IR-4 Advisory #2005-02 (December 7, 2005)

Title: **Field Research Director Disposal of Field Data Book Copies**

Issue/ Question: **Can IR-4 researchers discard copies of Field Data Books from their files after Final Reports have been signed by the Study Director?**

Background: During the process of Quality Control (QC), Quality Assurance, and Study Director (SD) review of a Field Data Book (FDB), additional original entries are often made by QC or SD, as appropriate, on pages of the original FDB. Copies of these revised pages do not always get returned to the Field Research Director (FRD) for replacement of the corresponding pages in their copy of the FDB. Inspection reports from EPA auditors have noted on occasion (when they had access to a copy from the FRD and IR-4 Headquarters [HQ] of the same FDB) that copies of FDBs at the test site were not exactly the same as the original provided from IR-4 HQ.

At the time of study completion (final report signed by the Study Director), all original FDBs and other study data are archived at IR-4 HQ. When an EPA inspection at an IR-4 field site is announced, all relevant data for the study/studies of interest are provided to the field site from HQ. Therefore, copies of FDBs do not need to be maintained (for GLP compliance) at IR-4 field sites. Some FRDs who have been in the program for many years have accumulated dozens of FDB copies in their files, and in some cases, storage is becoming a problem.

Resolution: 1) FRDs can maintain copies of FDBs in their facility files indefinitely (or as required by their Regional Field Coordinator or SOPs), to use as references, etc. However, these copies should not be provided to an EPA auditor during a field site inspection. Original raw data provided from the HQ archives should be the only FDBs presented for an EPA auditor to review.

2) FRD can dispose of copies of FDBs in their facility files after the Study Director has signed the final report for the study. Determining when FDB disposal is acceptable can be done in the same way as IR-4 Advisories #2003-02 and #2005-01 provide resolution for disposal of test substance containers. When test substance container disposal is acceptable for a study, disposal of FDB copies is also acceptable for all trials in that study.

If you have any questions, please contact your Regional/ARS Field Coordinator or the appropriate Study Director for further guidance.