Appendix 3

Informed Consent Form

(Based on IRB Guidebook)

GENERAL INFORMATION

Title of Research	[insert title]
Funding Agency/Sponsor, if any:	
Names of the Leading Researcher and Those Individuals Who will Obtain Consent	
Contact Person Phone Office Hours	[Insert LR name in the absence of a contact person] [insert phone number]

RESEARCH STUDIES: MATERIALS & METHODS

Statement About the Research Studies	[the study involves ……]
Purpose(s) of the Research	
Expected Duration of the Subject's Participation	
Description of the Procedures to be Followed	
Detailed Experimental Procedures	
Approximate Number of Subjects Involved in the Study	
Profile of the Research Subjects	
Circumstances Under Which the Subject's Participation May be Terminated by the Leading Researcher Without Regard to the Subject's Consent	

RISKS & BENEFITS

Foreseeable Risks or Discomforts to the Subject	
Benefits Expected from the Research	
Disclosure	Description of appropriate alternative procedures or courses of treatment if any, that might be advantageous to the subject
Confidentiality Statement	Describe the extent, if any, to which confidentiality of records identifying the subject will be maintained
Medium to High Risks	Explain as to whether any treatments are available if injury damage and, if so, what they consist of, or where further information may be obtained
Subject's Compensation to be expected (if any)	

Consent Statement (Based on *IRB Guidebook*)

Being informed that any particular treatment or procedure may involve risks which are currently unforeseeable; I, [insert name], state hereby that my participation in the research study is voluntary. Any refusal to participate will involve no penalty or loss of benefits to which I am entitled. I may as well discontinue participation at any time without penalty or loss of benefits to which I am entitled.

_____, Signature(s) of the participant(s) or guardian

_____, Signature of the Leading Researcher (LR)

_____, Signatures of the witnesses (where appropriate)

Evaluation criteria: (For experimental purposes only the NDU-IRB will adopt the evaluation criteria as developed in the *IRB Guidebook*).

l. Do the researchers plan to involve a particularly vulnerable subject population?

2. Do the proposed explanations of the research provide an accurate assessment of its risks and anticipated benefits? Is the possibility (or improbability) of direct benefit to the subjects fairly and clearly described?

3. Is the language and presentation of the information to be conveyed appropriate to the subject population? (Consider the level of complexity and the need for translation into a language other than English.)

4. Are the timing of and setting for the explanation of the research conducive to good decision making? Can anything more be done to enhance the prospective subjects' comprehension of the information and their ability to make a choice?

5. Who will be explaining the research to potential subjects? Should someone in addition to or other than the Leading Researcher be present?

6. Should subjects be reeducated and their consent required periodically?

7. Should the NDU-IRB monitor incoming data to determine whether new information should be conveyed to participating subjects? How often should this occur? Who is responsible for bringing new information to the attention of the NDU-IRB between scheduled reviews?

8. If a waiver of some or all of the consent requirements is requested, does the importance of the research justify such a waiver? Is more than minimal risk involved? Can the research design be modified to eliminate the need for deception or incomplete disclosure? Will subjects be given more information after completing their participation? Would the information to be withheld be something prospective subjects might reasonably want to know in making their decision about participation?