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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 (BDP), Leidos Biomedical Research, Inc., (LBR) and for the release of products for Phase 0/I/II, and *non-pivotal* Phase III Clinical use. This procedure describes the approval process for initiation of work on new projects that enter the BDP, 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 BDP after all work is completed on the project.

2.0 Scope

BDP Projects are received through, but not limited to, the government FFRDC (Federally Funded Research & Development Centers) and FCAS (Federal Contract Administration System). Projects can come from a variety of sources including other government agencies (other than NCI), academic institutions, and companies.

3.0 Authority and Responsibility

3.1 The Program and Technical Director, BDP, or designee is responsible for coordinating the request for projects to be initiated in the BDP, through the FCAS as a Task Order Request for Proposal (TORFP), reviewing project requests, coordinating authorization for project initiation, obtaining authorization for changes to scope, and obtaining final authorization to release and ship product.

3.2 The BDP reviews the Statement of Work (SOW) and prepares the Technical Report and Pricing File. The Technical Report and Pricing File are submitted to Leidos Biomedical Research (LBR) Project Management Operations Office (PMOO).

3.3 The BDP Program and Technical Director (or designee) is responsible for reviewing with BDP Staff, the project requests and preparing the BDP Technical Response. The BDP Program and Technical Director (or designee) 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.

3.4 The Safety Officer in the BDP is responsible for reviewing the safety considerations of the project requests.

3.5 Biopharmaceutical Quality Assurance (BQA) is responsible for quality and compliance oversight, project review, and release of GLP and GMP products in the BDP.

3.6 BDP Manufacturing Manager and BQA Engineering Manager are responsible for evaluating whether any modifications are needed per 4.1.3 if a new product type or cell source is to be introduced into the GMP facility**.**

4.0 Biopharmaceutical Development Program Procedures

4.1 Project Acceptance

4.1.1 Leidos PMOO, LBR Contracts, and/or NCI/DCTD will notify the BDP when approval of the project is received.

4.1.2 Form 10001-01 – BDP Project Information Request is completed by a BDP Program Manager and sent to the Biological Resources Branch (BRB) for approval. Form 10001-02 – BDP Project Review form is also completed by a BDP Program manager. An electronic project file folder on the BDP network will be opened by the BDP Program Manager or designee at the initiation of work on the project. During this work, documentation will be placed in the appropriate project file folder.

4.1.3 If a new product type or cell source will be introduced into the GMP areas (as indicated on **Form 10001-02**), once process development is completed, the Manufacturing Manager along with the BQA Engineering Manager will evaluate whether any modifications are needed to the current gowning, material flow, equipment or equipment procedures, or cleaning procedures to maintain GMP room classifications.

4.1.4 BDP Program Manager will assign the BDP Project Number and notify the administrator of MasterControl. A copy of the completed Form 10001-02 will be provided to the Manufacturing Manager and the BQA Engineering Manager.

4.2 Acceptance of Project Scope Changes

4.2.1 BDP Program Manager is responsible for completing the Impact Analysis Report (IAR) process with regards to a change of scope or budget impact. The IAR is then submitted and approved through the FCAS.

4.3 Lot Release and Project Completion

4.3.1 BQA will prepare a memo to the BDP Program and Technical Director indicating when the documentation for manufacture and testing of the product is completed to support product release. The memo will indicate whether the product is acceptable for release and the quantity of material to be delivered to the NCI. Refer to ***SOP 21002 - Product Release*** for an example of the memo.

4.3.2 The memo will confirm LBR, 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 release memo.

4.3.3 Once the BDP Program and Technical Director receives the product release approval memo, the BDP Project Scientist or designee can initiate a distribution form for shipment of product to its appropriate destination per ***SOP 20201 - Distribution of Products and Materials to External Recipients***

4.3.4 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.

5.0 References and Related Documents

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

SOP 21002 *Product Release*

Form 10001-02 *BDP Project Review Form*

6.0 Change Summary