Response to OMB Further Questions (October 15, 2007)

Last bullet for item 2: NIH's responses echo our concerns regarding potential for (and inability to measure) survivor bias and recall bias. For that reason, we remain uncomfortable with statements that suggest we are approving an approach that will improve model objectivity. We are much more comfortable approving this study that sticks to statements about testing the sensitivity of your assumptions to what survivors may recall. You can take care of this concern by avoiding the use of the terms 'objective' and 'accurate' in describing this study in the supporting statement.

Response: We have used “more informed” and “improved”, as appropriate.

Item 3: Since NIH has responded that "The results of this study are not expected to “alter current scientific understanding of biological effectiveness of internal and external radiation exposures”. We request that NIH delete the following passage from page 6 of Part A of the supporting statement: " Detailed information on milk consumption is especially critical and may result in modified dose estimates that could alter the current scientific understanding of the relative biological effectiveness (RBE) of internal compared to external radiation exposures."

> **Response**: We have deleted this sentence.

Item 4: The response provided seems to contradict what is written in the supporting statement. Can NCI clarify? For example, the supporting statement says that SSMA will maintain all the participant data. The supporting statement also says that personally identifiable information will not be given to NCI or RTI. Yet the response seems to say that SSMA (and other international collaborators) will not have the identifiable data and that individual participant data will be maintained by NCI.

> **Response**: SSMA will maintain a list of study participants with only personal identifies, and NCI or RTI will not have this list. SSMA, NCI and RTI will all have focus group response data that are anonymized and thus cannot be linked to individuals on the above list. We have revised paragraph 2 of section 10, “Assurance of Confidentiality .. “ in supporting document A to provide clearer descriptions on this matter.

Also, if NCI does not have statutory authority to provide assurances of confidentiality (IRB approval is not the same thing), then the wording on the consent forms should be revised to say “Your participation and any comments you make will be kept private to the extent permitted by law” rather than “… kept confidential.” If in doubt about statutory authority, please check with your general counsel.

Response: We have revised the wording as suggested. See attached revised consent form.

I**tem 5:** You use the term "represent" often throughout Part B of the supporting statement. Based on your response, we gather that you are using the term "represent" to mean "illustrative of" or "show." Since Part B is designed to focus on statistical issues, we suggest either using a different word or adding a statement before the first use of the term 'represent' to clarify that you are not using this term in a statistical sense.

Response: We have changed the wording to resolve this difficulty (see B1, para 1, lines 8-9 and 19, numbered para 1 under Participant Inclusion Criteria, lines 7 and 10, and para 3 under Data Collection of Information).