Office of Research and Innovation
Office of Research Subjects Protection
BioTechnology Research Park
800 East Leigh Street, Suite 3000
Box 980568
Richmond, Virginia 23298-0568

(804) 828-0868
Fax: (804) 827-1448

TO: April Kimmel
CC: Rose Bono

RE: April Kimmel ; IRB HM20018229_Ame1 Antiretroviral Improvement among Medicaid Enrollees (AIMS): An Insurance-based Data to Care Initiative for Medicaid Enrollees in Virginia

On 9/8/2021, the **change(s)** to the referenced research study were ***approved*** in accordance with 45 CFR 46.110 by VCU IRB Panel A .

This study is approved under **Expedited Categories**

Category 5	Involves materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes including medical treatment or diagnosis.
Category 6	Involves the collection of data from voice, video, digital, or image recordings made for research purposes.
Category 7	Is research that will be performed on individual or group characteristics or behavior OR will employ a survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The VCU IRB approved the Research Project for **waiver or alteration of HIPAA Authorization** based on the following: The VCU IRB has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
    - An adequate plan to protect the identifiers from improper use and disclosure;
    - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
    - Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

2. The research could not practicably be conducted without the waiver or alteration; and
3. The research could not practicably be conducted without access to and use of the protected health information.

Please note that we will need to get reliance agreements in place and submitted before we can fully approve the HIPAA pathways for relying sites. The submission will require continuing review as there are some components (reliance agreements for IRB review) that still need to be submitted, approved, and executed.

Also, note that I've made some changes to the HIPAA authorization language for clarity. If you feel changes are needed, we can address these when the reliance agreements are submitted.

The information found in the electronic version of this study's smart form and uploaded documents now represents the currently approved study, documents, informed consent process, and HIPAA pathway (if applicable). You may access this information by clicking the Amendment Number above.

COVID-19 Notice

In the context of the COVID-19 pandemic, the IRB expects the research will proceed in accordance with other institutional policies and as outlined in this submission and if applicable, in the study's COVID-19 Contingency Protocol. IRB approval does not necessarily mean that your research may proceed. For more information on investigator responsibilities and institutional requirements, please see https://research.vcu.edu/covid-19.htm

The Principal Investigator is also reminded of their responsibility to ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space. See WPP #: IX-1 Principal Investigator Eligibility and Statement of Responsibilities

During this review, it was determined that ongoing continuing review is required, and a new expiration date was set. The approval for this study now expires on 8/31/2022 . Federal Regulations/VCU Policy and Procedures require continuing review prior to continuation of approval past that date. A Continuing Review notice will be sent to you prior to the scheduled review.

If you have any questions, please contact the Office of Research Subjects Protection (ORSP) or the IRB reviewer(s) assigned to this study.

Thank you for your continued collaboration in maintaining VCU's commitment to protecting human participants in research.

Attachment – Conditions of Approval

Conditions of Approval for Expedited and Full Board Studies (version 1/21/2019)

In order to comply with federal regulations, industry standards, and the terms of this approval, the investigator must (*as applicable*):

1. Conduct the research as described in and required by the IRB-approved protocol/smartform.
2. Obtain approval from the VCU IRB before implementing any changes in the approved research unless such changes are necessary to protect the safety of human research participants.
    - Report any departure from the approved protocol/smartform or documents to the VCU IRB immediately through a report submission.
    - Obtain approval from the VCU IRB before use of any advertisement or other material (print or electronic) for recruitment of research participants.
    - Obtain approval from the VCU IRB before implementing any changes related to the future sharing of individual-level research data.
3. Obtain informed consent from all prospective participants or the participant's legally authorized representative without coercion or undue influence, and provide the potential participant sufficient opportunity to consider whether or not to participate (unless a Waiver of Consent was specifically approved).
    - Obtain informed consent using only the most recently approved consent document (unless a Waiver of Consent was specifically approved).
    - Provide non-English speaking participants with a written translation of the approved consent document (or a translated version of the Short Form Consent document) in language understandable to the research participant. The IRB must approve the translated version and/or the use of a short form consent process prior to use.
4. Monitor all problems (anticipated and unanticipated) associated with risk to research participants or others.
5. Report all Unanticipated Problems (UPs) involving risk to participants or others following the VCU IRB requirements and timelines detailed in WPP VII-6.
6. Respond promptly to all inquiries from the VCU IRB and Office of Research Subjects Protection concerning the conduct of the approved research.

The VCU IRB operates under the regulatory authorities as described within:

a. *U.S. Department of Health and Human Services Title 45 CFR 46, Subparts A, B, C, and D and related guidance documents.*
b. *U.S. Food and Drug Administration Chapter I of Title 21 CFR 50 and 56 (for FDA regulated research only) and related guidance documents.*
c. *Commonwealth of Virginia Code of Virginia 32.1 Chapter 5.1 Human Research (for all research).*

IRB PERFORMANCE SURVEY:
We value your feedback! Please take 1-2 minutes to complete the IRB Performance Survey in relation to your experience with this approved submission: https://IRBperformancesurvey.questionpro.com