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.

It is acceptable, but not required, to insert the MSDS/SDS for the test substance in this section.

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, 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 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 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 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.”
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, fax) ___________________________________
(Include telephone notes or copy of email or fax 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 2020

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