

SAMPLE AGREEMENT 1 CO-DEVELOPMENT AGREEMENT

Source: Mahoney RT (ed.). 2004. Handbook of Best Practices for Management of Intellectual Property in Health Research and Development. MIHR: Oxford, U.K. Reproduced with permission.

Public Sector Research Centre

(To be used in circumstances where PSRC and a party, ABC, are agreeing to a research program primarily to be carried out in the laboratories of ABC)

1.0 Introduction

This Co-development Agreement (“Agreement”) between ABC Company (“ABC”) and the Public Sector Research Centre (“PSRC”) will be effective when signed by all Parties. The research and development activities that will be undertaken by each of the Parties in the course of this Agreement are detailed in the Research Plan (“RP”), which is included as Appendix A. The funding and staffing commitments of the Parties are set forth in Appendix B. Any exceptions or changes to the Agreement are set forth in Appendix C.

2.0 Definitions

As used in this Agreement, the following terms shall have the meanings provided herein:

- 2.1 ***Invention*** means any invention or discovery that is or may be patentable.
- 2.2 ***Principal Investigator(s) or PIs*** means the person(s) designated respectively by the Parties to this Agreement that will be responsible for the scientific and technical conduct of the RP.
- 2.3 ***Proprietary/Confidential Information*** means confidential scientific, business, or financial information provided that such information does not include:
 - 2.3.1 information that is publicly known or available from other sources that are not under a confidentiality obligation to the source of the information
 - 2.3.2 information that has been made available by its owners to others without a confidentiality obligation
 - 2.3.3 information that is already known by or available to the receiving Party without a confidentiality obligation
 - 2.3.4 information that relates to potential hazards or cautionary warnings associated with the production, handling, or use of the subject matter of the Research Plan of this Agreement
- 2.4 ***Research License*** shall mean a nontransferable, nonexclusive license under any Intellectual Property (IP) license to make and use a licensed invention for purposes of research and not for purposes of commercial manufacture or distribution or in lieu of purchase.
- 2.5 ***Research Materials*** means all tangible materials other than Subject Data first produced in the performance of this Agreement.
- 2.6 ***Research Plan or RP*** means the statement in Appendix A of the respective research and development commitments of the Parties to this Agreement.

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- 2.7 **Subject Invention** means any Invention of the Parties, conceived or first actually reduced to practice in the performance of the Research Plan of this Agreement.
- 2.8 **Subject Data** means all recorded information first produced in the performance of this Agreement by the Parties.
- 3.0 Cooperative Research**
- 3.1 **Principal Investigators.** ABC research work under this Agreement will be performed by the ABC laboratory identified in the RP, and the ABC PI designated in the RP will be responsible for the scientific and technical conduct of this project on behalf of ABC. Also designated in the RP is the PSRC PI who will be responsible for the scientific and technical conduct of this project on behalf of the PSRC.
- 3.2 **Research Plan Change.** The RP may be modified by mutual written consent of the Principal Investigators. Substantial changes in the scope of the RP will be treated as amendments under Article 13.5.
- 4.0 Reports**
- 4.1 **Interim Reports.** The Parties shall exchange formal written interim progress reports on a schedule agreed to by the PIs, but at least within twelve (12) months after this Agreement becomes effective and at least within every twelve (12) months thereafter. Such reports shall set forth the technical progress made, identifying such problems as may have been encountered and establishing goals and objectives requiring further effort, any modifications to the Research Plan pursuant to Article 3.2, and all Agreement-related patent applications filed.
- 4.2 **Final Reports.** The Parties shall exchange final reports of their results within four (4) months after completing the projects described in the RP or after the expiration or termination of this Agreement.
- 5.0 Financial and Staffing Obligations**
- 5.1 **ABC and PSRC Contributions.** The contributions of the Parties, including payment schedules, if applicable, are set forth in Appendix B. ABC shall not be obligated to perform any of the research specified herein or to take any other action required by this Agreement, if the funding is not provided as set forth in Appendix B. ABC shall return excess funds to PSRC when it sends its final fiscal report pursuant to Article 5.2, except for staffing support pursuant to Article 10.3.
- 5.2 **Accounting Records.** ABC shall maintain separate and distinct current accounts, records, and other evidence supporting all its obligations under this Agreement, and shall provide the PSRC a final fiscal report pursuant to Article 4.2.
- 5.3 **Capital Equipment.** Equipment purchased by ABC with funds provided by the PSRC shall be the property of ABC. All capital equipment provided under this Agreement by one party for the use of another Party remains the property of the providing Party unless other disposition is mutually agreed upon in writing by the Parties. If title to this equipment remains with the providing Party, that Party is responsible for maintenance of the equipment and the costs of its transportation to and from the site where it will be used.

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6.0 Intellectual Property Rights and Patent Applications

- 6.1 Reporting.** The Parties shall promptly report to each other in writing each Subject Invention resulting from the research conducted under this Agreement that is reported to them by their respective employees. Each Party shall report all Subject Inventions to the other Party in sufficient detail to determine inventorship. Such reports shall be treated as Proprietary/Confidential Information in accordance with Article 8.4.
- 6.2 PSRC Employee Inventions.** If the PSRC does not elect to retain its IP rights, PSRC shall offer to assign these IP rights to the Subject Invention to ABC pursuant to Article 6.5. If ABC declines such assignment, the PSRC may release its IP rights as it may determine.
- 6.3 ABC Employee Inventions.** ABC may elect to retain IP rights to each Subject Invention made solely by ABC employees. If ABC does not elect to retain IP rights, ABC shall offer to assign these IP rights to such Subject Invention to PSRC pursuant to Article 6.5.
- 6.4 Joint Inventions.** Each Subject Invention made jointly by ABC and PSRC employees shall be jointly owned by ABC and PSRC. PSRC may elect to file the joint patent or other IP application(s) thereon and shall notify ABC promptly upon making this election. If PSRC decides to file such applications, it shall do so in a timely manner and at its own expense. If PSRC does not elect to file such application(s), ABC shall have the right to file the joint application(s) in a timely manner and at its own expense. If either Party decides not to retain its IP rights to a jointly owned Subject Invention, it shall offer to assign such rights to the other Party pursuant to Article 6.5. If the other Party declines such assignment, the offering Party may release its IP rights as provided in Articles 6.2 and 6.3.
- 6.5 Filing of Patent Applications.** With respect to Subject Inventions made by PSRC as described in Article 6.2, or by ABC as described in Article 6.3, a Party exercising its right to elect to retain IP rights to a Subject Invention agrees to file patent or other IP applications in a timely manner and at its own expense and after consultation with the other Party. The Party may elect not to file a patent or other IP application thereon in any particular country or countries provided it so advises the other Party ninety (90) days prior to the expiration of any applicable filing deadline, priority period or statutory bar date, and hereby agrees to assign its IP right, title, and interest, in such country or countries, to the Subject Invention to the other Party and to cooperate in the preparation and filing of a patent or other IP applications. In any countries in which title to patent or other IP rights is transferred to PSRC, PSRC agrees that ABC inventors will share in any royalty distribution that PSRC pays to its own inventors.
- 6.6 Patent Expenses.** The expenses attendant to the filing of patent or other IP applications generally shall be paid by the Party filing such application. If an exclusive license to any Subject Invention is granted to PSRC, PSRC shall be responsible for all past and future out-of-pocket expenses in connection with the preparation, filing, prosecution and maintenance of any applications claiming such exclusively licensed inventions and any patents or other IP grants that may issue on such applications. PSRC may waive its exclusive license rights on any application, patent or other IP grant, at any time, and incur no subsequent compensation obligation for that application, patent, or IP grant.
- 6.7 Prosecution of Intellectual Property Applications.** Within one month of receipt or filing, each Party shall provide the other Party with copies of the applications and all documents received from or filed with the relevant patent or other IP office in connection with the prosecution of such applications. Each Party shall also provide the other Party with the power to inspect and make copies of all documents retained in the patent or other IP

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application files by the applicable patent or other IP office. Where licensing is contemplated by PSRC, the Parties agree to consult with each other with respect to the prosecution of applications for ABC Subject Inventions described in Article 6.3 and joint Subject Inventions described in Article 6.4. If PSRC elects to file and prosecute IP applications on joint Subject Inventions pursuant to Article 6.4, ABC will be granted an associate power of attorney (or its equivalent) on such IP applications.

7.0 Licensing

- 7.1 **Option for Commercialization License.** With respect to ABC's IP rights to any Subject Invention not made solely by the PSRC's employees for which a patent or other IP application is filed, ABC hereby grants to the PSRC an option to elect an exclusive or nonexclusive commercialization license. The terms of the license will fairly reflect the nature of the invention, the relative contributions of the Parties to the invention and the Agreement, the risks incurred by the PSRC, and the costs of subsequent research and development needed to bring the invention to the marketplace.
- 7.2 **Exercise of License Option.** The option of Article 7.1 must be exercised by written notice mailed within three (3) months after PSRC receives written notice that the patent or other IP application is filed. Exercise of this option by the PSRC initiates a negotiation period that expires nine (9) months after the patent or other IP application filing date. If the last proposal by the PSRC has not been responded to in writing by ABC within this nine-month (9) period, the negotiation period shall be extended to expire one (1) month after ABC so responds, during which month the PSRC may accept in writing the final license proposal of ABC. In the absence of such acceptance, ABC will be free to license such IP rights to others. In the event that the PSRC elects the option for an exclusive license, but no such license is executed during the negotiation period, ABC agrees not to make an offer for an exclusive license on more favorable terms to a third party for a period of six (6) months without first offering PSRC those more favorable terms.
- 7.3 **Joint Inventions Not Exclusively Licensed.** In the event that the PSRC does not acquire an exclusive commercialization license to IP rights in all fields in joint Subject Inventions described in Article 6.4, then each Party shall have the right to use the joint Subject Invention and to license its use to others in all fields not exclusively licensed to PSRC. The Parties may agree to a joint licensing approach for such IP rights.

8.0 Proprietary Rights and Publication

- 8.1 **Right of Access.** ABC and PSRC agree to exchange all Subject Data produced in the course of research under this Agreement, whether developed solely by ABC or jointly with PSRC. Research Materials will be shared equally by the Parties to the Agreement unless other disposition is agreed to by the Parties. All Parties to this Agreement will be free to utilize Subject Data and Research Materials for their own purposes, consistent with their obligations under this Agreement.
- 8.2 **Ownership of Subject Data and Research Materials.** Subject to the sharing requirements of Paragraph 8.1 and the regulatory filing requirements of Paragraph 8.3, the producing Party will retain ownership of and title to all Subject Inventions, all Subject Data and all Research Materials produced solely by their investigators. Jointly developed Subject Inventions, Subject Data and Research Materials will be jointly owned.

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- 8.3 **Dissemination of Subject Data and Research Materials.** To the extent allowed under law, PSRC and ABC agree to use reasonable efforts to keep Subject Data and Research Materials confidential until published or until corresponding patent applications are filed. Any information that would identify human subjects of research or patients will always be maintained confidentially. PSRC shall have the exclusive right to use any and all Agreement Subject Data in and for any regulatory filing by or on behalf of PSRC, except that ABC shall have the exclusive right to use Subject Data for that purpose, and authorize others to do so, if the Agreement is terminated or if PSRC abandons its commercialization efforts.
- 8.4 **Proprietary/Confidential Information.** Each Party agrees to limit its disclosure of Proprietary/Confidential Information to the amount necessary to carry out the Research Plan of this Agreement, and shall place a confidentiality notice on all such information. Confidential oral communications shall be reduced to writing within 30 days by the disclosing Party. Each Party receiving Proprietary/Confidential Information agrees that any information so designated shall be used by it only for the purposes described in the attached Research Plan. Any Party may object to the designation of information as Proprietary/Confidential Information by another Party and may decline to accept such information. Subject Data and Research Materials developed solely by PSRC may be designated as Proprietary/Confidential Information when they are wholly separable from the Subject Data and Research Materials developed jointly with ABC investigators and advance designation of such data and material categories is set forth in the RP. The exchange of other confidential information, for example, patient-identifying data, should be similarly limited and treated. Jointly developed Subject Data and Research Material derived from the Research Plan may be disclosed by PSRC to a third party under a confidentiality agreement for the purpose of possible sublicensing pursuant to the Licensing Agreement and subject to Article 8.7.
- 8.5 **Protection of Proprietary/Confidential Information.** Proprietary/Confidential Information shall not be disclosed, copied, reproduced, or otherwise made available to any other person or entity without the consent of the owning Party. Each Party agrees to use its best efforts to maintain the confidentiality of Proprietary/Confidential Information.
- 8.6 **Duration of Confidentiality Obligation.** The obligation to maintain the confidentiality of Proprietary/Confidential Information shall expire at the earlier of the date when the information is no longer Proprietary Information as defined in Article 2.3 or three (3) years after the expiration or termination date of this Agreement. PSRC may request an extension to this term when necessary to protect Proprietary/Confidential Information relating to products not yet commercialized.
- 8.7 **Publication.** The Parties are encouraged to make publicly available the results of their research. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about a Subject Invention, Subject Data, or Research Materials, the other Party shall be provided thirty (30) days to review the proposed publication or disclosure to ensure that Proprietary/Confidential Information is protected. The publication or other disclosure shall be delayed for up to thirty (30) additional days upon written request by any Party as necessary to preserve patent or other IP rights.
- 9.0 **Representations and Warranties**
- 9.1 **Representations and Warranties of ABC.** ABC hereby represents and warrants to PSRC that the official signing this Agreement has authority to do so.

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9.2 Representations and Warranties of PSRC.

- (a) PSRC hereby represents and warrants to ABC that PSRC has the requisite power and authority to enter into this Agreement and to perform according to its terms, and that PSRC's official signing this Agreement has authority to do so. PSRC further represents that it is financially able to satisfy any funding commitments made in Appendix B.
- (b) PSRC certifies that the statements herein are true, complete, and accurate to the best of its knowledge. PSRC is aware that any false, fictitious, or fraudulent statements or claims may subject it to criminal, civil, or administrative penalties.

10.0 Termination

- 10.1 **Termination by Mutual Consent.** ABC and PSRC may terminate this Agreement, or portions thereof, at any time by mutual written consent. In such event the Parties shall specify the disposition of all property, inventions, patent, or other IP applications, and other results of work accomplished or in progress, arising from or performed under this Agreement, all in accordance with the rights granted to the Parties under the terms of this Agreement.
- 10.2 **Unilateral Termination.** Either ABC or PSRC may unilaterally terminate this entire Agreement at any time by giving written notice at least thirty (30) days prior to the desired termination date, and any rights accrued in property, patents, or other IP rights shall be disposed of as provided in paragraph 10.1.
- 10.3 **Staffing.** If this Agreement is mutually or unilaterally terminated prior to its expiration, funds will nevertheless remain available to ABC for continuing any staffing commitment made by PSRC pursuant to Article 5.1 above and Appendix B, if applicable, for a period of six (6) months after such termination. If there are insufficient funds to cover this expense, PSRC agrees to pay the difference.
- 10.4 **New Commitments.** No Party shall make new commitments related to this Agreement after a mutual termination or notice of a unilateral termination and shall, to the extent feasible, cancel all outstanding commitments and contracts by the termination date.
- 10.5 **Termination Costs.** Concurrently with the exchange of final reports pursuant to Articles 4.2 and 5.2, ABC shall submit to PSRC for payment a statement of all costs incurred prior to the date of termination and for all reasonable termination costs including the cost of returning PSRC property or removal of abandoned property, for which PSRC shall be responsible.

11.0 Disputes

- 11.1 **Governing law.** This Agreement shall be governed by the law of _____.
- 11.2 **Settlement.** Any dispute, controversy, or claim arising under, out of, or in connection with this agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach, or termination, as well as noncontractual claims, that is not disposed of by agreement of the Principal Investigators, shall be submitted jointly to the signatories of this Agreement to reach an amicable settlement. If an amicable settlement cannot be reached within 30 days for any reason, the dispute shall be referred

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to and finally settled by arbitration in accordance with the UNCITRAL Arbitration Rules then obtaining. The appointing authority shall be the Secretary-General of the Permanent Court of Arbitration, the number of arbitrators shall be three, and the language to be used in the arbitral proceedings shall be English. The place of arbitration shall be determined by mutual agreement, but if agreement cannot be reached the proceedings shall take place in _____.

Either party to this agreement may request any judicial authority to order any interim measures of protection for the preservation of its rights and interests to the extent permitted by law, including, without limitation, injunctions and measures for the conservation of such property and information that form part of the subject matter in dispute. Such requests shall not be deemed incompatible with, or as a waiver of, this agreement to arbitrate. In respect of any requests for interim measures of protection, and without limitation to proceeding in any other forum, the parties hereby consent to the exercise of jurisdiction by the judicial authorities of _____.

In the event a party fails to proceed with arbitration, unsuccessfully challenges the arbitrator's award, fails to comply with the arbitrator's award, or fails to comply with any interim measure of protection issued by any competent authority, the other party shall be entitled to costs of suit, including reasonable attorney's fees, for having to compel arbitration or defend or enforce the award or interim measure.

- 11.3 **Continuation of Work.** Pending the resolution of any dispute or claim pursuant to this Article, the Parties agree that performance of all obligations shall be pursued diligently in accordance with the direction of the ABC signatory.

12.0 Liability

- 12.1 **No Warranties.** Except as specifically stated in Article 9, the parties make no express or implied warranty as to any matter whatsoever, including the conditions of the research or any invention or product, whether tangible or intangible, made, or developed under this agreement, or the ownership, merchantability, or fitness for a particular purpose of the research or any invention or product.
- 12.2 **Indemnification.** PSRC agrees to hold the ABC harmless and to indemnify ABC for all liabilities, demands, damages, expenses, and losses arising out of the use by PSRC for any purpose of the Subject Data, Research Materials, and/or Subject Inventions produced in whole or part by ABC employees under this Agreement, unless due to the negligence or willful misconduct of ABC, its employees, or agents. PSRC shall be liable for any claims or damages it incurs in connection with this Agreement. ABC will hold PSRC harmless for liabilities, demands, damages, expenses and losses caused by the negligence or willful misconduct of ABC, its employees or agents.
- 12.3 **Force Majeure.** Neither Party shall be liable for any unforeseeable event beyond its reasonable control, not caused by the fault or negligence of such Party, that causes such Party to be unable to perform its obligations under this Agreement, and that it has been unable to overcome by the exercise of due diligence. In the event of the occurrence of such a force majeure event, the Party unable to perform shall promptly notify the other Party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the force majeure event.

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13.0 Miscellaneous

- 13.1 **Entire Agreement.** This Agreement constitutes the entire agreement between the Parties concerning the subject matter of this Agreement and supersedes any prior understanding or written or oral agreement.
- 13.2 **Headings.** Titles and headings of the articles and subarticles of this Agreement are for convenient reference only, do not form a part of this Agreement, and shall in no way affect its interpretation.
- 13.3 **Waivers.** None of the provisions of this Agreement shall be considered waived by any Party unless such waiver is given in writing to the other Party. The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any Party.
- 13.4 **Severability.** The illegality or invalidity of any provisions of this Agreement shall not impair, affect, or invalidate the other provisions of this Agreement.
- 13.5 **Amendments.** If either Party desires a modification to this Agreement, the Parties shall, upon reasonable notice of the proposed modification or extension by the Party desiring the change, confer in good faith to determine the desirability of such modification or extension. Such modification shall not be effective until a written amendment is signed by the signatories to this Agreement or by their representatives duly authorized to execute such amendment.
- 13.6 **Assignment.** Neither this Agreement nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party.
- 13.7 **Notices.** All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative and shall be delivered by hand or sent by certified mail, return receipt requested, with postage prepaid, to the addresses indicated on the signature page for each Party. Any Party may change such address by notice given to the other Party in the manner set forth above.
- 13.8 **Independent Contractors.** The relationship of the Parties to this Agreement is that of independent contractors and not as agents of each other or as joint venturers or partners. Each Party shall maintain sole and exclusive control over its personnel and operations. PSRC employees who will be working at ABC facilities may be asked to sign a Guest Researcher or Special Volunteer Agreement appropriately modified in view of the terms of this Agreement.
- 13.9 **Use of Name or Endorsements.** By entering into this Agreement, ABC does not directly or indirectly endorse any product or service provided, or to be provided, whether directly or indirectly related to either this Agreement or to any patent or other IP license or agreement that implements this Agreement by its successors, assignees, or licensees. PSRC shall not in any way state or imply that this Agreement is an endorsement of any such product or service by the ABC or any of its organizational units or employees. PSRC issued press releases that reference or rely upon the work of ABC under this Agreement shall be made available to ABC at least seven (7) days prior to publication for review and comment.

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13.10 **Exceptions to this Agreement.** Any exceptions or modifications to this Agreement that are agreed to by the Parties prior to their execution of this Agreement are set forth in Appendix C.

13.11 **Reasonable Consent.** Whenever a Party’s consent or permission is required under this Agreement, such consent or permission shall not be unreasonably withheld.

14.0 **Duration of Agreement**

14.1 **Duration.** It is mutually recognized that the duration of this project cannot be rigidly defined in advance, and that the contemplated time periods for various phases of the RP are only good-faith guidelines subject to adjustment by mutual agreement to fit circumstances as the RP proceeds. In no case will the term of this Agreement extend beyond the term indicated in the RP unless it is revised in accordance with Article 13.5.

14.2 **Survivability.** The provisions of articles 4.2, 5–8, 10.3–10.5, 11.1, 12.2–12.4, 13.1, 13.10, and 14.2 shall survive the termination of this Agreement.

Agreement SIGNATURE PAGE

FOR ABC: _____ Date _____

Mailing Address for Notices: _____

FOR PSRC: _____ Date _____

Mailing Address for Notices: _____

[Include additional signature and address blocks as necessary for all Parties to this Agreement.]

CO-DEVELOPMENT AGREEMENT**APPENDIX A
RESEARCH PLAN**

Title of Agreement: _____

ABC Principal Investigator: _____

His/Her Laboratory: _____

PSRC PRINCIPAL INVESTIGATOR: _____

Term of Agreement: _____ (____) years.

The Research Plan that follows should be concise but of sufficient detail to permit reviewers of this Agreement to evaluate the scientific merit of the proposed collaboration. The RP should explain the scientific importance of the collaboration and the research goals of ABC and PSRC. The respective contributions in terms of expertise and/or research materials of ABC and PSRC should be summarized. Initial and subsequent projects contemplated under the RP, and the time periods estimated for their completion, should be described and pertinent methodological considerations summarized. Pertinent literature references may be cited and additional relevant information included. Include additional pages to identify the Principal Investigators of all other Parties to this Agreement.

**APPENDIX B
FINANCIAL AND STAFFING CONTRIBUTIONS OF THE PARTIES****APPENDIX C
EXCEPTIONS OR MODIFICATIONS TO THIS AGREEMENT**