

CONSENT DISCUSSION FORM

SUBJECT NAME: _____

STUDY I.D. # _____

WAS THE PATIENT INITIALLY ENROLLED USING DEFERRED CONSENT: **YES** **NO**

If no proceed to back of page to document the informed consent process

Reason informed consent could not be obtained prior to enrolment:

Please document all attempts to make contact with the family to obtain informed consent following enrolment via deferred consent:

DATE (DD-MMM-YY)	TIME (HH:MM)	DESCRIPTION OF CONTACT ATTEMPT	STUDY STAFF INITIALS

WAS INFORMED CONSENT OBTAINED AFTER ENROLMENT VIA DEFERRED CONSENT?

- N/A, INFORMED CONSENT OBTAINED PRIOR TO ENROLMENT**
- YES, OBTAINED FOLLOWING DEFERRED CONSENT**
- NO, REFUSED**

Refused at Date ___/___/___ *and time* ____: ____

Did the legal guardian give permission to:

- Continue data collection?* YES NO
- Analyze the blood sample?* YES NO N/A
- Retain collected data?* YES NO

INFORMED CONSENT Signed

Date ___/___/___ **and time** ____: ____

mm dd yy
24-hour clock

Persons present in consent discussion:

	Name	Relationship/Title
1.	_____	_____
2.	_____	_____
3.	_____	_____

Check either YES or NO for the following questions:

(If the answer is NO to any of these questions, please explain below)

- | | |
|--|--|
| 1. Study purpose, procedures, potential risk & benefit explained? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 2. Were questions from legal guardian encouraged & answered? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 3. Were all questions resolved? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 4. Were all outstanding issues resolved at the end of the discussion? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 5. Did the patient/legal guardian seem to understand the consent form? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 6. Was the patient/legal guardian given time to consider the informed consent? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 7. Was a copy of the informed consent placed in the chart? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 8. Was the patient/legal guardian given a copy of the informed consent? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 9. Was the patient asked for assent? | <input type="checkbox"/> YES <input type="checkbox"/> NO |

Study purpose, specific procedures and potential risks and benefits were explained to the legal guardian by:

Study staff name, printed

Study Staff Signature

Date ___/___/___

mm dd yy