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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* |