Title: Communication with Regulatory Agencies

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Table of Contents

1.0 Purpose

2.0 Scope

3.0 Authority and Responsibility

4.0 Procedure

5.0 Attachments

1.0 Purpose

The purpose of this SOP is to define the procedure for Biopharmaceutical Development Program (BOP) communication with the FDA and other Regulatory Agencies and to build and maintain a positive rapport with them . Purposeful communication with Regulatory Agencies can expedite the workflow of submissions.

2.0 Scope

This SOP applies to BOP correspondences and verbal communic tions with the FDA and other Regulatory Agencies as directed by the BOP or NCI-Frederick.

Communication with Regulatory Agencies includes formal meetings, correspondences, telephone conversations, teleconferences, faxes, e-mails, and any other means of communication. Also included are short conversations at off-site meetings or seminars regarding BOP products.

3.0 Authority and Responsibility

· 3.1 The Director of Regulatory Affairs (RA), Director of Biopharmaceutical Quality Assurance (BOA), or the BOA/RA designee has the authority and responsibility to initiate communications (via telephone, e-mail, fax, etc.) with FDA or other Regulatory Agencies regarding BOP submissions or questions.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN2612 00800001E.

3.2 The Director of RA, Director of BQA, or the BQA/RA designee has the authority and responsibility to channel any response or inquiry of a particular individual from BDP, NCI or from any Regulatory Agencies to appropriate BDP and NCI staff.

3.3 BQA is responsible for quality oversight of this procedure.

4.0 Procedure

4.1 When a communication is received by any individual at the BDP from a Regulatory Agency, the communication has to be directed to the Director of RA, Director of BQA, and/or the RA/BQA designee. If no one is available, a message will be taken and the call will be returned as soon as possible.

4.2 If the inquiry from the Regulatory Agency is regarding a specific issue, the responsible person for that project (for example, NCI Project Manager, Project Scientist, BDP Technical Director), or his/her designee may be requested to provide the response, review a response, or to participate in a conference call that includes the Director of RA, Director of BQA, or RA/BQA designee.

4.3 When a BDP individual has a particular inquiry to be made to a Regulatory Agency, he or she must inform the Director of RA, Director of BQA, and/or the RA/BQA designee regarding the subject matter to be discussed with that agency prior to initiating communication. The NCI/Biological Resources Branch (BRB) Project Manager should also be included in discussions with the FDA, when appropriate. Some projects may require Cancer Therapy Evaluation Program (CTEP/NCI) individuals to communicate BDP inquiries. The BQA Director or RA Director can provide guidance to determine which communications may need to be conducted by CTEP/NCI individuals. The BQA Director or RA Director initiates and manages Regulatory Agency contacts when CTEP is not involved as requested by the NCI/BRB.

4.4 Under urgent situations, in the absence of the Director of RA, Director of BQA or the RA/BQA designee, the BDP staff will inform the RA/BQA administrative assistant about the communication to be made with a specific Regulatory Agency. The BRB Project Manager and/or the BDP Program and Technical Director is the backup person in urgent situations if communication needs to be made with a Regulatory Agency.

4.5 Notes are taken during contact with Regulatory Agencies. After contacts with regulatory agencies, a contact report must be prepared from the notes taken, using the Regulatory Agency Contact Report (Form 24300-01, Attachment 1). The Contact Report should be initiated within 24 hours of the contact or as soon as possible. Print-outs of e-mails and faxes should be attached to the Contact Report form with the specific details filled in.

4.6 The contact report is initiated and finalized by the Director of RA, Director of BQA, or the RA/BQA designee. The contact report may be routed to other BDP or NCI participants to ensure the completeness and accuracy of the content. Pertinent BDP staff should be included in the distribution list if the issue involves a specific project.

4.7 The completed contact report is filed with the corresponding project.

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5.0 Attachments

5.1 **Attachment 1** Form 24300-01 Regulatory Agency Contact Report

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Attachment 1: Regulatory Agency Contact Report

NCI-Frederick
Form No.: 24300-01
SOP No.: 24300
Revision 03: APR 14 2014

Regulatory Agency Contact Report		
Regulatory Agency	**Date of Contact**	**Time of Contact**
Agency Contact Name	**Agency Contact Title/Position**	**Phone Number/E-mail Address**
Product	**Topic/Subject**	
BDP/NCI Individuals involved		
Summary (Attach a copy of any written correspondence to this form)		
Actions/Follow Up/Responsibilities		
Distribution		
Printed Name and Signature		**Date**

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