

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

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 2011

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