

US EPA ARCHIVE DOCUMENT

## Changes in SCI-001 Consent Form Version of 11/06/07

The revised consent form for SCI-001 approved by IIRB on November 6, 2007, reflected the following changes from the consent form approved by IIRB on January 22, 2007:

1. On p. 2 of 10 in the consent form approved 11/06/07 the highlighted text was added to the first paragraph:

The sponsor, Scientific Coordination, Inc. has contracted Carroll-Loye Biological Research to conduct the study. Scott Carroll, Ph.D., of Carroll-Loye Biological Research is the Principal Investigator in charge of the study. **Data for this study were originally collected in July 2007. More data are needed to complete this study due to an administrative error that took place then. At that time, the sponsor added a new test repellent to the study, for which the Principal Investigator did not obtain proper approval. While regulatory authorities at the US Environmental Protection Agency have not suggested that participants were at risk due to that error, the data collected at that time are likely not acceptable for ethical reasons. Accordingly, your participation would serve to replace some of those data. The repellent formulation added in July is not being tested now.**

2. On p. 3 of 10 in the consent form approved 11/6/07 the first paragraph under the heading "Study Design" was altered as indicated below:

The study will also test ~~four~~ **two** different insect repellent lotions. You will be randomly (by chance) assigned to receive one product, so your chance of receiving any one product is one-in-~~four~~ **two**.

3. On p. 4 of 10 in the consent form approved 11/6/07 the last sentence in the paragraph concerning pregnancy testing, carried over from the previous page, has been revised as indicated below:

Information regarding your pregnancy test results will be kept in confidence, **but it is nevertheless possible that obtaining pregnancy results in the research setting would cause you social discomfort.**

4. On p. 8 of 10 in the consent form approved 11/6/07 the hourly rate of compensation for participants has been raised as indicated below:

For participation in the study, each research study participant will receive a cash payment of ~~\$15.00~~ **\$20.00** per hour.