# Documentation of Informed Consent and Authorization Process for Research

**IRB Study #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Protocol ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Subject Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject Study ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| Consent/Authorization Process Task | Signature & Date of Staff Completing Task |
| Subject was provided with a copy of the informed consent and authorization documents to review during the consent discussion.  Version Dates Provided: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Method: \_\_\_\_\_\_ Email \_\_\_\_\_\_ Mail  \_\_\_\_\_\_ Other (describe): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Informed consent and authorization documents were reviewed with the subject, and the subject was given sufficient opportunity to ask questions.  Method: \_\_\_\_\_\_ Phone \_\_\_\_\_\_ Videoconference  \_\_\_\_\_\_ Other (describe): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Note any other individuals present with subject during consent discussion: | *Note any other individuals present with research staff during consent discussion:* |
| The subject expressed their voluntary willingness to participate and was instructed to sign the documents and return them to the study team. |  |
| Prior to any research related procedures for this study being conducted, proof of the subject’s signature was received by the study team.  Date of Receipt: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  By (Method): \_\_\_\_\_\_ Email \_\_\_\_\_\_ Mail \_\_\_\_\_\_ Text \_\_\_\_\_\_ In-Person  \_\_\_\_\_\_ Other (describe): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Contents: \_\_\_\_\_ Signature Page(s) only\* \_\_\_\_ Signed documents (all pages)  *see below* |  |
| \**IF APPLICABLE:* The entire signed consent and authorization documents (all pages) were returned to the study team at a later date.  Date of Receipt: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  By (Method): \_\_\_\_\_\_ Email \_\_\_\_\_\_ Mail \_\_\_\_\_\_ Text \_\_\_\_\_\_ In-Person  \_\_\_\_\_\_ Other (describe): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Signed copies of the informed consent and authorization document were provided for the subject to keep.  By (Method):  \_\_\_\_\_\_ Email \_\_\_\_\_\_ Mail \_\_\_\_\_\_ Text \_\_\_\_\_\_ In-Person  \_\_\_\_\_\_ Other (describe): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

**\*Note additional comments on reverse side, if applicable.**

Additional Comments (For each comment added, include author’s signature and date of entry):

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