REGIS UNIVERSITY

New Protocol Reviewer Form

Section 1: Purpose & Background

Adequate statement of the research problem & specific aims?	Yes ☐	No ☐	N/A ☐
Suitable justification for study involving human participants?	Yes ☐	No ☐	N/A ☐
Comments:			

Section 2: Subject Population(s)/Recruitment

Justifiable source of participant population (medical records, private physicians, advertising)?	Yes ☐	No ☐	N/A ☐
Equitable participant selection with inclusion/exclusion criteria?	Yes ☐	No ☐	N/A ☐
Recruitment procedures ensure voluntary participation?	Yes ☐	No ☐	N/A ☐
Rationale/justification for using special populations including children adequately addressed?	Yes ☐	No ☐	N/A ☐
Additional safeguards incorporated to protect the rights/welfare of participants likely to be vulnerable to coercion/undue influence?	Yes ☐	No ☐	N/A ☐
Comments:			

Section 3: Materials/Data Collection

Adequate description of all activities involving human participants?	Yes ☐	No ☐	N/A ☐
Clear explanation of frequency & duration of each activity proposed?	Yes ☐	No ☐	N/A ☐
Detailed summary of data collection (questionnaires, interviews, observations, standardized tests, etc.) and methods of data recording (audiotape, videotape, computer entry, etc.)	Yes ☐	No ☐	N/A ☐
Clear description and inclusion of all measures, interventions, and instruments used	Yes ☐	No ☐	N/A ☐
Comments:			

Section 4: Potential Risks/Benefits (includes physical, psychological, social, legal, and economic)

Risks (including physical, psychological, social, legal, and economic) to participants are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose participants to risk	Yes ☐	No ☐	N/A ☐

Risks (as stated above) are minimized by using procedures already being performed on the participants for diagnostic or treatment purposes?	Yes ☐	No ☐	N/A ☐
Risks are reasonable as compared to anticipated benefits to participants?	Yes ☐	No ☐	N/A ☐
Risks are reasonable in relation to the importance of the knowledge that may reasonably be expected to result from the investigation?	Yes ☐	No ☐	N/A ☐
Adequate provisions will be made to protect the privacy of participants and to maintain confidentiality of data	Yes ☐	No ☐	N/A ☐
Comments:			

Section 5: Informed Consent

Person(s) from whom informed consent will be obtained is/are appropriate	Yes ☐	No ☐	N/A ☐
Informed consent document includes a space for the investigator signature	Yes ☐	No ☐	N/A ☐
Informed consent is sought under circumstances that give the participant sufficient opportunity to consider whether to participate	Yes ☐	No ☐	N/A ☐
Informed consent is sought under circumstances that minimize possible coercion or undue influence	Yes ☐	No ☐	N/A ☐
Waiver of informed consent is requested for this study	Yes ☐	No ☐	N/A ☐
Comments:			

Section 6: Informed Consent (For Expedited or Full Board studies)

Statement that the study involves research	Yes ☐	No ☐	N/A ☐
Explanation of the purpose of the study	Yes ☐	No ☐	N/A ☐
Description of procedures to be followed	Yes ☐	No ☐	N/A ☐
Identifies procedures that are experimental	Yes ☐	No ☐	N/A ☐
Expected duration of participant's participation	Yes ☐	No ☐	N/A ☐

Description of foreseeable risks or discomforts to the participant	Yes ☐	No ☐	N/A ☐
Description of any benefits expected from the research	Yes ☐	No ☐	N/A ☐
Statement that confidentiality will be maintained	Yes ☐	No ☐	N/A ☐
Explanation of whom to contact for questions about the study	Yes ☐	No ☐	N/A ☐
Explanation for whom to contact regarding research participants' rights	Yes ☐	No ☐	N/A ☐
Statement that participation is voluntary and that refusal to participate will involve no loss or penalty	Yes ☐	No ☐	N/A ☐
Statement that a subject may discontinue participation at any time	Yes ☐	No ☐	N/A ☐
Comments:			

Section 7: Data Safety Monitoring

Adequate safety provisions for monitoring data that ensure the safety of subjects?	Yes ☐	No ☐	N/A ☐
Adequate provisions for ensuring confidentiality of data?	Yes ☐	No ☐	N/A ☐
Comments:			

Section 8: HIPAA & FERPA

HIPAA Authorization included	Yes ☐	No ☐	N/A ☐
Concerns with violating student FERPA rights	Yes ☐	No ☐	N/A ☐
Comments:			

Section 9: Reviewer Recommendations

Approval of the protocol as written	Yes ☐	No ☐	N/A ☐
Approval of the protocol with minor changes (specified below)	Yes ☐	No ☐	N/A ☐
Table protocol until major changes are incorporated and/or additional material is provided for review	Yes ☐	No ☐	N/A ☐
Refer protocol for Full Board Review	Yes ☐	No ☐	N/A ☐

Comments:			

Section 10: Overall Comments

Click here to enter text.