

## PART 7

### HOW TO CONDUCT A SUCCESSFUL COLLABORATIVE STUDY

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## HOW TO CONDUCT A SUCCESSFUL STUDY

### 1. Saving Time

One of the biggest time savers for the collaborative study process is realizing that there is plenty of work to do immediately after the protocol is submitted to AOAC for review. Obviously developing an effective method, writing it and submitting a study protocol are all important. However, waiting until the protocol is approved before doing any additional work is a common mistake made by Study Directors (SD). Most protocols are approved as submitted with only minor revisions. During this time, it is important to recognize that a number of activities can be performed concurrently while the protocol is in review such as:

- a. Soliciting collaborators for the study.
- b. If not already done, writing the method in AOAC style (see Part 8). AOAC staff is available to assist you in this task.
- c. Preparing test sample reporting sheets. More than just the method is required for a good study; usually, data reporting sheets and injection sequences are desirable.
- d. Preparing test samples in advance, if materials are stable for extended periods.
- e. Even if materials are not stable, you can prepare labels and shipping containers in advance. Frequently the most time-consuming portion of a collaborative study is simply getting all of the test samples together, getting them properly labeled to meet study and mailing requirements, and getting all shipments organized.

### 2. Finding Collaborators

#### Contact professional associations when soliciting collaborators

Generally, collaborators should be recruited as early as possible (see examples of solicitation letter and postcard). There are several important factors to keep in mind when doing this activity.

#### Don't Be Late

Collaborators must schedule this volunteer work around their normal workload. Some studies require special analyses that may be done at only a select time of year by the collaborator. A potential collaborator may have to refuse, not because of disinterest, they may be very interested, but because the notification of the study was too short.

#### But -- Don't Be Too Early

If there are doubts at the very beginning about your study protocol, or study materials aren't readily available, you may want to delay some before soliciting collaborators. It is difficult and embarrassing to try and reschedule the work with all of your collaborators--collaborators that had already penciled in your project in their activity list.

#### Make Replies Easy

Enclose a self-addressed, pre-paid, return postcard that they merely have to check and throw into a mailbox. A typical example of a postcard follows.

#### Give the Pertinent Information

Generally, a potential collaborator should be given a good idea about what will be required in the study; What equipment is needed; How many test samples must be analyzed and for how many analytes; How much laboratory time is required; What is the total length of time of the analyses; and When must the results be returned? These are all common questions that should be answered up front in the cover memo requesting their help. Sometimes, a

potential collaborator will want to see the method. This doesn't necessarily have to be provided up front (often, getting a copy of the method in advance by being a collaborator is viewed as a bonus for doing the study).

### **Be Lenient in Setting Time Frames**

As mentioned, collaborators are participating voluntarily. They have a regular job to do, too. The larger the window you allow for returning results, the more likely it is that you will get a volunteer. When a volunteer accepts a short time frame, they usually don't meet it anyway.

### **Providing Equipment**

If your budget allows, lending (or buying) things like columns, filter packs, nutrient broth, etc. for the collaborator to use can make a difference between getting a volunteer or being turned down.

### **Providing Extra Standard**

Analytical or reference standards are often hard or expensive to obtain, and providing that extra amount may also serve as an enticement for collaborators.

### **Acknowledging the Volunteer**

Don't forget to tell them that you plan on recognizing them in a planned publication about your study. They might like the idea.

### **Offering Disposal**

Many methods require the use of poisons, infectious microorganisms, and other hazardous chemicals and materials. If a disposal system is already available at your site, consider offering to take care of any of these materials that are properly mailed back to you.

## **3. Obtaining and Preparing Test Samples**

Materials should be obtained, depending on stability, as soon as possible. If they are stable, for example, in the freezer, test samples might be prepared well in advance. Obviously, materials must be very homogeneous if precise results are to be obtained. Often, this means the test samples being forwarded to the collaborator must also be homogenized by them before weighing. Take this into account when supplying the test sample and its container.

Furnish only enough test sample to provide the number of test portions specified in the instructions. If additional test portions are required, the collaborator must request them, with an explanation.

### **Watch the fullness of containers**

If test samples must be shaken to mix them, don't fill a vial or bottle almost totally full so that there is no room for mixing action (not to mention vapor space for expansion).

### **Don't underestimate the response to your solicitation for collaborators**

Generally, you can't have too many collaborators, but you can have insufficient test samples for everyone. It would be a shame to turn down volunteers. Prepare bottles or containers early, even if test samples cannot be made up early, by labeling since this can be quite a chore.

### **Prepare shipment papers early, whether they are required internally or simply by a mailing agency**

Different shippers require different amounts of paperwork and often companies and agencies keep internal paper work also. If a collaborative study will be performed internationally, obtain in advance the information on customs

regulations. Test samples destined for several laboratories in a certain country or region could be shipped to a single source within that country or region and distributed from that source.

#### **Look for legally acceptable shortcuts when filling containers for shipping**

The first container may need to be weighed to 2 g. All the other containers can probably be filled to the same level as the first rather than weighing each separately. This can save a lot of time.

#### **Bundle shipments that can be prepared in advance**

With an approved protocol, once a collaborator asks to participate, you may already have extra test samples ready that can simply be sealed and mailed.

#### **4. Providing Paperwork**

Naturally the collaborators need the method and test samples, but they should also know you received their post card and you are glad that they are volunteering to help. They should be informed that the test samples will be forwarded and in what condition to expect them. They should be aware of any special handling required on receipt, such as freezing the reagents or test samples. Don't forget the MSDSs, or equivalent. See examples of shipment of test samples letter below. Consider enclosing a pre-paid postcard confirming the test samples arrived safely. An example is shown below. This can save a lot of time and future problems.

#### **5. Data Reporting Forms**

The method must stand on its own; however, it is frequently very useful to add forms for reporting certain information to ensure that you obtain all of the raw data the first time. This minimizes confusion and provides you with documentation you can review in detail and keep indefinitely.

For instrumentation methods, it is often useful to show the injection sequence. While the injection sequence is detailed in the method, it is desirable to have it outlined to minimize the chance that an improper sequence is followed. An injection sequence other than what is required by the method can greatly complicate interpretation of the data and could conceivably invalidate data. Often such a sequence is used in combination with the reporting form, making only one form for the collaborator to fill out (see example of the study reporting form below).

#### **6. Follow-Up Letter**

It is appropriate to send each collaborator a follow-up letter at the conclusion of the study, informing each one of their results relative to the other laboratories. Generally, it includes a tabulation of all data with that laboratory's data normally marked with an asterisk and all other laboratories are not identified. Be courteous and send your collaborators a copy of the collaborative study report after the method is adopted as an *Official Method*<sup>SM</sup> by AOAC.

## EXAMPLE OF INVITATION LETTER

[Date]

[Study Director's Name, Affiliation and Address]

[Potential Collaborator Name, Affiliation and Address]

Dear [ ]:

AOAC INTERNATIONAL is in the process of validating a method as an AOAC® *Official Method*<sup>SM</sup> for the determination of [analyte] in [matrix] by [method]. As a Study Director for this method, I am soliciting potential collaborators for an interlaboratory collaborative study.

This method requires [a liquid chromatograph equipped with a UV detector (capable of operating at 230 nm) and a 250' 4.6 mm id column packed with £10mm CN (cyanopropyl) bonded silica gel. The method uses an acetonitrile-water mobile phase under isocratic conditions.]

The study will consist of [single analyses of 6 test samples. I estimate that 3.5-4 hours will be required to prepare reagents and solutions, make calculations, and fill out the reporting forms. The total instrument run time for the analysis (excluding a Familiarization Test Sample) should be approximately 3.5 hours. Therefore, the entire procedure including instrumental time should normally be only 1 day.]

Sufficient portions of the analytical standard, internal standard, and test samples, as well as a copy of the method, will be provided to collaborators. AOAC and I would appreciate your participation in this program. All collaborators will be given credit in the publication of the study results in the *Journal of AOAC INTERNATIONAL*. In addition, I will send you a copy of the results of the study (with your results annotated) as soon as they are compiled and analyzed.

[Once a study is completed, you may return any of the test samples, chemicals or solutions to our facility for disposal, if needed. Make sure these are properly labeled and all shipping regulations are met.]

Please reply by [time frame], using the postcard provided, or call me if you have any additional questions. Test samples will be forwarded to you shortly after the study protocol has been reviewed and accepted by AOAC. I will keep you informed of the schedule. My goal is to have all of the collaborators complete their analyses by no later than [time frame]. Thank you for your consideration and support for development of reliable, sound, valid methods of analysis through AOAC INTERNATIONAL.

Very sincerely yours,

Your Name  
Title  
Phone Number  
Fax Number  
Email Address

### EXAMPLE OF INVITATION POSTCARD FOR A COLLABORATIVE STUDY

Title of study: _____	
Applicability: _____	
_____	
We will participate <input type="checkbox"/>	_____
	Name (please print)
Sorry, we cannot participate <input type="checkbox"/>	_____
	Phone (please include area code)/ Email Address
We'd be interested in a future study <input type="checkbox"/>	_____
	Affiliation

- Front Side - Self addressed and stamped.

### EXAMPLE OF LETTER NOTIFYING SHIPMENT OF MATERIALS

[Study Director's Name, Affiliation and Address]	[Date]
[Collaborator's Name, Affiliation and Address]	
Dear [ ]:	
As the AOAC Study Director for [analyte] in [matrix] by [method], I wish to thank you for agreeing to participate in the collaborative study of the proposed AOAC® <i>Official Method</i> <sup>SM</sup> . A copy of the test method, reporting forms, and a postage paid return envelope are enclosed for your use.	
The test samples should arrive [by overnight courier.] Please check all the vials upon receipt for any signs of leakage and report any to me. The analyte reference standard should be refrigerated at below 0°C until used. The test samples may be stored at room temperature. Ensure that the reference standard has reached room temperature before opening to prevent condensation problems. If all materials arrive properly, without damage and no omissions are found, return the enclosed postage paid postcard to me.	
This study consists of [preparing and analyzing two similar samples of ..., two similar samples of ..., and ..., etc.]. Only a single determination of the analyte level in each sample is to be performed.]	
Please analyze the vial marked "Familiarization Test Sample" first. You should obtain a value of [25 ± 1%]. Do not proceed with the analysis of the test samples unless adequate results on the Familiarization Test Sample are obtained first. I will be happy to discuss any problem you are having with the analysis.	
I estimate that approximately [3-4 hours] are required to prepare reagents and solutions, calculations, and fill out reporting forms. Test sample analysis should require [an additional 3.5 hours]. [No special] safety precautions are required for this study. A Material Safety Data Sheet for [ ] will be enclosed with the laboratory samples.	
No modifications to the method should be performed except for routine [instrument-to-instrument] variables such as [injection volumes, detector attenuation, and column manufacturer.] Please return the completed reporting forms in the enclosed envelope by [ ] . [Upon completion of the study, you may return any test samples to me, properly labeled and shipped, for disposal if you do not have access to proper disposal facilities.]	
Please do not hesitate to call me if you have any questions. My office hours are [7 -3:30 (CST).] I will give you a copy of the results of the collaborative study as soon as they are compiled and analyzed. Again, thank you for your cooperation as a collaborator on this study.	
Very sincerely yours,	
Your Name	
Title	
Phone Number, Fax Number and Email Address	

**EXAMPLE OF POSTCARD CONFIRMING RECEIPT OF TEST SAMPLES**

<b>AOAC INTERNATIONAL COLLABORATIVE STUDY</b>	
Title of study: _____	
Applicability: _____	
Study Director: _____	Contact _____
The test samples arrived safely: _____	
	Name (please print)
	Affiliation
Comments: _____	
_____	
Please indicate if you need anything (test sample, information, etc.): _____	
_____	
_____	

- Front Side - Self addressed and stamped.

**EXAMPLE OF DATA REPORTING FORM**

Injection	Internal STD Peak Area	Test Sample Peak Area	Peak Area Ratio, R	Analyte, %
Standard				
Standard				
Test Sample 1				
Test Sample 2				
Test Sample 3				
Standard				
Standard				
Test Sample 5				
Test Sample 6				
Standard				