



JAN - 8 2010

Mr. Justin R. Fidler
President
SONA SYSTEMS, Ltd.
Uus 17-7
10111 Tallinn
Estonia

**RE: SONA SYSTEMS' Experiment Management System and Compliance with U.S.
Department of Health and Human Services Regulations at 45 CFR Part 46**

Dear Mr. Fidler:

Thank you for taking the time to meet with staff from our office on September 28, 2009 to discuss your company's web-based Experiment Management System (EMS) that is used to manage student subject pools and for subsequently providing additional information describing the configuration of EMS.

As we noted during our meeting with you, an individual contacted our office and expressed concern about the EMS feature of automatically assessing penalty credits to students who fail to show up for scheduled appointments with investigators without cancelling in advance by a specified deadline. This individual was concerned in particular that the EMS penalty function may violate the requirements of U.S. Department of Health and Human Services (HHS) regulations at 45 CFR 46.116(a)(8) that participation in research be voluntary and refusal to participate involve no penalty or loss of benefits to which the subject is otherwise entitled.

We understand that when a penalty is assessed under EMS, the system either deducts credits previously earned by the student subject for participation in other research studies or increases the number of credits that the student would have to earn in order to receive an equivalent amount of course credit. This penalty is in addition to the student not receiving any credit for the study for which the student failed to show up.

After careful consideration, we have determined that the penalty function of EMS does violate the requirements of HHS regulations at 45 CFR 46.116(a)(8) and therefore may not be implemented by institutions either for (a) research conducted or supported by HHS that is not otherwise exempt under HHS regulations at 45 CFR 46.101(b), or (b) non-federally supported human subjects research to which a Federalwide Assurance approved by our office applies. Under the provisions of 45 CFR 46.116(a)(8), students must be free to choose not to participate in research that they have signed up for at anytime prior to the start of their involvement in the research. Furthermore, students must be free to communicate their decisions not to participate in research in whatever way they choose, including by simply not showing up for the research.

We acknowledge that your company plans to (a) notify all institutions that use EMS about our determination regarding the penalty function of EMS; and (b) modify the configuration of EMS so that your customers are advised not to use the penalty function for the categories of research referenced in the preceding paragraph. We commend you for taking these helpful steps.

You may also wish to consider modifying the configuration of EMS to incorporate options that encourage students to show up for scheduled appointments without imposing a penalty for no-shows. The following two options would not violate the requirements of HHS regulations at 45 CFR 46.116(a)(8):

- (1) Students who show up for an appointment as scheduled could be awarded a credit point, or some fraction thereof.
- (2) Students who fail to show up for a scheduled appointment could have a decrease in the number of credits that can be earned through participation in research for a particular course, provided such students can still earn the same maximum number of credits by substituting an alternative non-research activity that involves a comparable amount of time and effort (see our guidance on this topic at <http://www.hhs.gov/ohrp/informconsfaq.html#q9>). For example, consider circumstances where students enrolled in a course can earn up to 3 extra credit points toward their final grade by participating in 3 separate studies (1 extra credit point per study). Under this option, if a student in the course fails to show up for an appointment for one study without cancelling by the specified deadline, the student is allowed to earn a maximum of 2 extra credit points by participating in two other research studies. However, the student must be able to earn a third extra credit point by completing an alternative non-research activity.

We would be happy to discuss with you other alternatives to the penalty function.

Please note that we intend to communicate our determination regarding the EMS penalty function directly to the individual who originally contacted our office about this issue. Furthermore, we intend to make this letter available to the public by posting it on our website.

We appreciate the commitment of your company to the protection of human subjects. Please feel free to contact me if you have any questions regarding this matter.

Sincerely,

/s/

Michael A. Carome, M.D.
Captain, U.S. Public Health Service
Associate Director for Regulatory Affairs