

NIH CRADA Clearance Document
(Cooperative Research And Development Agreement)

After the provisions of a Cooperative Research And Development Agreement have been negotiated, the CRADA must go through clearance procedures. This form helps gather required data and it documents the approval process.

CRADA Type: Standard Clinical Materials **Total Term:** _____ years **Effective Date:** _____
 Amendment Amendment # _____ Letter Of Intent execution date: _____

TITLE: _____

NIH Institute/Center Information

IC _____ **IC Ref.:** _____

Principal Investigator
 PI Name: Last _____ First _____ MI _____
 Lab/Branch: _____ Bldg/Rm _____
 Address: _____
 City: _____ State _____ Zip _____
 Phone: _____ Fax: _____
 Tenured or tenure-track Extramural Other

Co-Investigator
 PI Name: Last _____ First _____ MI _____
 Lab/Branch: _____ Bldg/Rm _____
 Address: _____
 City: _____ State _____ Zip _____
 Phone: _____ Fax: _____
 Tenured or tenure-track Extramural Other

Collaborator Information

Collaborator 1

Collaborator: _____
 Previous name, if changed _____
 PI Name: Last _____ First _____ MI _____
 Address: _____
 City: _____ State _____ Zip _____
 Phone: _____ Fax: _____
 U.S. Foreign Country _____
 Large Small
 For-profit Non-profit Academic Government

Collaborator 2

Collaborator: _____
 Previous name, if changed _____
 PI Name: Last _____ First _____ MI _____
 Address: _____
 City: _____ State _____ Zip _____
 Phone: _____ Fax: _____
 U.S. Foreign Country _____
 Large Small
 For-profit Non-profit Academic Government

NIH Clearance Signatures

IC Approval for Primary PI	IC Approval for Co-PI	NIH Review (not required for M-CRADAs)
IC Principal Investigator _____ Date _____	IC Co-Investigator _____ Date _____	NIH Office of Technology Transfer _____ Date _____ Bonny Harbinger, PhD, JD, Deputy Director, NIH OTT
IC Laboratory Chief _____ Date _____	IC Laboratory Chief _____ Date _____	NIH Legal Advisor _____ Date _____ Barbara McGarey, JD, NIH OGC
IC TDC _____ Date _____		CRADA Subcommittee, Chair _____ Date _____ Charles Gerfen, PhD
IC Scientific Director _____ Date _____		NIH Director _____ Date _____ Michael Gottesman, MD, Deputy Director, NIH OIR

CRADA Information Overview

Part I Collaborator Selection Criteria

(Check all that apply, briefly state facts pertinent to each checked item, attaching pages if necessary)

- Proprietary/patented technology (provide patent #s) _____
- Unique unpatented material(s)/equipment _____
- Unique facilities/expertise _____
- Previous or ongoing informal collaboration (dates) _____
- Government invention licensed to Collaborator (provide case reference no(s).) _____
- Was the opportunity to develop the PHS technology and/or to enter this CRADA publicly announced? Yes No
 If yes, date of first announcement: _____ how/where was it disclosed? _____
 # small-business respondents: _____ # large-business respondents: _____ # non-profit respondents: _____
- Other _____

Part II CRADA Research

- Has the CRADA model been modified at all (including any Supplement paragraphs)? Yes No
 For M-CRADA only: Unmodified Model or Pre-approved modifications only Other modifications
- Does PHS own rights in any background technologies that Collaborator likely will have to license to commercialize CRADA inventions?
 Yes No If yes, give patent or application number(s): _____
- Will PHS use materials in this CRADA that PHS obtained from a third party? Yes No If yes: MTA [M-]CRADA Other
- This CRADA involves (check all applicable): Basic research Clinical research Other _____
- Will this CRADA use live animals? Yes No If yes, do all sites have Assurances? Yes No Exempt
- Will this CRADA use human subjects at PHS? Yes No
- Will this CRADA use human subjects at PHS-funded sites? Yes No
- Will the PHS PI(s) personally conduct studies on humans at a site other than PHS and PHS-funded sites?
 Yes No If yes: Exempt Site's Assurance No. _____
- Will this CRADA use or collect human tissue? Yes No If yes: Exempt Owner's Assurance No. _____
- Will this CRADA use identifiable private information collected before (or otherwise outside the scope of) the CRADA?
 Yes No If yes: Exempt Coded Appropriate Assurance No(s). _____
- Estimated person-years per year IC: _____ Collaborator #1: _____ Collaborator #2: _____

Collaborator Contributions

- | | | |
|---|--|--|
| | <u>Collaborator #1</u> | <u>Collaborator #2</u> |
| Supplying proprietary materials not on the market | Yes <input type="checkbox"/> No <input type="checkbox"/> | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Providing financial support to PHS | Yes <input type="checkbox"/> No <input type="checkbox"/> | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| | If yes, total for CRADA \$ _____ | If yes, total for CRADA \$ _____ |

SUBJECT INVENTIONS -- KEYWORDS: (Check all applicable boxes)

Probable Types	Primary Field(s) of Use			Research Modality
<input type="checkbox"/> Diagnostic	<input type="checkbox"/> AIDS/HIV	<input type="checkbox"/> Genetics	<input type="checkbox"/> Musculoskeletal	<input type="checkbox"/> Bioinformatics
<input type="checkbox"/> Palliative	<input type="checkbox"/> Biochemistry	<input type="checkbox"/> Histopathology	<input type="checkbox"/> Nanotechnology	<input type="checkbox"/> Device/Instrument
<input type="checkbox"/> Preventative	<input type="checkbox"/> Biodefense	<input type="checkbox"/> Immunology	<input type="checkbox"/> Neuro-optical	<input type="checkbox"/> Drug Discovery
<input type="checkbox"/> Prognostic	<input type="checkbox"/> Cancer	<input type="checkbox"/> Infectious Diseases	<input type="checkbox"/> Vaccine	<input type="checkbox"/> Drug Development
<input type="checkbox"/> Therapeutic	<input type="checkbox"/> Cardiovascular	<input type="checkbox"/> Metabolic Diseases		Epidemiological Research
<input type="checkbox"/> Research Tool	<input type="checkbox"/> Cell Biology	<input type="checkbox"/> Microbiology	<input type="checkbox"/> Other: _____	<input type="checkbox"/> Software Development

PART III All Other Active CRADAs and M-CRADAs within the Lab/Branch of PHS PI(s)

(attach pages as necessary)

PI last name	Collaborator	IC Ref.	Title

THIS PAGE (AND ATTACHMENTS) CONTAINS CONFIDENTIAL INFORMATION