Certificate of Privilege to Use CARET Specimens and/or Data

The Scientific Review Committee of the Carotene and Retinol Efficacy Trial (CARET) and the Institutional Review Boards (IRBs) of the Fred Hutchinson Cancer Research Center (FHCRC) and your institution have approved the use of CARET specimens and/or data for the protocol entitled entitled <***Study title***>. This certificate documents your rights and responsibilities with regard to these specimens.

You will receive from the CARET the following:

<description of numbers, volumes, and types of specimens and/or datasets>

The numbers of specimens and/or data are those specified in the protocol named above. If any specimens are unusable (due to, for example, compromised vials or insufficient sample in vials), CARET will replace them, subject to availability of replacement specimens.

You are approved to perform the following analyses:

<list of analyses; if some analyses are to be performed on only a subset of samples (e.g., analyses done only on cases) then the subset must be specified.>

This is a complete list of approved analyses based on the protocol. You may not perform any analyses not on this list. Performing unapproved analyses is a violation of OHRP (Office for Human Research Protections) regulations and may lead to sanctions from your institution including prevention of your publishing your results; it will also result in a revocation of your privilege to use CARET specimens and/or data for this or any future protocol.

If you wish to perform additional analyses not currently approved, you must first receive written approval from the CARET Scientific Review Committee, your institutional IRB, and the FHCRC IRB. Once approval is granted, you will receive a new certificate listing the additional analyses you are approved to perform. You may not begin an analysis until you receive a certificate listing that analysis as approved.

Sample Return:

When you have completed your approved analyses, you must return to CARET any residual specimen within **12 weeks** of analysis completion, including specimens that were considered unusable and usable specimen products (e.g., extracted DNA). Any datasets created from specimen analyses must be returned to CARET for archiving.

Dataset Return:

When you have completed your approved analyses, all datasets must be returned to CARET for archiving, and the original CARET dataset sent must be destroyed.

Blinding Policy:

All laboratory analyses will be conducted in blinded fashion with respect to case-control status. CARET will maintain the blind until all laboratory assay data have been delivered to CARET and all samples exhausted or returned. Any exception to the blinding policy will require approval of the CARET Scientific Committee.

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Investigator's Statement

I have read the conditions of this certificate and I agree to abide by its terms.

_____ _____

Name Date