FIELD ID NO: _____

IR-4 FIELD DATA BOOK

PART 10. PROTOCOL & PROTOCOL CHANGES

The protocol shall be inserted into this IR-4 Field Data Book after this 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.

This part may be kept in the back of the FDB, or moved to the front of the FDB (ahead of Part 1), or inserted between other FDB Parts.

PAGES IN THIS SECTION DO NOT NEED TO BE NUMBERED.

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

INSTRUCTIONS FOR COMPLETING THE PROTOCOL/SOP DEVIATION FORM:
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 or email). Also notify the Regional Field Coordinator (via phone call 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 emailed 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 Part 10. The return copy (signed by the Study Director) should be placed in Part 10 of the Field Data Book.

The brief description of the deviation should make clear what the protocol or SOP requirement is, and what was done that is different from this requirement. For example, *"The application interval was 10 days instead of the 7(±1) days required by the protocol."*

CHEMICAL/CROP/FIELD ID NO:_____

IR-4 FIELD DATA BOOK

DEVIATION FORM *(photocopy this part if necessary)*

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)* _____
(Include telephone notes or copy of email in Part 3 of this book)

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 THIS DEVIATION ON THE STUDY:

_____

_____

_____

_____

APPROVED BY:

_____ _____

Study Director/Date Sponsor/Date

PROTOCOL CHANGE NUMBER_____

cc: QA Field Research Director:

Regional Field Coordinator:

Laboratory Research Director:

Trial Year 2024

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