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| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.**NOTE: This form is designed to be a starting point on the Pregnancy Testing Documentation. Update it as necessary for your specific study.** * This form is only necessary if documentation of procedure completion is not available anywhere else in study records AND results are not documented in a case report form, data collection form, or in the study database. This form is only meant to provide space for documentation if this information does not appear anywhere else in the study records.
* Delete the CRRO template version date and add in the study-specific version date of this document.
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| Pregnancy Testing Completed Per Protocol |
| Yes | *Type of Test*[ ]  Urine – results completed by clinical laboratory[ ]  Urine – dipstick read by clinically-licensed research staff [ ]  Blood | *Results*[ ]  Pregnant [ ]  Not Pregnant[ ]  Inconclusive, repeat test required | *Date of Test:* \_\_\_\_\_\_\_\_\_\_\_\_*Time of Test:* \_\_\_\_\_\_\_\_\_\_\_\_ |
| Results Located: |
| No | *Explain why pregnancy testing was not completed per protocol on a participant requiring testing:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Not Applicable | *Unable to become pregnant due to surgical means*[ ]  Hysterectomy[ ]  Salpingectomy[ ]  Oophorectomy[ ]  Tubal Ligation[ ]  Other surgery, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of Surgery: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  Considered Post-MenopausalDate of Last Menstrual Period \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | [ ]  Male | [ ]  Other, specify why a pregnancy test is not required for this specific participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Study Staff Completing Pregnancy Test Procedure Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ |