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| **APPROVAL CRITERIA CHECKLIST**  **PI**:       **IRB-HSR Meeting Date**         **IRB-HSR#/ UVA Study Tracking #** | | | |
| 1. Do you feel the IRB has the expertise needed to review this protocol?   If NO, what expertise is needed? | **Yes** | **No** | **NA** |
| 1. Should the consent process be observed by a PAM compliance monitor?   If YES, how many should they observe?  *IRB-HSR AG 2-19 stipulates they must observe at least one out of the first 5 subjects enrolled.* |  |  |  |
| 1. Based on the risk, should the review take place more than annually? |  |  |  |
| 1. Does the study meet the criteria for IRB Approval per Federal Regulations? |  |  |  |
| 1. Risks to participants are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose participants to risk. |  |  |  |
| 1. Risks to participants are minimized by using procedures, whenever appropriate, that are already being performed for diagnostic or treatment procedures. |  |  |  |
| 1. Risks to participants are reasonable in relation to anticipated benefits to participants directly or society in knowledge that may be expected to result.   Direct benefit to subjects No direct benefit to subjects societal benefit |  |  |  |
| 1. Selection of subjects is equitable, taking into account the purposes of the research, the setting in which the research will be conducted, the special problems of research involving vulnerable populations, the selection criteria and the recruitment process. |  |  |  |
| 1. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by the regulations. |  |  |  |
| 1. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants |  |  |  |
| 1. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. |  |  |  |
| 1. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as **children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons,** additional safeguards are included in the study to protect the rights and welfare of these participants. |  |  |  |
| Comments: |  |  |  |
| If any of the questions under D above are answered NO, the protocol cannot be approved. | | | |

**IRB-HSR Chair/ Vice Chair Name**

**Version Date: June 8, 2020**