University of Virginia

**Office of the Vice President for Research**

# Post-Approval Monitoring Report

**HSR-IRB#** **IRB of Record:**  **Principal Investigator:**

**Review Type:** ***( PICK ONE)*** Exempt OR Exempt with Limited IRB Review **Regulated by: (*PICK ONE)***  Pre 2018 Common Rule OR 2018 Common Rule

**Title:**

**Study Coordinator:**  **Date of Review:**

**Introduction of what was reviewed:**

*Electronic study files (Excel spreadsheets and copies of protocol, Exempt application, etc.) were reviewed.*

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| Findings: | Regulations/Guidance: | Recommendations: | Resolution (to be completed by investigator/study team) |
| *Regulatory documentation:* | UVA IRB-HSR Exempt Determination Process:  Investigator Responsibilities:   * If the investigator feels the project meets the criteria for exempt determination, he/she should submit an Exempt application to the IRB-HSR office. The application is obtained via Protocol Builder. In order to fulfill requirements for the proper review of research, investigators cannot "self-exempt" from IRB review. |  |  |
| *Documentation of informed consent*:  N/A – Exempt Determination. | *COPY AND PASTE THE EXEMPT CATEGORY THAT STUDY WAS EXEMPTED UNDER FROM IRB ONLINE*  *(May be found on Determination Documentation from the IRB-HSR)*  Investigator Responsibilities:   * The exemption is granted only for the study as written at the time of the initial review when the decision to exempt was determined. * Investigators who conduct research exempt from IRB oversight must report any changes that will alter the study in such a way that it is no longer exempt from federal regulations. |  |  |
| *Subject Selection Criteria:* | Investigator Responsibilities:   * The exemption is granted only for the study as written at the time of the initial review when the decision to exempt was determined. * Investigators who conduct research exempt from IRB oversight must report any changes that will alter the study in such a way that it is no longer exempt from federal regulations. |  |  |
| *Documentation that approved protocol was implemented as outlined:* | *COPY AND PASTE THE EXEMPT CATEGORY THAT STUDY WAS EXEMPTED UNDER FROM IRB ONLINE*  *(May be found on Determination Documentation from the IRB-HSR)* |  |  |
| *Data Security Plan:* | IF STUDY REGULATED UNDER  **PRE 2018 COMMON RULE** INSERT:  [University of Virginia Data Security Policies](https://security.virginia.edu/information-policy)  IF STUDY REGULATED UNDER  **2018 COMMON RULE:**  Add the following here if the study is approved under exempt criteria requiring Limited IRB Review per any of the following criteria:   * *45CFR46.104(d)(2)(iii)* * *45CFR46.104(d)(3)(i)(c)* * 45CFR46.104(d)(4)(iii) :   There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data per 45CFR46.111(a)7).  [University of Virginia Data Security Policies](https://security.virginia.edu/information-policy) |  |  |

**General Comments**: