Appendix 2

Application Form

(Based on the *IRB Guidebook*[1])

Title of the Study	
Sponsored by	
Purpose	
Concise Summary of Project [200 words]	
Profile of the Research Subjects	
Recruitment Methods and Consenting Process	
Potential Risks (such as discomfort, inconveniences expected)	
Potential Benefits (solution to social/environmental problems, advance of knowledge, treatment of any kind, etc.)	
Subject Safety and Data Monitoring	
Procedures to Maintain Confidentiality	

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

1. Are both risks and anticipated benefits accurately identified, evaluated, and described?

2. Are the risks greater than minimal risk? Has the NDU-IRB taken into account any special vulnerabilities among prospective subjects that might be relevant to evaluating the risk of participation?

3. Has due care been used to minimize risks and maximize the likelihood of benefits?

[1] The *IRB Guidebook*: http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

4. Are there adequate provisions for a continuing reassessment of the balance between risks and benefits? Should there be a data and safety monitoring committee?