Informed Consent Checklist

Study Title:

IRB Control #:

Subject #

Consent Form(s) Used:

Approval Date of Consent Form:     /     /  

Expiration Date of Consent form:    /     /  

Note: Modify if more than one consent form is used (e.g. main consent and sample collection consent.

Date of Consent:     /     /  

☐ If subject took consent form home, a new copy was used for the consent process.

☐ The most recent version of the consent form(s) was used.

☐ The subject was given the opportunity to read the consent form.

☐ All elements of consent were discussed with the subject.

☐ The information on all pages of the consent form was discussed with the patient.

☐ The subject was given the opportunity to ask questions and that all the questions were answered.

☐ The subject was able to re-state the important aspects of the study.

☐ The subject initialed and dated each page.

☐ All signatures and dates were obtained.

☐ NA ☐ If an investigator was not present, the investigator was available.

☐ The subject received a copy of the signed and dated consent form(s).

☐ The subject received copy(ies) of the following materials (e.g. wallet card, drug administration instructions):

☐ No study related activities/procedures were done before consent.

Note: Add any other important aspects of the process that you feel should be documented.

Name of Person Conducting Consent Discussion

Signature of Person Conducting Consent Discussion       Date