

FIELD ID NO: \_\_\_\_\_

## IR-4 FIELD DATA BOOK

### PROTOCOL & PROTOCOL CHANGES

*The protocol shall be inserted into this IR-4 Field Data Book after this protocol cover page. Sequentially insert all relevant protocol amendments and deviations that have been received from the Study Director. Protocol changes are sent only to those field trials to which they pertain, thus the changes that are received during the course of this trial may not comprise a complete set. **Protocol changes pertinent to this trial that have been signed by the Study Director or received by the Field Research Director (FRD) after the Field Data Book has left the custody of the FRD do not need to be inserted into the Field Data Book.***

**PAGES IN THIS SECTION DO NOT NEED TO BE NUMBERED.**

**PAGES IN THIS SECTION DO NOT NEED LINING OUT IF NO ENTRIES ARE MADE**

CHEMICAL/CROP/FIELD ID NO: \_\_\_\_\_

## IR-4 FIELD DATA BOOK

### DEVIATION FORM (**PHOTOCOPY THIS PART IF NECESSARY**)

*INSTRUCTIONS: Every effort should be made to follow the protocol, and standard operating procedures. If an unforeseen or an unavoidable circumstance results in a change, the Study Director must be notified as soon as practical (via phone call, email or FAX). Also notify the Regional Field Coordinator (via phone call, fax, or cc on an email message). If possible, contact the Study Director prior to taking actions that differ from the protocol. The Study Director will provide instructions and/or appropriate protocol change authorization. Otherwise, document the deviation with completion of this or similar form for each individual deviation. **If the deviation is faxed or e-mailed to the Study Director, then the original should be mailed to the Study Director. A true copy should be retained in the Field Data Book in the Protocol and Protocol Changes section. The return copy (signed by the Study Director) should be placed in the Protocol/Protocol Changes section of the Field Data Book.***

THE DATE THAT THE DEVIATION OCCURRED \_\_\_\_\_

THE DATE THAT THE DEVIATION WAS RECOGNIZED \_\_\_\_\_

THE DATE THAT THE STUDY DIRECTOR WAS NOTIFIED \_\_\_\_\_

METHOD OF NOTIFICATION (e.g. telephone, email, fax) \_\_\_\_\_

THE DEVIATION IS FROM (check appropriate) PROTOCOL \_\_\_\_\_ SOP'S \_\_\_\_\_

SECTION OF THE PROTOCOL OR SOP'S THAT IS AFFECTED \_\_\_\_\_

BRIEF DESCRIPTION OF DEVIATION: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

EXPLAIN WHY THE DEVIATION OCCURRED: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

ABOVE DATA ENTERED BY: \_\_\_\_\_ DATE: \_\_\_\_\_

### **FIELD PERSONNEL: DO NOT WRITE BELOW THIS LINE**

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STUDY DIRECTOR'S ASSESSMENT OF IMPACT OF DEVIATION ON STUDY: \_\_\_\_\_

\_\_\_\_\_

APPROVED BY:

\_\_\_\_\_  
Study Director/Date

\_\_\_\_\_  
Sponsor/Date

PROTOCOL CHANGE NUMBER \_\_\_\_\_

cc: QA Field Research Director:

Laboratory Research Director:

Regional Field Coordinator:

Trial Year 2010

**This protocol change form when copied on colored paper is an exact copy of the original.**