unless it receives the written permission from the NCI and enters into an Agreement with such third party with confidentiality terms at least as stringent as those set forth herein.
- 6.1.1 **CBC Database.** Investigators will enter data into the CBC Database to be used by the CBC Project Team to support and advance the Project. Any information obtained from the CBC Database is considered Confidential Information and will be protected in accordance with the confidentiality provisions of this Agreement.
- 6.2 **Confidential Information.** Each Party agrees to limit its disclosure of Confidential Information to the amount necessary to carry out their obligations under this Agreement and will place a confidentiality notice on all such Confidential Information. A Party orally disclosing Confidential Information to the other Party will summarize the disclosure in writing and provide it to the other Participants within fifteen (15) days of the disclosure. Each Party receiving Confidential Information agrees to use it only for the purposes described by the CBC.
- 6.3 **Protection of Confidential Information.** Confidential Information will not be disclosed, copied, reproduced or otherwise made available to any other person or entity without the consent of the owning or providing Party except as required by a court or administrative body of competent jurisdiction, or law or regulation. Each Party agrees to use reasonable efforts to maintain the confidentiality of Confidential Information, which will in no instance be less effort than the Party uses to protect its own Confidential Information. Each Party agrees that a Party receiving Confidential Information will not be liable for the disclosure of that portion of the Confidential Information which, after notice to and consultation with the disclosing Party, the receiving Party determines may not be lawfully withheld, provided the disclosing Party has been given a reasonable opportunity to seek a court order to enjoin disclosure.
- 6.4 **Duration of Confidentiality Obligation.** The obligation to maintain the confidentiality of Confidential Information will expire five (5) years from completion of the CBC Project.
- 6.5 **Publications.**
- 6.5.1 The Parties are encouraged to make publicly available the results of their activities under the CBC. The Parties may not publish or publicly disclose any Confidential Information provided by the CBC as described in Article 6 of the CBC Participant Agreement including data accessed from the Central CBC Database or CBC Project Team without permission from the CBC Project Team and the NCI. Before

Participant submits any publication or public disclosure which includes Confidential Information, the Participant will provide the disclosure to the CBC Project Team who will then have thirty (30) days to review the proposed publication to ensure that Confidential Information is protected. If Confidential Information provided by a Confidential Information Provider is included in the publication, the Confidential Information Provider may request in writing within the thirty (30) day review period, that the proposed publication be delayed until such time that the CBC Project Team and the Confidential Information Provider agrees the information is appropriate to publish or edited in such a way that the Confidential Information is not disclosed.

- 6.5.2 Should a Confidential Information Provider no longer be a member of the CBC Project Team, the CBC Project Team will provide the proposed disclosure to the Confidential Information Provider at least thirty (30) days prior to publication to allow the Confidential Information Provider to exercise their rights as described in the previous paragraph.

Article 7. Expiration and Termination

- 7.1 **Expiration.** This Agreement will expire on the seven (7) years from the Effective Date of this Agreement. In no case will the term of this Agreement extend beyond the term indicated unless it is extended in writing in accordance with Paragraph 9.5.
- 7.2 **Unilateral Termination.** Either Party may unilaterally terminate this Agreement and withdraw from the CBC Program at any time by providing written notice at least thirty (30) days before the desired termination date. Upon termination Participant's Investigators will be withdrawn from the CBC Program.

Article 8. Liability

- 8.1 **NO WARRANTIES.** NO WARRANTIES. THE PARTIES MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO ANY MATTER WHATSOEVER, INCLUDING THE CONDITIONS OF THE RESEARCH OR ANY INVENTION OR MATERIAL, WHETHER TANGIBLE OR INTANGIBLE, MADE OR DEVELOPED UNDER OR OUTSIDE THE SCOPE OF THIS AGREEMENT, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY INVENTION OR MATERIAL, OR THAT A TECHNOLOGY UTILIZED BY A PARTY IN THE PERFORMANCE OF THIS AGREEMENT DOES NOT INFRINGE ANY THIRD-PARTY PATENT RIGHTS.
- 8.2 **Indemnification and Liability.** To the extent permitted by law, Participant agrees to hold the United States Government harmless and to indemnify the United States Government for all liabilities, demands, damages, expenses and losses arising out of the use by Participant for any purpose of the under this Agreement, unless due to the negligence or willful misconduct of NCI, its employees, or agents. Each Party otherwise will be liable

for any claims or damages it incurs in connection with this Agreement, except that NCI, as an agency of the Government, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. Chapter 171.

Article 9. Miscellaneous

- 9.1 **Authority.** The Parties have the requisite power and authority to enter into this Agreement and to perform according to its terms, and the Party's official signing this Agreement has authority to do so.
- 9.2 **Governing Law.** The construction, validity, performance and effect of this Agreement will be governed by U.S. federal law, as applied by the federal courts in the District of Columbia. If any provision in this Agreement conflicts with or is inconsistent with any U.S. federal law or regulation, then the U.S. federal law or regulation will preempt that provision.
- 9.3 **Compliance with Law.** Participant agrees that they will comply with, and advise any contractors, grantees, or agents they have engaged to participate in the CBC to comply with, all applicable Executive Orders, statutes, and HHS regulations relating to safety, research on human subjects (45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56) and relating to the appropriate care and use of laboratory animals (7 U.S.C. §§ 2131 et seq.; 9 C.F.R. Part 1, Subchapter A).
- 9.4 **Severability.** The illegality or invalidity of any provisions of this Agreement will not impair, affect, or invalidate the other provisions of this Agreement.
- 9.5 **Amendments.** Minor modifications to this Agreement may be made by NCI to reflect program changes. Substantial changes to this Agreement, including extensions of the term, will become effective only upon a written amendment signed by the signatories to this Agreement or by their representatives duly authorized to execute an amendment.
- 9.6 **Disputes.** Any dispute arising under this Agreement which is not disposed of by agreement will be submitted jointly to the signatories or their designees of this Agreement. If the signatories, or their designees, are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the NCI Director (or his/her designee). Nothing in this Paragraph will prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.

The Parties acknowledge and agree that in the event of any breach of this Participants Agreement, including, without limitation, the actual or threatened disclosure of Confidential Information, the Parties and all Confidential Information Providers may suffer an irreparable injury, such that no remedy at law will afford it adequate protection against, or appropriate compensation for, such injury. Accordingly, the Parties hereby agree that the Confidential Information Provider may be entitled to specific performance of the obligations described under this Participants Agreement, as well as such further equitable

relief as may be granted by a court of competent jurisdiction. With respect to NIH or other federal government Participant, the Confidential Information Provider would only be entitled to injunctive relief. For purpose of this Participants Agreement the Confidential Information Provider is considered a third-party beneficiary and has the right, but is not required, to enforce the provisions of this Agreement.

- 9.7 **Use of Name.** By entering into this Agreement, the Participant will not directly or indirectly endorse any product or service that is or will be provided by the Government or another Participant, whether directly or indirectly related to this Agreement. Participant will not in any way state or imply that this Agreement is an endorsement of any product or service by another Participant or any of its organizational unites or employees.
- 9.8 **Export Controls.** Participant agrees to comply with U.S. export law and regulations, including 21 U.S.C. 382 and 21 CFR Part 312.110.
- 9.10 **Entire Agreement.** This Agreement and Appendices A-B constitute the entire agreement between the Parties concerning the subject matter of this Agreement and supersedes any prior understanding or written or oral agreement, including Participants Agreements.
- 9.11 **Survivability.** The provisions of Paragraphs 5.1, 5.2, 6.1-6.5, 7.1, 7.2, 8.1, 8.2, 9.2, 9.3, 9.6, 9.7, and 9.11 will survive the expiration or early termination of this Agreement.

SIGNATURES BEGIN ON THE NEXT PAGE

SIGNATURE PAGE

By executing this agreement, each Participant represents that all statements made herein are true, complete, and accurate to the best of its knowledge.

FOR NATIONAL CANCER INSTITUTE:

James H. Doroshow, Ph.D.

Director, Division of Cancer Treatment and Diagnosis, NCI

Date

Jeffrey W. Thomas, Ph.D.

Frederick Unit Supervisor, TTC, NCI

Date

NCI CBC Contact:

Barbara Mroczkowski, Ph.D.
Director, NCI Experimental Therapeutics
(NExT) Program
Bldg 31, Suite 3A44
31 Center Drive
Bethesda, MD 20892
Ph: (240) 781 - 3320
Email: mroczkowskib@mail.nih.gov

NCI Technology Transfer Contact:

Jeffrey W. Thomas, Ph.D.
Frederick Unit Supervisor, TTC,
NCI Technology Transfer Center, NCI
Riverside 5, Suite 400
8490 Progress Drive
Frederick, MD 21701
Ph: (301) 624 – 8775
Email: NCITTCFrederick@mail.nih.gov

NCI Technology Transfer Project Manager:

Dr. Jason Cristofaro (Cristofaroj@mail.nih.gov)

FOR CBC PARTICIPANT:

Signature

Date

Name: _____

Title: _____

Institution: _____

Participant CBC Contact:

Technology Transfer Representative:

**THE NATIONAL CANCER INSTITUTE'S
CHEMICAL BIOLOGY CONSORTIUM
GOOD FAITH AGREEMENT**

I am an Investigator of a CBC Participant (Institution), I have read and understood the terms of **The National Cancer Institute's Chemical Biology Consortium (CBC) Participants Agreement** and agree to comply with its terms, including those outlined below.

1. **Confidential Information.** The obligation to maintain the confidentiality of Confidential Information (as defined in the CBC Participants Agreement), including all information obtained from the CBC Database, will expire five (5) years from the date of disclosure.
2. **Protection of Credentials.** All Investigators will use reasonable effort to ensure the protection of their CBC Database credentials and will not disclose or otherwise make available said credentials to any other person or entity.
3. Investigator shall continue to remain employed by their respective Participant, if any Investigator ceases to be employed by the Participant, they will provide timely written notice, such Investigator will be removed from the CBC Program.
4. The provisions of Paragraphs 5.1, 5.2, 6.1-6.5, 7.1, 7.2, 8.1, 8.2, 9.2, 9.3, 9.6, 9.7, and 9.11 of the CBC Participants Agreement will survive the expiration or early termination of this Agreement or Investigators removal from the CBC Program.

By executing this agreement, I represent that all statements made herein are true, complete, and accurate to the best of my knowledge.

Institution: _____
Name: _____
Title: _____
Phone #: _____
Email: _____

Signature

Date

Signed CBC Good Faith Agreements should be returned to:

Jena M. Kidwell
Program Specialist
Division of Cancer Treatment & Diagnosis, NCI
31 Center Drive, Suite 3A44
Bethesda, Maryland 20892

Email: Jena.Kidwell@nih.gov or CBCTechTransfer@mail.nih.gov
Tel: (240) 781 – 3337

APPENDIX B

CBC Invention Reporting Guidance

Invention Reporting

Inventor's Technology Transfer Office (TTO) will notify the CBC Project Manager and the NExT Program Director within fifteen (15) days of receiving an Employee Invention Report ("EIR") for invention related to a CBC Project. The CBC Project Manager will distribute a summary of the EIR ("Invention Summary") to the CBC Project Team. The EIR will be distributed only to members of the CBC Project Team who report they may be contributors to the reported invention. Members of the CBC Project Team will have thirty (30) days from receipt of Invention Summary to review and respond to the CBC Project Manager. The CBC Project Manager will send responses from members of the Project Team to TTOs.

Invention Disclosure

TTO will provide the following to CBC Project Manager and the NExT Program Director;

- a. Invention Summary. Brief summary of EIR
- b. EIR (Restricted distribution)

Contributor Form

Standardized form for CBC Project Team Members to support/justify their contributor claims. *Will be available on the CBC website*

Inter-institutional Agreement ("IIA")

Suggested if CBC Project Team Members from more than one Institution claim contributions to an invention developed under a CBC Project, the TTOs at the respective institutions negotiate an IIA prior to filing a Patent Application.

Inventorship/Contributor Dispute

Inventorship will be determined in accordance with U.S. patent law.

TTOs should in good faith negotiate to resolve inventorship disputes.

If the TTOs are unable to resolve the dispute, they will need to mutually agree upon an independent law firm to conduct an Invention Analysis to determine inventorship.

Institutions will be responsible for expenses incurred from Invention Analysis as stated in the IIA .

License (*Recommendations, Not Required*)

Lead Institution will have a first opportunity to license Invention for commercial development consistent with terms available in a Third-Party license.

Inventors added after submission of Patent Application will be responsible for a pro-rated share of expenses.

CBC Project Manager

Contact information for the CBC Project Manager and NExT Program Director can be obtained from Jena Kidwell at NIH CBCTechTransfer@mail.nih.gov.