Review Criteria by IRB Application Section

|  |
| --- |
| RESEARCH DESIGN |
| Does the application meet the definition of regulatory “research”? i.e. the activity is a systematic investigation designed to develop or contribute to generalizable knowledge. If no, the project is not human subject research. |
| Does the application meet the definition of involving a “human subject”? i.e. a living individual(s) about whom an investigator conducting research obtains data through intervention or interaction with the individual, obtains identifiable private information, or obtains human specimens. If no, the project is not human subject research. |
| If not research, is the project a quality improvement or program evaluation activity?(see [Chart contrasting evaluation and research.](http://www.neomed.edu/research/research-administration/orsp/researchcompliance/irb-folder/resolveuid/982ed30152d04033ae912e4b728426b7)) |
| Does the investigator provide sufficient information to understand the theoretical bases for this study? |
| Are the experiences of the subjects clearly described in the protocol? |
| Are all of the study materials provided, such as questionnaires, interview questions, data collection instruments?  |
| SUBJECT SELECTION |
| Is the subject population described in sufficient detail? |
| Does the researcher say how many subjects he/she hopes to enroll? Is the number listed on the protocol consistent with the number listed on the informed consent sheet? |
| Are all recruitment materials included (e.g., website posting, flyers, letters of introduction)? |
| Do the recruitment materials for adult populations state that subjects must be age 18 or older?  |
| If there are different experimental groups, is it clear how subjects will be assigned? |
| If the study involves using NEOMED students as subjects, is the PI aware of the need to get permission from the College of Pharmacy (Seth Brownlee) and/or College of Medicine (Eugene Mowad)? |
| Is the study environment conducive to the protection of confidentiality?  |
| If the study is to be conducted at another location besides NEOMED, have the appropriate letters of support/permission to enter the facility and conduct the research been obtained?  |
| Have cultural and social considerations been taken into account when enrolling and consenting subjects? |
| Are the risks presented in the protocol minimized?  |
| Are foreseeable risks reasonable in relation to anticipated benefits? |
| If no benefits to individual subjects are likely, are the benefits to society at large or to the field of study stated in the protocol? |
| CONFIDENTIALITY |
| Are all direct and indirect identifiers clearly described in the protocol? |
| Are the terms “confidentiality” and “anonymous” used correctly throughout the protocol and consent forms? |
| If identifiable data about illegal activities are to be collected, does the researcher intend to secure a Certificate of Confidentiality? |
| If subjects are to be videotaped, photographed, or audio-taped, and the recordings will be made publicly accessible, is a release form provided?  |
| If the data are to be collected and stored via the Internet, is the data protection plan technologically sound? (This may signal the need for review by the IT department for security concerns.) |
| Are there any limits to the confidentiality that the researcher can provide, e.g. the requirement to report suspected child abuse? |
| COMPENSATION |
| Is the compensation offered appropriate for the study and relevant to the level of effort required by the subject? |
| If subjects will be required to provide their social security numbers in order to receive payment, have the subjects been informed? |
| If the study is funded, does the PI understand that compensation must be an allowable cost to the sponsor as determined by the Grants Accounting department? |
| INFORMED CONSENT |
| Is the consent form/information sheet consistent with how the project is described in the protocol?  |
| Is the informed consent process culturally appropriate? |
|  *Adequate Comprehension:*  |
| Will the subjects understand the terminology used and is the reading level appropriate? |
| If the subjects' primary language is not English, has the researcher provided the consent form in the appropriate language, in addition to the English version? Is a back translation needed? |
|  *Voluntary Participation:*  |
| Is the researcher in a position of authority over the research subjects? If so, has the possibility of undue influence been addressed?  |
| If subjects are offered the right to withdraw their data, is there a clear mechanism for doing so? |
| If the researcher's own students or employees will be subjects of the research, is the potential for perceived undue influence adequately managed? |
| If the researcher wishes to contact the subjects in the future, has it been explained how and why that contact will take place, and do subjects have the option to decline further contact? |
| If the subjects are students, have they been informed that participation will not affect their academic standing? |
|  *Questions /Contacts:*  |
| Does the consent process allow the subjects to ask questions before making a decision to participate? |
| Is contact information provided for subjects who have questions during the course of the research or after the research?  |
| If the research will be conducted abroad or in a low-technology environment, would it be appropriate to identify a local contact that could answer questions about subjects' rights? |
|  *Documentation of Consent:*  |
|  If the subjects are illiterate, and documentation of consent is required, is the procedure respectful and culturally appropriate?  |
|  When research will take place on-line, does the protocol request a waiver of the requirement for a written consent?  |