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**Initial Exempt Approval Letter** 

Date: March 09, 2022

PI: Erica Lee Laipply, MD

RE: IRB Number: 21176

Protocol Title: Relationship between anal cancer and smoking

The IRB has reviewed and determined that the above project is exempt from IRB review. This exemption is approved effective 03/09/2022. This review and exemption approval was processed in accordance with federally defined categories of exempt review per 45 CFR 46.104 Category 4(iii).

The Summa Health IRB also determined that all specific criteria for waiver or alteration of authorization in accordance with 45 CFR 164.512 were met for this study that will involve the PHI listed in the study application.

Annual renewals/progress reports are not required for exempted projects. A 3-year project period will be given to the project. If the project is not completed by 03/08/2025 then the study will need to be re-submitted for IRB review. Should your project significantly change, please contact the Summa Health IRB Office prior to initiating those changes to assess whether the study will or will not continue to be exempt.

Sincerely,

Christy Wise, BA, CIP IRB Coordiantor (Designated Exempt/Expedited Reviewer)