



Title: Project Acceptance and Completion of Projects for Clinical Use

SOP Number: 10001

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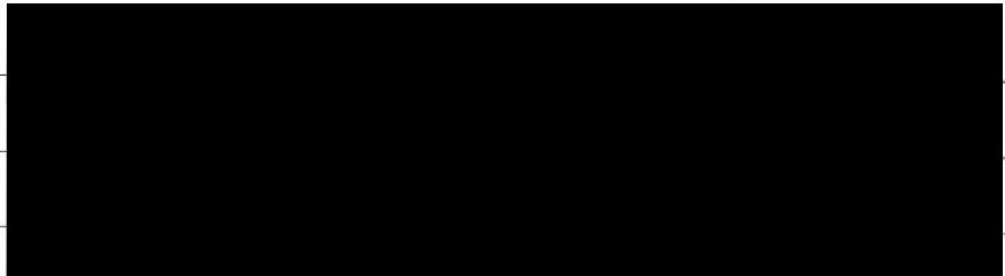


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1.0 Purpose

This procedure defines the process for the acceptance and completion of projects submitted by the NCI to be developed and/or manufactured by the Biopharmaceutical Development Program (BOP), Leidos Biomedical Research, Inc., and for the release of products for Phase 0/1/11, and *non-pivotal* Phase II clinical use. This procedure describes the approval process for initiation of work on new projects that enter the BOP, the course of action to follow for scope of work changes, and steps for approval prior to work being performed. The procedure also describes how the project is reviewed and released by the BOP after all work is completed on the project.

2.0 Scope

Projects may come from the NCI _____ Frederick National Laboratory for Cancer Research (FNLRC) cCRADA, Intramural, Extramural, work through the Economy Act supporting other U.S. Government Agencies such as the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) or the National Institute of Allergy and Infectious Diseases (NIAID), and other sources.

3.0 Authority and Responsibility

- 3.1** The Director, BDP, or designee is responsible for coordinating the request for projects to be initiated in the BDP, reviewing project requests, obtaining authorization for project initiation, obtaining authorization for changes to scope, and obtaining final authorization to release and ship product. (See Attachment 1 – Project Acceptance Flowchart.)
- 3.2** The BDP Project Scientist is responsible for reviewing the project requests, preparing the BDP Statement of Work (SOW) and schedule, reporting the status of ongoing projects to BDP management, project team members and the Biological Resources Branch (BRB) Project Officer (PO), or other project sponsor. The BDP Project Scientist is responsible for proactively identifying activities that may deviate from the approved scope, in a timely manner, during the project and, upon approval, implementing the necessary steps to change the scope. (See Attachment 6 – Change in Project Scope of Work Flowchart.)
- 3.3** The Safety Officer in the BDP is responsible for reviewing the safety considerations of the project requests.
- 3.4** The Program Manager, or designee, will review the project description for the proposed project and is responsible for preparing project budgets, reporting budget status of ongoing projects, and requests for changes to the budget.
- 3.5** Requests for Project Acceptance by the BDP can be initiated by Principal Investigators, through the National Cancer Institute/Biological Resources Branch (NCI/BRB).
- 3.6** If a project request comes through a U.S. Government Agency other than the NCI, an Interagency Agreement must be prepared through the Developmental Therapeutics Program (DTP) Administrative Office with the Contracting Officer's Approval. The BDP Director or designee will coordinate with the BRB PO, AO and the NCI Office of Technology Transfer, the required information and authorizations to initiate the program.
- 3.7** The Branch Chief, BRB or designee initiates and reviews project requests and requests for changes in scope to the project prior to being accepted into the Biopharmaceutical Development Program (BDP).
- 3.8** The BRB Branch Chief, or designee, submits a BDP Project Information Request Form (See Attachment 2), through the NCI Contractor Office to the BDP Director or designee. A project description giving further detail about the project must accompany the BDP Project Information Form.
- 3.9** Biopharmaceutical Quality Assurance (BQA) is responsible for quality and compliance oversight, project review, and release of GLP and GMP products in the BDP.

4.0 Biopharmaceutical Development Program Procedures

4.1 New Project Acceptance

- 4.1.1** The BDP Director, upon receipt of the BDP Project Information Request Form (Attachment 2) and the attending information, will initiate a review of the project. A BDP Project Review Form (See Attachment 3 – Form 10001-02A (OTS Contract Project) or Attachment 4 – Form 10001-02B (TO/IDIQ - Task Order/ Indefinite Delivery Indefinite Quantity) Project will be given to the BDP Project Scientist by the Director or designee to complete, where applicable. The BDP Project Scientist will give the BDP Project Review Form to the BDP Safety Officer to complete. The

BDP Safety Officer will return the completed BDP Project Review Form to the Director or designee.

- 4.1.2 The BDP Director or designee prepares a summary of the project initiation documentation for review by the Product Review and Release Board (PRRB) and Prime Contract Administrators (See Attachment 7). The Product Review and Release Board will confirm that product liability insurance can be obtained in accordance with Article B.4. Advance Understandings: Product Liability Insurance and Licensing of the Operation and Technical Support Contract No. [REDACTED].
- 4.1.3 A project file will be opened by the BDP Director or designee at the initiation of work on the project. During the course of work, documentation will be placed in this file.
- 4.1.4 Upon electronic concurrence from the PRRB and Prime Contract Administrators of the initial review of the project, the BDP Director will formally respond in writing to the NCI/BRB. The response will confirm Leidos Biomedical Research, Inc., BDP's intent to manufacture the specified material, and will be approved by the BDP Director and Director of Contracts and Administration.
- 4.1.5 Upon receipt of the reviewed acceptance letter (Attachment 7) from the NCI/BRB, appropriate funding will be initiated based on the project scope, schedule, and budget.
- 4.1.6 BDP will be notified by NCI/BRB for project initiation.

4.2 Acceptance of Project Scope Changes

- 4.2.1 The BDP Project Scientist is responsible for proactively identifying any change in scope of work and implementing the necessary steps to notify the NCI/BRB Project Officer and BDP Director.
- 4.2.2 The NCI/BRB Project Officer (PO) will submit a 'Scope Change Form' (Attachment 5) to the BDP Director or designee with a revised statement of work (SOW). BDP Operations Management will assist the PO, as requested, to develop the defined revised SOW.
- 4.2.3 The BDP Director reviews the statement of work and determines if the changes made to the project require approval by the Product Review and Release Board (PRRB). If it is determined that a PRRB review is required, the BDP Director or designee would submit documents for review. Upon electronic concurrence from the PRRB and Prime Contract Administrators, the NCI/BRB will be informed of Leidos Biomedical Research, Inc., BDP's intent to perform the specified work.
- 4.2.4 Upon receipt of the reviewed Project Scope Change Form (Attachment 5) from the NCI/BRB, the BDP Director will coordinate authorization for appropriate funding (if required) according to the approved scope, schedule, and budget.
- 4.2.5 If it is determined after review of the statement of work and/or scope change that PRRB approval is not required, then the BDP will proceed with developing a schedule and budget module for the scope change and will obtain required approvals detailed in 4.2.4.

4.3 Lot Release and Project Completion

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [REDACTED].

- 4.3.1 Biopharmaceutical Quality Assurance (BQA) will prepare a memo to the BDP Director indicating whether the documentation for manufacture and testing of the product support release. The memo will indicate whether the product is acceptable for release, quantity of material to be delivered to the NCI and, if appropriate, notification that the Chemistry, Manufacturing, and Controls section of the IND or amendment is completed along with documentation that support the release. Any known hazards identified during manufacturing will be noted in the memo.
- 4.3.2 The BDP Director will prepare a memo requesting review and release of the product by the Leidos Biomedical Research, Inc. Product Review and Release Board (PRRB) to ensure that the product conforms to the scope of the project. Upon electronic approval from the PRRB to release the product, the BDP Director will formally respond in writing to the NCI/BRB.
- 4.3.3 The response will confirm Leidos Biomedical Research, Inc., BDP manufactured the product to the customer's specifications and quantity of material to be delivered to the NCI. Any known hazards identified during manufacturing will be noted in the transmittal letter (See Attachment 8).
- 4.3.4** Once the BDP Director receives the product release approval form and signed distribution form from the NCI. Materials Management and Inventory Control (MMIC) can initiate shipment of product to its appropriate destination per **SOP 20201 - Distribution of Products and Materials to External Recipients**
- 4.3.5 The project file will be considered complete when all deliverables in the original project description and amendments to the project description have been produced and released and all stability testing for any clinical trial has been closed. At this time, the business project file will be closed.

5.0 References and Related Documents

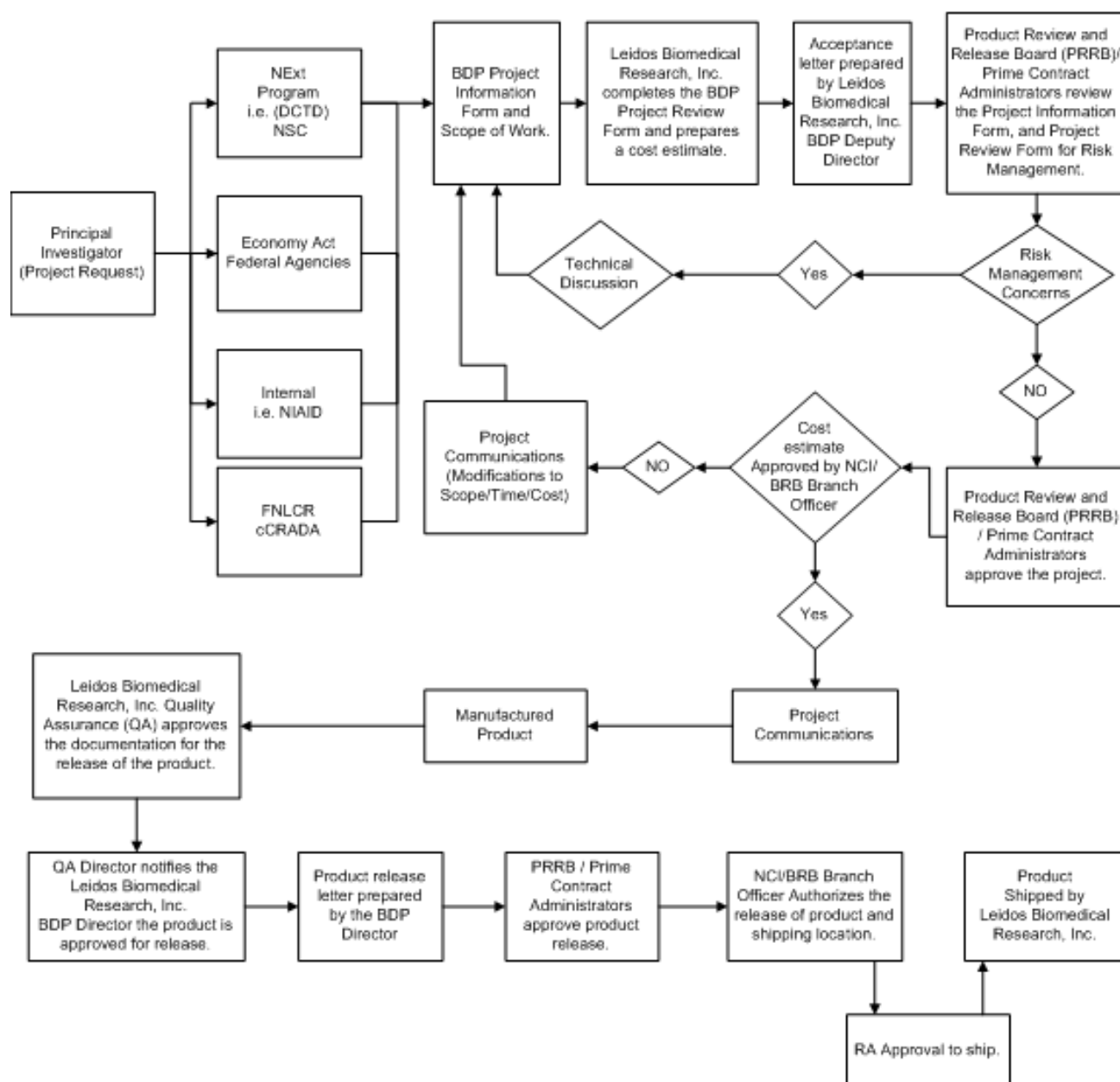
- 5.1 SOP 20201** *Distribution of Products and Materials to External Recipients*

6.0 Attachments

- 6.1 Attachment 1** Project Acceptance Flowchart
- 6.2 Attachment 2** Form 10001-01, BDP Project Information Request Form
- 6.3 Attachment 3** Form 10001-02A, BDP Project Review Form (OTS)
- 6.4 Attachment 4** Form 10001-02B, BDP Project Review Form (TO/IDIQ)
- 6.5 Attachment 5** Form 10001-03, BDP Project Change in Scope Information Form
- 6.6 Attachment 6** Change in Project Scope of Work Flowchart
- 6.7 Attachment 7** Product Review and Release Board (PRRB) Project Initiation Approval Acceptance Letter to NCI – Example Only
- 6.8 Attachment 8** Product Review and Release Board (PRRB) Product Release Approval, Product Release Acceptance Letter to NCI – Example Only

Attachment 1

Project Acceptance Flowchart



Attachment 2

Form 10001-01, BDP Project Information Request Form

FNLCR, BDP
Form No.: 10001-01
SOP No.: 10001
Revision 08: JUL 28 2017

BDP Project Information Request Form (To be completed by NCI/BRB)

BRB Requestor: _____

Principal Investigator _____ Project #: _____
Institution/Affiliation _____
Address: _____ Telephone: _____

Customer: ☐ Federal/Non-DOD ☐ Non-Profit Institute ☐ DOD ☐ Other _____ (Specify)

Project Name _____
Budgeted Project: Yes ☐ No ☐ Identify Funding Source _____
☐ Manufacturing Site BDP
☐ Contract Manufacturing ☐ other _____

General Description of Project

Attach Supporting Information

1. Project Scope: _____
2. Provide general description of the project including cell lines; seed stocks MCB; WCB; Analytical requirements etc. _____ (Attach additional pages as necessary)
3. Quantity Requested _____
4. Material to be used for:

<input type="checkbox"/> Research Purposes Only	<input type="checkbox"/> Exploratory IND Production	<input type="checkbox"/> Clinical Grade Ex Vivo (GMP)
<input type="checkbox"/> Pre-Clinical Safety Product (GLP)	<input type="checkbox"/> Phase I Clinical Trial	<input type="checkbox"/> Non-Pivotal Phase III Clinical Trial
<input type="checkbox"/> Clinical Grade Production (GMP)	<input type="checkbox"/> Phase II Clinical Trial	

 Complete the following
 Target Disease _____
 Estimated Number of Participants _____
 Estimated Start Date and Length of Clinical Trial _____
 Who will conduct the Clinical Trial _____
5. Concerns about physical properties and stability of product _____
6. Is Stability testing required? _____
7. Clinical trial outside USA? No ☐ Yes ☐ (If the answer is Yes, please explain) _____
8. Is Regulatory Documentation Required?: No ☐ Yes ☐ If the answer is Yes, which of the following is required? ☐ CMC ☐ Manufacturing Report ☐ Other (Please describe) _____

Safety Considerations Yes ☐ No ☐ If the answer is Yes, please explain.

1. Is this a Select Agent? No ☐ Yes ☐ Explain _____
2. Are employee immunizations required? No ☐ Yes ☐ Explain _____
3. Will employee health screening be required? No ☐ Yes ☐ Explain _____
4. Use of hazardous materials or other safety considerations? No ☐ Yes ☐ Explain _____
5. Does this product contain any of the following ingredients? (Accutane or Isotretinoin, Diethylstilbestrol or DES, Contraceptive Drugs, Swine Flu Vaccine, L Tryptophan, Dexfenfluramine, Fenfluramine, Phentermine, Thalidomide, Silicone, or Latex)
No ☐ Yes ☐ Explain _____

NCI Reviews and Approvals

BRB Requestor Signature: _____ Date _____

BRB Branch Officer: _____ Date _____

Attachment 3 Form 10001-02A, BDP Project Review Form (OTS)

FNLCR, BOP
Form No.: 10001-02A
SOP No.: 10001
Revision 08: JUL 28 2017

BOP Project Review Form (To be completed by BOP, Leidos Biomedical Research, Inc.)

Project Name:

Project #: _

BRB Requester: •

Principal Investigator

Institution/Affiliation:

Address: Telephone:

- Leidos Biomedical Research, Inc. may only accept work approved by the NCI and to be performed as authorized by the OTS contract.
- All work accepted under the OTS Contract must be performed as a research effort on a **"best-efforts", "cost-reimbursable" basis** with no warranties implied or expressed. This means that Leidos Biomedical Research, Inc. will make reasonable efforts to accomplish the work requested under the project; however, it does not guarantee that the work requested can, or will be, successfully accomplished within the budget or estimated cost agreed upon.

Section 1. Project Acceptance

	Yes	No
1. The project is a permitted activity within the Operations and Technical Support Contract's Statement of Work.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2. Leidos Biomedical Research, Inc. has the facilities, equipment and technical skills that are necessary to safely and effectively undertake this project on a best efforts basis. This does not constitute a warranty.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3. Is this project going to be outsourced? If no, complete Section 2.	<input type="checkbox"/>	<input type="checkbox"/>
4. Leidos Biomedical Research, Inc. cannot obtain liability insurance for the following: (Accutane or Isotretinoin, Diethylstilbestrol, DES, Contraceptive Drugs, Swine Flu Vaccine, L-Tryptophan, Dexfenfluramine, Fenfluramine, Phentermine, Thalidomide, Silicone, or Latex. Does this project utilize any of these substances?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Section 2. Safety

The forms referenced below are as follows

A) IBC Research Registration Form found at [REDACTED]

B) BOP Safety Data Sheet.doc found on [REDACTED]

Safet Considerations					No
1. Is there use of a Select Agent? If yes, please attach an explanation describing how this will be managed and contact EHS.	<input type="checkbox"/>	<input type="checkbox"/>	6. Are employee vaccinations required? If yes, please attach an explanation describing how this will be managed and contact EHS.	D	<input type="checkbox"/>
2. Is there use of rDNA? If yes, complete IBC Research Registration Form.	<input type="checkbox"/>	<input type="checkbox"/>	7. Are there any known chemical hazards? If yes, complete BDP Material Safety Data Sheet.	<input type="checkbox"/>	<input type="checkbox"/>
3. Culture volume > 10L?	<input type="checkbox"/>	<input type="checkbox"/>	8. Are any other potential hazards known? If yes, please attach an explanation describing how this will be managed.	<input type="checkbox"/>	<input type="checkbox"/>
4. Is there use of human/animal pathogens, oncogenes, toxins or other materials potentially pathogenic to humans? If yes, complete IBC Research Registration Form.	<input type="checkbox"/>	<input type="checkbox"/>			
5. Is special health screening required? If yes, please attach an explanation describing how this will be managed and contact EHS.	<input type="checkbox"/>	<input type="checkbox"/>	9. What is the biosafety containment level?	BSL1	BSL2
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>

*If Viral Production Facility, please refer to the following SOP's: 17102, 17103, 17109, 21504.

Other Risks or Concerns

Leidos Biomedical Research, Inc. Reviews and Approvals

BDP Responsible Scientist	Signature	Date
BOP Safety Officer	Signature	Date
BOP Director	Signature	Date

Attachment 4 Form 10001-028, BDP Project Review Form (TO/IDIQ)

FNLCR, BOP
Form No.: 10001-02B
SOP No.: 10001
Revision 08 JUL 28 2017

BOP Project Review Form

(To be completed by **BOP**, Leidos Biomedical Research, Inc.)

Project Name :
BRB Requestor: -
Principal Investigator:
Institution/Affiliation:
Address: Telephone: _

Project #: _

- **Leidos Biomedical Research, Inc. may be performed by the NCI and to be performed as a research effort on a "best-efforts," cost-reimbursable basis** with no warranties implied or expressed. This means that Leidos Biomedical Research, Inc. will make reasonable efforts to accomplish the work requested under the project; however, it does not guarantee that the work requested can, or will be, successfully accomplished within the budget or estimated cost agreed upon.

Section 1. Project Acceptance					
	Yes	No			
1. The project is a permitted activity within the above reference Statement of Work.	<input type="checkbox"/>	<input type="checkbox"/>			
2. Leidos Biomedical Research, Inc. has the facilities, equipment and technical skills that are necessary to safely and effectively undertake this project on a best efforts basis. This does not constitute a warranty.	<input type="checkbox"/>	<input type="checkbox"/>			
3. Is this project going to be outsourced? If no, complete Section 2.	<input type="checkbox"/>	<input type="checkbox"/>			
4. Leidos Biomedical Research, Inc. cannot obtain liability insurance for the following: (Accutane or Isotretinoin, Diethylstilbestrol or DES, Contraceptive Drugs, Swine Flu Vaccine, L Tryptophan, Dexfenfluramine, Fenfluramine, Phentermine, Thalidomide, Silicone, or Latex). Does this project utilize any of these substances?	<input type="checkbox"/>	<input type="checkbox"/>			
Section 2. Safety					
The forms referenced below are as follows:					
A) IBC Research Registration Form found at [REDACTED]					
B) BOP Safety Data Sheet.doc found on [REDACTED]					
Safety Considerations	Yes	No			
1. Is there use of a Select Agent? If yes, please attach an explanation describing how this will be managed and contact EHS.	<input type="checkbox"/>	<input type="checkbox"/>	6. Are employee vaccinations required? If yes, please attach an explanation describing how this will be managed and contact EHS.	<input type="checkbox"/>	<input type="checkbox"/>
2. Is there use of rDNA? If yes, complete IBC Research Registration Form.	<input type="checkbox"/>	<input type="checkbox"/>	7. Are there any known chemical hazards? If yes, complete BOP Material Safety Data Sheet.	<input type="checkbox"/>	<input type="checkbox"/>
3. Culture volume > 10L?	<input type="checkbox"/>	<input type="checkbox"/>	8. Are any other potential hazards known? If yes, please attach an explanation describing how this will be managed.	<input type="checkbox"/>	<input type="checkbox"/>
4. Is there use of human/animal pathogens, oncogenes, toxins or other materials potentially pathogenic to humans? If yes, complete IBC Research Registration Form.	<input type="checkbox"/>	<input type="checkbox"/>			
5. Is special health screening required? If yes, please attach an explanation describing how this will be managed and contact EHS.	<input type="checkbox"/>	<input type="checkbox"/>	9. What is the biosafety containment level?	<input type="checkbox"/>	<input type="checkbox"/>
			BSL1	BSL2	BSL3*
*If Viral Production Facility, please refer to the following SOP's: 17102, 17103, 17109, 21504.					
Other Risks or Concerns					
Leidos Biomedical Research, Inc. Reviews and Approvals					
BOP Responsible Scientist	Signature			Date	
BOP Safety Officer	Signature			Date	
BOP Director	Signature			Date	

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [REDACTED]

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Attachment 5**Form 10001-03, BDP Project Change in Scope Information Form**

FNLCR, BDP

Form No.: 10001-03

SOP No.: 10001

Revision 08: JUL 28 2017

**BDP Project Change in Scope Information Form
(To be completed by NCI/BRB for existing projects)****BRB Requestor:** -

Principal Investigator _____

Project #: _____

Project Name _____

Current Scope

☐ Manufacturing Site BDP☐ Contract Manufacturing ☐ other _____Customer: ☐ Federal/Non-DOD ☐ Non-Profit Institute ☐ DOD ☐ Other _____ (Specify)**General Description of Project****Attach Supporting Information**

- Provide a description of the change in the Project Scope including additional studies, supplemental manufacturing or changed analytical testing requirements: _____
- The change will modify the following:

<input type="checkbox"/> Research Purposes Only	<input type="checkbox"/> Exploratory IND Production
<input type="checkbox"/> Pre-Clinical Safety Product (GLP)	<input type="checkbox"/> Phase I Clinical Trial
<input type="checkbox"/> Clinical Grade Production (GMP)	<input type="checkbox"/> Phase II Clinical Trial
	<input type="checkbox"/> Clinical Grade <i>Ex Vivo</i> (GMP)
	<input type="checkbox"/> Non-Pivotal Phase III Clinical Trial

 Complete the following
 Target Disease _____
 Estimated Number of Participants _____
 Estimated Start Date and Length of Clinical Trial _____
 Who will conduct the Clinical Trial _____
- Clinical trial outside USA? No ☐ Yes ☐ (If the answer is Yes, please explain) _____
- Change in Regulatory Documentation Required? No ☐ Yes ☐ If the answer is Yes, which of the following is required? ☐ CMC ☐ Manufacturing Report Other (Please describe) _____
- The reason for scope change is:

<input type="checkbox"/> Modified customer requirement	<input type="checkbox"/> Revised program schema (e.g. change in scale)
<input type="checkbox"/> Additional development studies	<input type="checkbox"/> New regulatory requirement
<input type="checkbox"/> BDP request for additional effort	<input type="checkbox"/> Other _____

Safety ConsiderationsYes ☐ No ☐ If the answer is Yes, please explain.

- Are there any changes to the original application? No ☐ Yes ☐
- Is this a Select Agent? No ☐ Yes ☐ Explain _____
- Are employee immunizations required? No ☐ Yes ☐ Explain _____
- Will employee health screening be required? No ☐ Yes ☐ Explain _____
- Use of hazardous materials or other safety considerations? No ☐ Yes ☐ Explain _____
- Does this product contain any of the following ingredients? (Accutane or Isotretinoin, Diethylstilbestrol or DES, Contraceptive Drugs, Swine Flu Vaccine, L Tryptophan, Dexfenfluramine, Fenfluramine, Phentermine, Thalidomide, Silicone, or Latex) No ☐ Yes ☐ Explain _____

NCI Reviews and Approvals

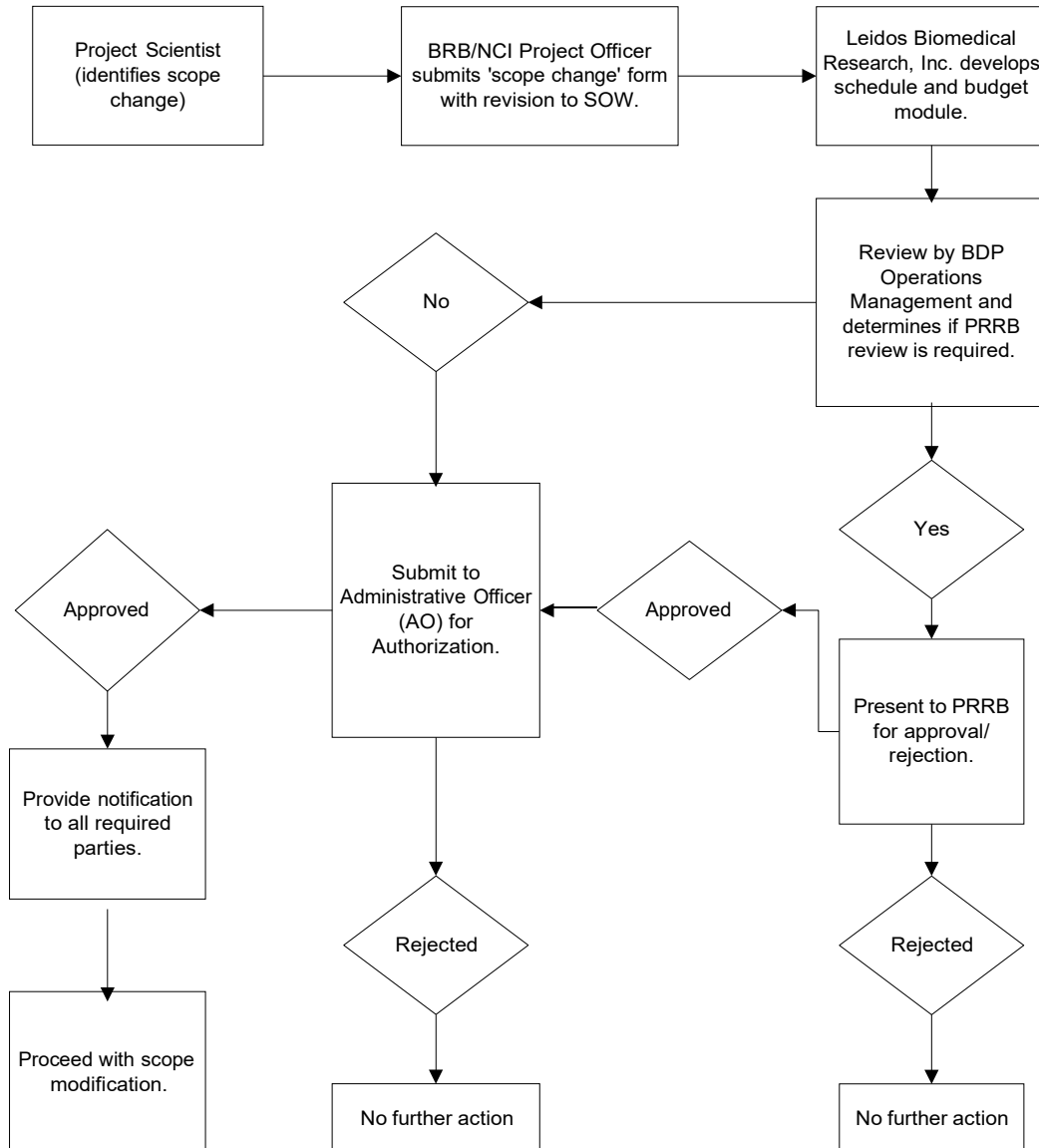
BRB Requestor Signature: _____ Date _____

BRB Branch Officer: _____ Date _____

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [REDACTED].

Attachment 6

Change in Project Scope of Work Flowchart



Attachment 7
EXAMPLE Product Review and Release Board (PRRB) Project Initiation Approval,
Acceptance Letter to NCI

Date _____
BDP Tracking Number: _____

Name of NCI-BRB Branch Officer
Title of NCI-BRB Branch Officer
Frederick National Laboratory Cancer Research
Frederick, Maryland 21702-1201

Through: Name of Chief Government Contracting Officer
Chief Government Contracting Officer
National Cancer Institute

Through: Name of Director, Contracts and Administration
Director, Contracts and Administration
Leidos Biomedical Research, Inc.

Through: Name of Program and Technical Director, Biopharmaceutical Development Program (BDP),
Biopharmaceutical Development Program, BDP
Leidos Biomedical Research, Inc.

References: Contract Number

Dear NCI Contracting Officer:

SUBJECT: PROJECT INITIATION APPROVAL FOR (PROJECT NAME), (PROJECT #)

Leidos Biomedical Research, Inc. has reviewed the documentation provided by the Biological Resources Branch (BRB) and has determined it has the resources and technical skills that are necessary to safely and effectively undertake (PROJECT NAME) project on a best efforts basis and in accordance with Article B.4.r. Project Liability Insurance and Licensing of the referenced contract.

Upon your approval, the BDP will proceed with this project.

Respectfully submitted,

Name of Director
Director, Biopharmaceutical Development Program (BDP)
Leidos Biomedical Research, Inc.

Attachments

Cost Estimate Acceptance _____ Date: _____
Name of NCI-BRB Branch Officer
Title of NCI-BRB Branch Officer, Branch

cc: DCTD Administrative Officer, Deputy Chief, NCI Office of Management BDP Scientist
Program Manager BDP Finance
Project File

Attachment 8
EXAMPLE Product Review and Release Board (PRRB) Product Release Approval, Product Release Acceptance Letter to NCI

Date _____
BDP Tracking Number: _____

Name of NCI-BRB Branch Officer
Title of NCI-BRB Branch Officer, Branch
Frederick National Laboratory Cancer Research Frederick, Maryland 21702-1201

Through: Name of Chief Government Contracting Officer
Chief Government Contracting Officer
National Cancer Institute

Through: Name of Director, Contracts and Administration
Director, Contracts and Administration
Leidos Biomedical Research, Inc.

Through: Name of Program and Technical Director, Biopharmaceutical Development Program (BDP)
Director, Biopharmaceutical Development Program, BDP
Leidos Biomedical Research, Inc.

References: Contract Number

Dear NCI Contracting Officer:

SUBJECT: COMPLETED MANUFACTURING OF (PRODUCT NAME), PROJECT _____

A request had been made to the BDP to develop and produce under CGMP conditions (PRODUCT NAME) for (INTENDED USE).

Leidos Biomedical Research, Inc.'s has completed the manufacture of (LOT #) using Current Good Manufacturing Practices (CGMP). The product was manufactured for (INTENDED USE). Leidos Biomedical Research, Inc. does not authorize the use of this product for any purpose other than that for which it was manufactured. As per this letter, a total of (NUMBER OF VIALS) from (LOT #) are being formally transferred to the NCI. All future control and distribution of the product will be under the control of the NCI.

It is Leidos Biomedical Research, Inc. policy to disclose known and possible risks that may be associated with biologic products manufactured for the NCI. There are no known risks currently associated with this lot of product. As with any biological product, there is a remote chance that adventitious agents may be present that are currently unknown or for which assays were not conducted. Additionally, assays may not be available yet or the level of adventitious agent, if present, may be below the sensitivity of an assay. This product may only be used in FDA-approved clinical studies. This product is not for commercial distribution or use. The BDP Quality Assurance group has reviewed all documentation associated with the production of the drug product and has approved the release of (PRODUCT NAME).

There is no product warranty of fitness for a particular purpose. This letter officially closes (PROJECT #_____).

Respectfully submitted,

Name of Director
Director
Biopharmaceutical Development Program (BDP)
Leidos Biomedical Research, Inc.

Attachments

Acceptance of Product: _____
Name of NCI-BRB Branch Officer
Title of NCI-BRB Branch Officer, Branch

Date: _____

cc: DCTD Administrative Officer
BDP Program Manager
BDP QC Director

BDP Project Scientist
Finance
Project File

BRB Project Scientist
BDP QA Director

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract _____.

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