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| **INCLUSION/EXCLUSION CRITERIA** |
| **IRB Number:** \_\_\_\_\_\_\_\_\_\_\_ | **Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_** | **Participant ID**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Inclusion Criteria***All choices must be marked YES to enroll* | **Source/Comments** | **Criteria Met?** | **Initials of Verifier** | **Date** |
| 1. *Age > or = XX years*
 | DOB: \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_\_Age at time of consent: \_\_\_\_\_Source:  | ⭘ Yes⭘ No |  |  |
|  | Source: | ⭘ Yes⭘ No |  |  |
|  | Source: | ⭘ Yes⭘ No |  |  |
|  | Source: | ⭘ Yes⭘ No |  |  |

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| **For All Female Participants of Child-Bearing Potential** *At least one choice must be marked YES* | **Criteria Met?** | **Initials of Verifier** | **Date** |
| 1. *Tubal Ligation*
 | Source:  | ⭘ Yes⭘ No |  |  |
| 1. *Hysterectomy*
 | Source: | ⭘ Yes⭘ No |  |  |
| 1. *Postmenopausal*
 | Source: | ⭘ Yes⭘ No |  |  |
| 1. *Negative Pregnancy Test*
 | Test Date: \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_\_⭘ Serum ⭘ Urine | ⭘ Yes⭘ No |  |  |

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| **Exclusion Criteria***All answers must be marked NO to enroll* | **Source/Comments** | **Criteria Met?** | **Initials of Verifier** | **Date** |
|  | Source:  | ⭘ Yes⭘ No |  |  |
|  | Source: | ⭘ Yes⭘ No |  |  |
|  | Source: | ⭘ Yes⭘ No |  |  |
|  | Source: | ⭘ Yes⭘ No |  |  |

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| **Please check one**:  |
| ⭘ I verify that the potential participant ***meets*** all criteria required for enrollment and does not have, in my  opinion, any findings or factors that may negatively impact compliance or the participant’s safety in this study. ⭘ I verify that this potential participant ***does not meet*** all criteria required for study enrollment. This potential  participant is considered a screen fail. The reason(s) for exclusion is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Signatures:**  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*Verifier Signature*  *Date* |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*PI Signature* *Date* |