

### Determinations for International Research

Necessary information under DHHS regulations that the investigator must communicate to the IRB in writing includes all of the following:

- the anticipated scope of the institution's research activities       Yes  No  Not Applicable
- the types of subject populations likely to be involved       Yes  No
- the size and complexity of the institution       Yes  No
- institutional commitments and regulations       Yes  No  Not Applicable
- applicable law       Yes  No  Not Applicable
- standards for professional conduct and practice       Yes  No
- method for equitable selection of subjects       Yes  No
- method for protection of privacy of subjects       Yes  No
- method for maintenance of confidentiality of data       Yes  No
- language(s) understood by prospective students       Yes  No
- method for minimizing the possibility of coercion or undue influence in seeking consent       Yes  No
- safeguards to protect the rights and welfare of vulnerable subjects       Yes  No

### Procedural Determinations from SUNY- New Paltz Policy Manual:

- Reviewed by the full IRB, regardless of the nature of the research:  Yes  No
- Research protocol follows basic principles of ethical human participants research:  Yes  No
- All materials, including consent forms, have English language translations included with the protocol  Yes  No  Not Applicable
- In localities where English is not the primary language, all materials presented to subjects must be understandable to them. An authority in the native language must provide documentation that the translated materials adequately convey the content of the English language version presented to the IRB.  Yes  No  Not Applicable
- Documentation of permission from local authorities is required before approval can be granted. (Present, if yes   No
- The investigator has provided the name of an individual(s) who has knowledge and/ or experience in conducting research in the particular location of study.  Yes  No
- Consultation with an authority has occurred.  Yes  No  Not Applicable
- In that the research involves minimal risk to subjects, the IRB obtained the necessary information, related to the research context through written materials from the investigators or others, and/ or discussions with appropriate consultants.  Yes  No  Not Applicable
- In that the research involves greater than minimal risk to subjects, the IRB obtained the federally required information through written materials, personal knowledge on the part of one or more IRB members,

discussions with consultants in person or via electronic means, and in interchange between the IRB and

elements of the local research context, etc.  Yes  No  Not Applicable

- If the project is federally funded, each site that is engaged in research must have a federal- wide assurance

on file with The Office for Human Research Protections.  Yes  No  Not Applicable

- In certain circumstances, a Memorandum of Cooperation may be required.

Yes  No  Not Applicable