



Bureau of Plant Industry  
**PROCEDURES MANUAL**

Document No.: BPI-QMS-BIOTECH-OPG

Effectivity Date: MAY 5, 2022

Revision No.: 2

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Operating Unit: BIOTECHNOLOGY OFFICE

Subject: OPERATIONALIZATION OF FIELD TRIAL MONITORING

1. **Objective:** to conduct field trial monitoring compliant to field trial guidelines
2. **Scope:** this procedure starts from the receipt of the application requirements by the technology developers, recording, risk assessment process, and ends with the approval for issuance of biosafety permits to the applicant for field trial. He monitoring is required in the conduct of field trial.

### 3. Definition of Terms

*"Biosafety"* – refers to the condition in which the probability of harm, injury and damage resulting from the intentional and unintentional introduction and/or use of a regulated article is within acceptable and manageable levels;

*"Field Trial "* – refers to any intentional introduction into the environment of a regulated article that passed the contained use and confined test, for purposes of research and development, and for which specific confinement and mitigating measures may be imposed. Field trial may be conducted in a single site or in multiple sites;

*"Monitoring form"*-a document filled in by the monitors to assess field trials if compliant to field trial guidelines as a basis for issuance of biosafety permit for field trial

*"Memorandum of Agreement (MOA)"*-a document exclusive between BPI and the proponent which states the responsibilities of the proponent/applicant on the conduct of field trial

*"Proponent"* - refers to any person or group of persons who submits a project proposal to the competent national authority through the institutional biosafety committee of the applicant for the purpose of conducting xperiments on GMOs;

Prepared by: BPI Biotechnology Secretariat

Approved by: OIC-Head



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Operating Unit: BIOTECHNOLOGY OFFICE


Subject: OPERATIONALIZATION OF FIELD TRIAL MONITORING

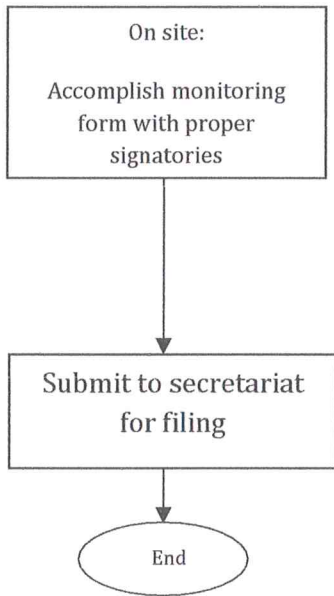
**4. Procedure**

| FLOW CHART FOR FIELD TRIAL MONITORING  | RESPONSIBLE PERSON/UNIT                      | DETAILED PROCESS   |
|--|--|--|
| <pre> graph TD     Start([START]) --&gt; Step1[Applicant will provide:<br/>Monitoring plan (schedule)<br/>Oath of Undertaking]     Step1 --&gt; Decision{SUFFICIENT?}     Decision -- NO --&gt; Return([Return to the applicant])     Return -.-&gt; Start     Decision -- YES --&gt; Step2[Communication with secretariat on scheduling]     Step2 --&gt; End[ ]           </pre> | <p>Applicant</p>                             | <p>Applicant shall provide the secretariat the Memorandum of Agreement between BPI and the applicant stating the responsibilities of the proponent on the duration of the field trial.</p> |
|  | <p>Applicant and BPI Biotech Secretariat</p> | <p>The proponent will provide a monitoring schedule to the secretariat and will arrange for trips accordingly.</p>   |

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| <b>Operating Unit:</b> BIOTECHNOLOGY OFFICE                                      |  |   |                    |
| <b>Subject:</b> OPERATIONALIZATION OF FIELD TRIAL MONITORING                     |  |   |                    |

|  |                     |   |
|--|---------------------|---|
|  | BPI and CNA monitor | The monitors will accomplish answering the monitoring form after the conduct of monitoring.                               |
|  | Secretariat         | The monitors will submit the original copy of the monitoring forms and the secretariat will consolidate the data present. |

### 5. FORMS USED FOR FIELD TRIAL MONITORING

- Monitoring forms
- Oath of Undertaking
- Monitoring plan
- Communication letters/ correspondence

**Prepared by:**  BPI Biotechnology Secretariat

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