

**BIOS Agreement for Health Technologies
Version 2.0
By Biological Innovation for Open Society (BIOS)**

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BIOS Agreement for Health Technologies Version 2.0

CAMBIA DRAFT Health Technologies BIOS 2.0 agreement

Background:

A. Access to enabling technologies, tools and platforms for basic innovation is important. It is undesirable that the delivery of products, whether for public good or for profit, should be encumbered by the terms under which such enabling technologies are made available. Research and development will be most efficient, effective, economical and equitable if these tools are available readily to all in a way that protects capability to use the technology and improvements.

B. The BIOS Initiative (www.bios.net) sets out to ensure common access to the tools of innovation, to promote the development and improvement of these tools, and to make such developments and improvements freely accessible to both academic and commercial parties.

C. A dynamic mutual non-assertion pool is a means by which such access can be protected. _____ [e.g. CAMBIA], ("Steward") owns or controls the rights to certain enabling technologies and associated patents, patent applications, knowhow, and materials in the sphere of activity of _____ [e.g. health, plant molecular enabling technologies] (the "IP and Technology") and is willing to grant the right to use IP and Technology to any party, without discrimination as to payment of fees of any kind, that agrees to all the terms of this Agreement.

D. Both research and creation of Products (defined as "tangible goods that are

a. not relevant to the use of the IP and Technology as an enabling

technology

- b. substantially distinct in function from the IP and Technology from which they were derived, and
- c. made solely for commercialization")

either for profit or for public good are expressly encouraged under this Agreement.

E. Expansion and improvement of the technology should be unfettered by uncertainty over IP rights. While patents are not a prerequisite to investment in research and development, some may wish to file patents or other intellectual property rights over technology derived using the IP and Technology. Proprietary rights of this nature may be appropriate if uncertainty about the assertion of rights does not slow research or hinder the delivery of products. Thus, it is in the interest of all parties to respect proprietary rights, but voluntarily set them aside in this particular Agreement for the benefit of all who have agreed to share in the same way.

F. The public benefits by transparency about technology, especially safety information. The parties agree that employees and students should be allowed to post, on steward-designated websites available to all who agree to these terms, or on any website of public record, any non-patentable improvements made to the technologies and, as a matter of public safety, any safety information relevant to use of the technology and potential regulatory approval of products embodying it.

Now, therefore, you and Steward agree on the following terms:

1. In return for Steward' s royalty-free grant to you of the right to use this IP and Technology and any derivatives without threat of assertion, **you agree**

- a. not to assert any intellectual property rights, including patents, pending patent claims, or bailments, to this IP and Technology and any derivatives, in any way, against any others that have agreed to these conditions; and
- b. not to accept any license or third party grant of rights conflicting with 1a.

Use of this IP and Technology under any conditions not conforming to the conditions above is not permitted.

If you are associated with a commercial entity or performing research for the benefit of a commercial entity, or your institution or employer requires it, please make copies of this Agreement and obtain the dated signature of an authorised person at the bottom of each copy. Return two copies to Steward at the address GPO Box 3200, Canberra, ACT 2601, Australia, Fax +61 (2) 6246 4533 or E-mail

licenses@cambia.org, and Steward will return one copy signed by an authorised person by the same means.

2. Collaboration You may freely cooperate with any other party to any agreement not in conflict with the terms of this Agreement. To facilitate such cooperation, particularly the expansion of the technology pool available to all parties to this Agreement, you agree to allow all other parties to acknowledge the existence of this Agreement in communications with or other disclosures to third parties.

This Agreement does not confer the right to use trademarks of any party nor create or imply the creation of any other business relationship between the parties.

3. Third Parties Obligations to third parties, for example under a Materials Transfer Agreement or Sponsored Research Agreement, that pre-date your receipt of any IP and Technology from Steward will be honoured except where they are in conflict with your obligations to the terms in this Agreement. You agree to make best efforts to obtain a waiver of any such conflicting obligations from such a third party.

Third parties, including your affiliates, may conduct research and and/or development activities (including field trials and clinical trials) and commercialization on your behalf if they may become party directly to an Agreement under these same terms.

4. Limited Warranty/Hold Harmless Steward and its employees and agents shall not be held liable for any use of the IP and Technology. Steward makes no representations and extends no warranties of any kind, either expressed or implied, except as required by applicable laws. All parties to this Agreement acknowledge that the IP and Technology and Improvements are experimental in nature (and may have hazardous properties). You agree to hold Steward and its employees and agents harmless for any loss, claim, damage or liability that may arise from any use of the IP and Technology by you. You agree to bear all risk to yourself and to others resulting from your own negligence or wrongful act or omission during or after the term of this Agreement, your own breach of this Agreement, and/or your own use, commercialization or distribution of IP and Technology or any material, technology or product derived through use of the IP and Technology.

You further explicitly acknowledge that components of the IP and Technology and their use may be subject to the intellectual property rights of other parties. Steward accepts no liability for non-licensed use and makes no representation or warranty that the use or supply of the IP and Technology will not infringe any patent, copyright, trademark or other right.

5. Material Transfer and Technology Support You may use the IP and Technology to carry out research and to create and sell Products. You may also use and distribute any derivatives you make using the IP and Technology that constitute enabling technology, but only if you make them available to others under the terms of this Agreement and at a price not to exceed reasonable cost of production.

You can obtain technical support, materials and future improvements by Steward or improvements of which Steward is aware if you register your use of the IP and Technology with Steward and provide a contribution through a BIOS Technology Support and Materials Transfer Agreement.

6. Termination and Survivability You may terminate this Agreement at any time by providing written notice of termination to Steward. This agreement will also terminate if you violate or fail to perform any term or obligation of this Agreement. You may appeal such termination to mediation or arbitration but agree to be bound by the results of such mediation or arbitration, and to repair any breaches found. Any failure by you to comply with the obligations of this Agreement (including but not limited to sharing IP and Technology) shall not be construed as a violation by Steward.

Within thirty (30) days of termination under any of the conditions listed above, you agree to destroy all materials and confidential information received from Steward and anything derived from them, except what has been incorporated into products completed prior to termination. Steward has the right to inform others of the termination.

Upon termination of this Agreement your rights and obligations and those of Steward under this Agreement shall cease except

- i. the non-assertion obligations under Article 1; and
- ii. the risk-bearing and hold harmless obligations under Article 4.

7. Miscellaneous

a. No waiver of any term or condition of this Agreement constitutes a continuing waiver, nor a waiver with respect to any other terms or conditions of this Agreement. If any part of this Agreement is declared invalid or unenforceable by any Court of competent jurisdiction, the rest of the Agreement shall remain in force to the fullest extent provided by law.

b. You or Steward may, with the written approval of the other party (such approval not to be unreasonably withheld) assign all, but no less than all, rights and delegate all, but no less than all, obligations under this Agreement, such approval to be sought by written notice to the other party within thirty (30) days of any change of control or sale of rights. Upon such approval, all obligations under this Agreement persist unless and until the execution of an instrument of legal assignment.

c. Steward may publish revised and/or new versions of this Agreement from time to time. Such new versions will be similar in spirit to the present version, but may differ in detail to address new or newly identified issues. Each version will be given a distinguishing version number. Upon written request to Steward, you may opt to be bound by the terms and conditions of a later published version. Where there is any conflict between versions or translations or any controversy between the parties respecting the interpretation or application of the terms of this Agreement, the latest English language version of the Agreement published by

Steward on a public website shall be controlling.

BiOS Technology Support and Materials Transfer Agreement

Background:

A. Access to enabling technologies, tools and platforms for basic innovation is important. It is undesirable that the delivery of products, whether for public good or for profit, should be encumbered by the terms under which such enabling technologies are made available. Research and development will be most efficient, effective, economical and equitable if these tools are available readily to all in a way that protects capability to use the technology and improvements.

B. The BIOS Initiative (www.bios.net) sets out to ensure common access to the tools of innovation, to promote the development and improvement of these tools, and to make such developments and improvements freely accessible to both academic and commercial parties.

C. A dynamic mutual non-assertion pool is a means by which such access can be protected. _____ [e.g. CAMBIA], ("Steward") owns or controls the rights to certain enabling technologies and associated patents, patent applications, knowhow, and materials in the sphere of activity of _____ [e.g. health, plant molecular enabling technologies] (the "IP and Technology") and is willing to provide such materials, protocols and other knowhow useful for the utility of the IP and Technology to any party who agrees to the BiOS Mutual Non-Assertion Agreement. Steward further encourages the posting, on steward-designated websites available to all who agree to these terms, or on any website of public record, any non-patentable improvements made to the technologies and, as a matter of public safety, any safety information relevant to use of the technology and potential regulatory approval of products embodying it.

D. Both research and creation of Products (defined as "tangible goods that are

- a. not relevant to the use of the IP and Technology as an enabling technology
- b. substantially distinct in function from the IP and Technology from which they were derived, and
- c. made solely for commercialization")

either for profit or for public good are expressly encouraged under this Agreement.

E. Those who benefit by the expansion of the pool wish to support the continuing provision of materials, website posting and other services in

furtherance of the BIOS Initiative and to facilitate implementation and use of the IP and Technology.

Now, therefore, you and Steward confirm that BY OPENING ANY PACKAGE DISPLAYING THIS AGREEMENT OR USING THE ENCLOSED MATERIALS YOU AGREE TO THE FOLLOWING:

1. You have read the BIOS Mutual Non-Assertion Agreement and agree to its terms. Use of any materials or other aspect of this IP and Technology under any conditions not conforming to the terms of the BIOS Mutual Non-Assertion Agreement is not permitted.

You may refuse to accept these conditions by destroying the contents of any materials packages and confidential documents, informing Steward upon so doing, or by returning all material and documents to Steward unopened.

If you are associated with a commercial entity or performing research for the benefit of a commercial entity, or your institution or employer requires it, please make copies of this Agreement and obtain the dated signature of an authorised person at the bottom of each copy. Return two copies to Steward at the address

GPO Box 3200, Canberra, ACT 2601, Australia, Fax +61 (2) 6246 4533 or E-mail licenses@cambia.org, and Steward will return one copy signed by an authorised person by the same means.

2. Technology Support Under this Agreement, if you register with Steward your willingness to discuss technical issues and patents, and share improved protocols, enabling technology materials, results, ideas, observations and data with all others that have agreed to the same Agreement, Steward agrees to provide you with technical support; specifically, if you within thirty (30) days of execution of the Mutual Non-Assertion Agreement and on each anniversary of such execution provided Steward a technology subscription fee in the amount listed in Annex C, Steward will during the subsequent year

a. share with you on your request, at cost, or if applicable, cost-free through a website, any improved protocols, enabling technology materials, results, ideas, observations and data that Steward develops or that come into Steward' s possession,

b. provide that Steward' s employees shall be available upon reasonable notice and for a reasonable time for discussion of data and questions with your employees via telephone or other electronic means, and

c. invite you to participate in meetings held among parties who have agreed to the same terms, and

d. receive and consider new project proposals from you and employ best efforts to collect, identify and provide potential means to accomplish them that may be available from among parties to this Agreement, which may include suggesting research schedules, development time-lines, and budgets subject to good-faith negotiations.

The parties agree that all outcomes of such collaboration will be made accessible under the same terms as this Agreement.

To encourage collaboration Steward is entitled to disclose the names of parties to this Agreement and whether they have provided technology subscription fees in a given year, but not the amount of the fees paid.

3. Improvements and Further Distribution and Use The materials made available under this agreement, and publications that should be cited in their use, are listed in Annex A. In your published and unpublished works you agree to describe the Materials as described in Annex A, and to describe any materials derived from them by explicitly stating how the derived material was constructed in or using these materials. However, no such derived materials should retain the designations used in Annex A, as such designations are reserved for materials developed and distributed by Steward.

You may use and distribute materials associated with the IP and Technology and any derivatives under the terms of this Agreement. You agree that any derivative materials that are published in any way or made available to any party, solely excepting any Product, will be made available by you

a. to all parties of this Agreement at a price not to exceed reasonable cost of production and distribution, or,

b. at Steward' s option, to Steward in at least a sufficient quantity to enable Steward to

(i) practice the enabling technology,

(ii) propagate the material for providing to others who have agreed to these terms, and

(iii) establish a long-term backup in a form that can be replicated for Steward to distribute at cost to any party that agrees to the terms of this Agreement. Such derived materials, and anything else that you would like to add to the dynamically expanding pool of IP and Technology, are to be listed in Annex B.

You agree to notify any prospective recipient of materials received under this Agreement that their use is subject to this Agreement with Steward, and upon supplying such materials you must provide a copy of this Agreement.

4. Limited Warranty/Hold Harmless Steward and its employees and agents shall not be held liable for any use you make of materials, protocols, or other intellectual assets made available to you under this Agreement. Steward makes no representations and extends no warranties of any kind, either expressed or

implied, except as required by applicable laws. All parties to this Agreement acknowledge that the materials made available to you under this Agreement are experimental in nature (and may have hazardous properties). You agree to employ reasonable efforts to ensure that the use, preparation, storage, handling, transport and/or disposition of provided Material will be conducted in strict accordance with all international, federal, state and/or local laws, statutes, regulations, guidelines, policies, permits, authorizations, industry standards, and/or agreements.

You further agree to hold Steward and its employees and agents harmless for any loss, claim, damage or liability that may arise from your acceptance, use, handling or storage of the material or use of any protocol made available to you under this Agreement. You further agree to bear all risk to yourself and to others resulting from your own negligence or wrongful act or omission during or after the term of this Agreement, your own breach of this Agreement, and/or your own use, commercialization, or distribution of any material, technology or product derived through use of materials, protocols, or other intellectual assets made available to you under this Agreement.

You further explicitly acknowledge that components of the materials and other intellectual assets made available to you under this Agreement and their use may be subject to the intellectual property rights of other parties. You are responsible for ensuring that all relevant licenses or permissions are obtained from the assignees of record, or other parties that may have acquired the rights. Steward accepts no liability for your non-licensed use and does not warrant freedom to operate in any jurisdiction.

5. Bailment This agreement does not confer or change any ownership of any intellectual property, materials, technology, knowhow or any other asset, nor does it create any joint venture, agency relationship or other business relationship between the parties. Thus, you may not sell, donate, abandon, or otherwise transfer ownership of any material under this Agreement to any third party, except for Products.

Materials or intellectual assets made available to you under this agreement may not be used in any consulting obligation or commercially directed or non-commercially directed work on behalf of any for-profit third party that is not a party to the BIOS Mutual Non-Assertion Agreement, regardless of whether or not such an obligation presently exists or previously existed or may be entered into in the future, without the express prior written permission of the providing party.

6. Term and Survivability You may terminate this Agreement three (3) years following the Execution Date by providing at least six (6) months' written notice of termination to Steward. This agreement will also terminate immediately if you violate or fail to perform any term or obligation of this Agreement. You may appeal such termination to mediation or arbitration but agree to be bound by the results of such mediation or arbitration, and to repair any breaches found. Any failure by you to comply with the obligations of this Agreement shall not be construed as a violation by Steward.

Within thirty (30) days of termination under any of the conditions listed above, you agree to destroy all materials received from Steward or derived from them, except any that have been incorporated into products made prior to termination.

Steward has the right to inform others of the termination

Upon termination of this Agreement your rights and obligations and those of Steward under this Agreement shall cease except

- (i) the non-assertion obligations under Article 1; and
- (ii) any obligations not yet performed or completed under Articles 3 and 7; and
- (iii) the risk-bearing and hold harmless provisions of Article 4

However, if you wish to re-enter a BIOS Technology Support Agreement, you may pay the agreed Subscription Fee according to Annex C to enter a renewed Agreement under the same terms but with a new Execution date.

7. Payment conditions, taxes and other charges Payments according to Annex C shall be paid on execution and on each anniversary of this Agreement as long as Technology Support is desired but for a minimum of three (3) years, within thirty (30) days from your receipt of Steward' s written wiring instructions, by wire transfer in immediately available funds to an account specified in writing by Steward.

You are entitled to withhold any taxes from any payments only if required by law or governmental regulation notified to Steward and translated into English in advance of such payments, and only unless and until a legally binding ruling is provided from the relevant authority granting you approval for reduced withholding or exemption. Your remittance of such withholding to the respective governmental authority while such a ruling is pending does not withdraw you from payment obligation under this Agreement, to be made promptly upon provision of said ruling.

You agree to pay for delivery costs of any material supplied under this Agreement, including postage, courier or haulage fees, duties, import-turnover taxes, Value Added Tax (VAT), and similar taxes and charges. You agree to take responsibility for any customs or other approvals or certificates required.

Other than regulated above, amounts due shall be understood without any applicable VAT, Goods and Services Tax (GST) or any similar tax, and shall be made without deduction of any bank or transfer or currency exchange charges. Your payment of such taxes or fees to a government or bank may not be considered as meeting your corresponding payment obligation to Steward.

8. Miscellaneous

- a. No waiver of any term or condition of this Agreement constitutes a continuing waiver, nor a waiver with respect to any other terms or conditions of this Agreement. If any part of this Agreement is declared invalid or unenforceable by any Court of competent jurisdiction, the rest of the Agreement shall remain in force to the fullest extent provided by law.

b. You or Steward may, with the written approval of the other party (such approval not to be unreasonably withheld) assign all, but no less than all, rights and delegate all, but no less than all, obligations under this Agreement, such approval to be sought by written notice to the other party within thirty (30) days of any change of control or sale of rights. Upon such approval, all obligations under this Agreement persist unless and until the execution of an instrument of legal assignment.

c. Steward may publish revised and/or new versions of this Agreement from time to time. Such new versions will be similar in spirit to the present version, but may differ in detail to address new or newly identified issues. Each version will be given a distinguishing version number. Upon written request to Steward, you may opt to be bound by the terms and conditions of a later published version. Where there is any conflict between versions or translations or any controversy between the parties respecting the interpretation or application of the terms of this Agreement, the latest English language version of the Agreement published by Steward on a public website shall be controlling.

d. In the case of conflict between the terms and conditions of this Agreement and the License Agreement, the License Agreement shall prevail.

Annex A. IP and Technology owned or controlled by Steward in the sphere of activity of Health Technologies

Material (Description): hTERT human telomerase subunit and kits using it to detect splice variants

Corresponding Publication or Patent (If Any): US Patents 6,916,642, US 6,846,662, and USPTO Application 2005/176022 and corresponding PCT applications, conversions, divisionals, continuations and continuations-in-part, and issued patents in any jurisdictions; *Human Molecular Genetics* 6 (12): 2011-2019.

Assignee or Owner: CAMBIA

Material (Description): β -glucuronidase and glucuronide permease genes of *Escherichia coli* for health applications

Corresponding Publication or Patent (If Any): US Patent Numbers 5,268,463, 5,432,081 and 5,599,670 and corresponding PCT applications, conversions, divisionals, continuations and continuations-in-part, and issued patents in any jurisdictions

Assignee or Owner: CAMBIA

Material (Description): Clones containing a sequence encoding a glucuronide repressor

Corresponding Publication or Patent (If Any): US Patent Numbers US 6,998,229, 5,879,906 and 6,429,292 and corresponding PCT applications, conversions, divisionals, continuations and continuations-in-part, and issued patents in any jurisdictions

Assignee or Owner: CAMBIA

Material (Description): CAMBIA plasmids containing GUSPlus gene cassettes for health applications

Corresponding Publication or Patent (If Any): US Patent 6,391,547, 6,641,996, 7,087,420 and 7,141,719 and corresponding PCT applications, conversions, divisionals, continuations and continuations-in-part, and issued patents in any jurisdictions; *Nature* **433**:629-633

Assignee or Owner: CAMBIA

This Annex A may be expanded; applicable changes will be executed with dated signatures below. Expansions may be executed in counterparts, the sum of which shall constitute the expanded Agreement.

Name of Your Representative

Signature

Title of Your Representative

Date

Name of Steward' s Representative

Signature

Title of Steward' s Representative

Date

Annex B. IP and Technology to be added to the IP and Technology Pool under the BIOS Mutual Non-Assertion Agreement

Material (Description) :

Corresponding Publication or Patent (If Any) :

Assignee or Owner :

Material (Description) :

Corresponding Publication or Patent (If Any) :

Assignee or Owner :

Material (Description) :

Corresponding Publication or Patent (If Any) :

Assignee or Owner :

This Annex B may be expanded; applicable changes will be executed with dated signatures below. Expansions may be executed in counterparts, the sum of which shall constitute the expanded Agreement.

Name of Your Representative

Signature

Title of Your Representative

Date

Name of Steward's Representative

Signature

Title of Steward's Representative

Date

Annex C.

Technology Support Subscription Fee Table

As of the date of execution of this BIOS Technology Support Agreement, the following annual fees in support of technology support subscription services are in effect. These amounts may be changed once annually to account for reasonable currency fluctuations and inflation, and are calculated from the total number of employees worldwide (including all personnel in research and technical development, and associated administration, business development,

regulatory and public affairs and marketing).

US\$ 150,000 for large commercial entities having more than 500 of such employees,

US\$ 50,000 for medium commercial entities having 50 to 500 of such employees, or

US\$ 10,000 for small commercial entities having 5-49 of such employees.

US\$ 5,000 for very small commercial entities, having fewer than 5 of such employees

The parties agree that registered not-for-profit institutions are not required to pay any Technology Support fee unless using the IP and Technology on behalf of a for-profit company. If you are a for-profit company and are not able to pay the above fees, you are encouraged to provide alternative support for expanding the pool of enabling technology available to all those who agree to these terms. Such support may be for example a combination of covering direct costs and in-kind contributions, which may include cost-free provision of materials or access to facilities for improvement and dissemination of the IP and Technology, to be made further available under the same terms as this Agreement; sponsorship of your employees, other skilled individuals such as patent office staff, or of Steward's students, postdocs to train in exchanges through the BIOS Initiative, and sponsorship of national, regional or international meetings to include Steward staff and other parties to this Agreement.

ACKNOWLEDGED BY:

Name of Your Representative

Signature

Title of Your Representative

Date

Name of Steward's Representative

Signature

Title of Steward's Representative

Date

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