Guidelines:
“Letter of Informed Consent”

These guidelines are offered to help you prepare a “Letter of Informed Consent” that meets the needs of your study and complies with federal-wide directives on research involving human subjects. If you have questions, contact IRB Chair and Professor Lauren Dundes (ldundes@mcdaniel.edu) or, if your research involves a grant project, you may contact Robin Dewey in the Office of Academic and Government Grants (rdewey@mcdaniel.edu). The McDaniel IRB web site also provides a sample “Letter of Informed Consent.”

Please be advised that this document is intended to offer a one-page overview and is not a substitute for the detailed guidelines provided by the Office of Human Research Protections (http://www.hhs.gov/ohrp/) on obtaining Informed Consent. That office also posts answers to the most frequently asked questions about Informed Consent (http://www.hhs.gov/ohrp/faq.html).

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(Note: This letter must be in a language understandable to the participant.)

¶ One – Introduction: Introduce yourself, the institution, and your study, then invite the subject to participate.

¶ Two – The Research: where applicable, describe (a) purpose; (b) procedures and methods, specifying if any are experimental; (c) duration; (d) risks that can be maximal, minimal, or foreseeable; (e) benefits to individual and society; (f) alternative treatments available; (g) pledge of confidentiality and process to maintain this; (h) number of people/population of this study.

¶ Three – Consequences of the Research: where applicable, describe (a) compensation and available treatment; (b) the possibility of unforeseeable risks; (c) circumstances under which you would halt the subject’s participation or violate the confidentiality clause; (d) any costs to the subject; (e) process to inform subject of new findings that would affect subject’s decision to participate.

¶ Four – Contact Information: (a) yourself, and (b) McDaniel IRB.

¶ Five – Voluntary Nature of Participation: Assurance that participation is voluntary and subject may withdraw, without penalty or loss of benefits, at any time.

¶ Six – Signatures: Statement that subject’s questions have been answered and s/he wishes to participate in this study, followed by (a) signature of participant, dated, and (b) printed name of participant; where applicable, include signature lines for (c) witness; (d) translator; (e) waiver of anonymity.