



November 18, 2015

TO: M. Arsenovic, T. Barkalow, B. Barney, J. Baron, M. Beran, R. Batts, S. Bierbrunner, M. Braverman, U. Burke, Z. Chen, K. Coleman, D. D'Angelo, K. Dorschner, C. Ferrazoli, J. Forder, K. Homa, C. Jolly, K. Knight, D. Kunkel, R. Leonard, G. Lennon, M. Lynn, K. Malamud-Roam, S. Nagahiro, K. Samoilo, K. Sims, V. Starner, J. Thompson, R. Federline, A. Hogle, L. Latham

FROM: D. Carpenter *DAC 11/18/15*

CC: PMC members (memo)

SUBJECT: SOP Amendment: AN SOP Alert

Headquarters SOP's 4.1 and 4.4 have been amended and signed by Management.

Please insert the attached copy of the amendments in the appropriate location(s) in your SOP manual.

After the effective date of these amendments, there will only be one study associated with a PR number. The designations A, B, C and so on will no longer be used.

The effective date of these SOP amendments is Nov 30, 2015.

IR-4 SOP AMENDMENT FORM

SOP amendment to: Headquarters SOP 4.1

Effective Date: November 30, 2015

Description of Amendment:

SOP 4.1 includes the following text for assigning a protocol number.

5. **Study Number.** Each study protocol is assigned a unique identification number. For studies with assigned PR numbers below 10000, the first digit of the identifier is assigned "Zero (0)" when the study is the first study under a particular PR number. The second study has "A" as the first character, the third study is assigned "B", the fourth study is "C"; each additional study associated with the same PR number is assigned the next letter in the alphabet. For studies with assigned PR numbers 10000 and higher, additional studies will have the letter placed before the five digit number, resulting in a six-character code. See current version of SOP# 9.0 when conducting non IR-4 Sponsored Studies.

Amend to read;

5. **Study Number.** Each study protocol is assigned a unique identification number. For studies with assigned PR numbers below 10000, the first digit of the identifier is assigned "Zero (0)" when the study is the first study under a particular PR number. Prior to the effective date of this amendment, the second study had "A" as the first character, the third study was assigned "B", the fourth study was "C"; each additional study associated with the same PR number was assigned the next letter in the alphabet. For studies with assigned PR numbers 10000 and higher, additional studies had the letter placed before the five digit number, resulting in a six-character code. See current version of SOP# 9.0 when conducting non IR-4 Sponsored Studies.

After the effective date of this amendment, there will only be one study associated with a PR number. The designations A, B, C and so on will no longer be used. When there is more than one study for a chemical/crop combination, a comment will be placed in the comment sections of the database indicating the first PR number used, and any subsequent PR numbers related to the first PR number.

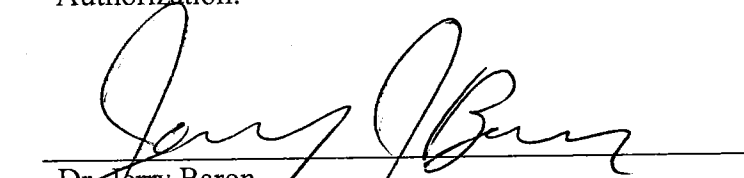
Reason for the SOP Amendment:

The database used to track study status will support only one status per PR number. When two or more studies were assigned to a PR number, the status was correct only for one of the multiple studies, unless the studies were at the same stage in study conduct.

Assessment regarding the impact of this SOP Amendment:

Allows for the status of each study to be correct, thus making it easier to track studies.

Authorization:



Dr. Jerry Baron
IR-4 Project Executive Director

17 Nov 2015

Date

Distribution: All IR-4 Users with full SOP sets.

IR-4 SOP AMENDMENT FORM

SOP amendment to: Headquarters SOP 4.4

Effective Date: November 30, 2015

Description of Amendment:

SOP 4.4 includes the following text for assigning a protocol number.

2a) The field "PR#" (study #) is a character value identifier for the study. When a number is the first character, this represents the first study for a particular request. When a letter precedes the PR#, this represents a project for which there are two or more studies.

Amend to read;

2a) The field "PR#" (study #) is a character value identifier for the study. When a number is the first character, this represents the first study for a particular request. Prior to the effective date of this amendment, a letter preceding the PR number was used to indicate a project for which there were two or more studies.

After the effective date of this amendment, there will only be one study associated with a PR number. The designations A, B, C and so on will no longer be used. When there is more than one study for a chemical/crop combination, a comment will be placed in the comment sections of the database indicating the first PR number used, and any subsequent PR numbers related to the first PR number.

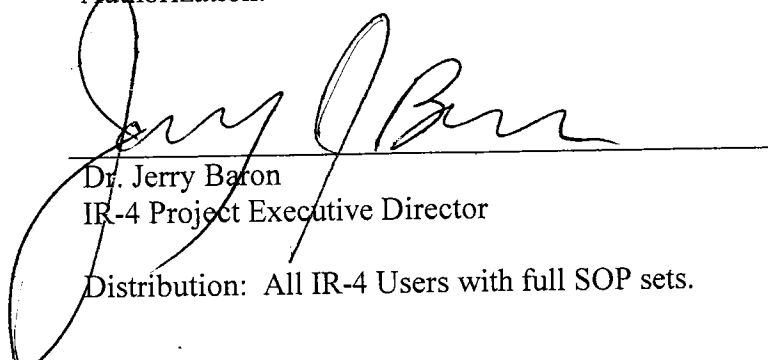
Reason for the SOP Amendment:

The database used to track study status will support only one status per PR number. When two or more studies were assigned to a PR number, the status was correct only for one of the multiple studies, unless the studies were at the same stage in study conduct.

Assessment regarding the impact of this SOP Amendment:

Allows for the status of each study to be correct, thus making it easier to track studies.

Authorization:



Dr. Jerry Baron
IR-4 Project Executive Director

17 Nov 2015
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