

## Handling Subject Complaints

By Norman M. Goldfarb

Study subjects may complain, rightly or wrongly, about many things in a study, ranging from a misunderstood comment to severe physical injury. The site's response to a complaint will, in large part, determine the subject's level of satisfaction and attitude towards the parties involved. If the response leaves the subject disgruntled, he or she may become uncooperative, drop out of the study, complain to his or her friends, or even file a lawsuit.

If a lawsuit is heard, the court will consider the site's response to the original complaint. The court will view callous or thoughtless handling of the complaint (or no response at all) unfavorably. On the other hand, plaintiff's counsel will surely seize on any admission of fault in the site's response. But, the subject may only want an apology and mea culpa (Latin for "my fault"). From the perspective of potential litigation, responding to complaints can thus be especially tricky.

### Possible Responses

Site personnel respond appropriately to the complaint. Depending on the nature of the complaint, characteristics of the subject, and the site's relationship to the subject, appropriate responses may include:

- Ignore the complaint.
- Acknowledge the complaint.
- Express sympathy and understanding to the subject.
- Ask the subject for additional information.
- Provide helpful information to the subject.
- Ask the subject what actions he or she would like the site to take to remedy the complaint.
- Inform the subject that the complaint is under investigation and approximately when the investigation will be completed.
- Inform the subject of corrective actions to address the subject's complaint and, if appropriate, prevent similar occurrences in the future.
- Assist the subject in obtaining medical care.
- Assist the subject in obtaining reimbursement from the sponsor and/or insurer(s).

The following responses may require consultation with legal counsel and insurer(s):

- Inform the subject that the complaint does not appear to be valid or is not the responsibility of the site.
- Inform the subject that he/she may file the complaint with the subject advocate (if one exists), site management, the institutional review board, or appropriate government agencies.
- Apologize to the subject.
- Admit responsibility to the subject.
- Offer restitution.

Apologies for injuries must be worded carefully to minimize the risk in potential litigation of admitting fault. For example, this apology from a study coordinator may be regretted:

I am so sorry about your bad reaction to the study drug. I told the doctor we should not enroll you in this study. Please keep us informed of how your adverse event resolves.

This apology finesses any admission of fault and focuses the subject on solving the problem together:

I am very sorry about the bad reaction you had to the study drug. I will inform the doctor and get back to you as soon as possible. What can we do to help?

### **Process for Handling Subject Complaints**

If a complaint is about something trivial, conduct the following process:

1. Acknowledge the complaint.
2. Express sympathy and understanding.
3. If appropriate, ask for more information.
4. If appropriate, apologize sincerely, keeping in mind that it is often easier to satisfy the subject with an apology than to explain why an apology is not necessary.
5. Confirm that the subject is satisfied.

If a subject complains about something substantive, conduct the following process:

1. Acknowledge the complaint.
2. Express sympathy and understanding.
3. Apologize, but not for causing the problem.
4. Document the date, time and details of the conversation.
5. If appropriate, have someone more qualified contact the subject.
6. If the person complaining is not the subject, determine the nature of his or her relationship with the subject and his or her authority to complain on behalf of the subject.
7. Obtain comprehensive information.
8. Ask the subject what actions he or she would like the site to take to remedy the complaint. If appropriate, offer assistance.
9. Determine the subject's level of dissatisfaction and plans to pursue the issue (without suggesting litigation or other serious measures).
10. Inform the subject that the complaint is under investigation and approximately when the investigation will be completed.
11. Investigate the complaint expeditiously. Determine if it is legitimate, substantive and merits action, and by whom.
12. If there is potential legal liability, review the pertinent clinical trial agreement and insurance policies. Discuss the matter with legal counsel and insurers, as appropriate.
13. Inform the subject if the investigation will take longer than expected.
14. Review the complaint with management and obtain approval of a suitable apology and resolution.
15. Apologize to the subject and resolve the complaint as soon as possible. To use the sales term, a "contingent close" can be effective: "If we pay for your medical treatment, will that resolve your complaint?"
16. Document the communications, findings and resolution of the complaint.

Do not:

- Make the subject wait to complain.

- Interrupt the subject while he or she is presenting his or her complaint.
- Communicate in a manner that suggests you are not taking the complaint seriously.
- Delay in responding to telephone or email messages.
- Allow the subject's anger or manner to cause you to respond angrily, defensively or impatiently.
- Tell the subject the matter is not your responsibility and he or she should talk to someone else about it.
- Ignore the complaint and hope it just goes away (although it can happen).
- Accept or assign fault without prior management authorization.

### **On the Bright Side...**

Complaints are not just problems; they are also opportunities to make improvements with significant long-term impact. Subjects who care enough to complain are often the most dedicated to the study. What sounds like a complaint may instead be a suggestion or constructive criticism. Subjects whose complaints have been addressed satisfactorily may become the biggest advocates for the current and also future studies.

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