FERRIS STATE UNIVERSITY
Institutional Review Board for Human Subjects in Research
Office of Academic Research, 220 Ferris Drive, PHR 308 · Big Rapids, MI 49307

Reviewer Checklist

Required Materials	YES	NO	NA	NOTES
Is the PI a regular level 2 or level 3 adjunct faculty or emeriti of FSU?				
Is appropriate CITI certification attached?				
Have all investigators signed the application?				
Does the project involve living individual(s) or data about living individual(s)?				
Is the project a *systematic investigation* (designed using step-by-step procedures organized according to a set of interrelated ideas/principles)?				
Is the project intended to develop or contribute to *generalizable knowledge* (benefits that extend beyond immediate population to society, other researchers, sholars, etc.; draws conclusions, tests or generates a hypothesis; publication or presentation to inform a field of study; or contributes to a theoretical framework or body of knowledge)?				
Research Design				
Does the investigator provide sufficient detail to understand the basis of the study?				
Is the study design sound?				
Is the experience of the subjects clearly described?				
Are all of the study materials attached (questionnaires, interview materials, etc.)?				
If the research is funded/seeking funding, is the agency or FSU department identified? Is a copy of the grant award included?				
Should funding not be awarded, is a statement included regarding how the project will be adjusted?				
Is the research category selected (exempt, expedited, full) appropriate?				
If the research is being conducted at another institution or agency outside Ferris State Univeristy, is outside IRB approval included?				
Subject Selection & Recruitment				
Is the subject population described in sufficient detail?				
Does the researcher say how many subjects he/she hopes to recruit?				
Does the researcher describe where recruitment will occur and by whom?				
Are all recruitment materials included (flyers, letters of introduction, etc.)?				
Do the recruitment materials state that the subject must be age 18 or older?				
If emails will be sent to recruit, does the investigator have permission to use emails?				
If a study population is excluded, is the risk to that population justified?				
Coercion and Compensation				
Is the researcher in a position of authority over the resesarch subjects? If so, how can the possibility of undue influence be addressed?				
If compensation is offered, is it appropriate for the study?				
If compensation is offered, will payment information be kept separate from study data?				
If participants will incur financial costs, has the investigator exposed this information?				
If extra credit is offred to participants, is a similar extra credit option offered for those who decline to participate?				
Use of Drugs, Medicial Devices or Biologics				
Are all drugs, medicial devices or biologics approved by the FDA?				
If FDA approval is not granted, is appropriate exemption for investigational devices included?				
Risks & Benefits				
Are there any foreseeable risks to the subjects?				
Are risks minimized?				
Are foreseeable risks reasonable in relation to anticiapted benefits?				
If no benefits to subjects are likely, are there benefits to society or to the field of study?				
Confidentiality				
Have all direct and indirect identifiers to be collected been described?				
If relevant, has the plan for protecting the confidentiality of the data been described, including storage (location, duration) of the data and access by others?				
If subjects are to be videotaped, photographed, or audio-taped, and the recording will be made publicly accessible, is a release included in the consent?				
Are there any limits to the confidentiality that the researcher can provide (requirement to report suspected child abuse)?				
Has the storage and access for consent forms been described?				
HIPAA & FERPA				
Does the protocol describe a plan to protect subject privacy?				
Does the protocol describe a plan to protect confidentiality of Protected Health Information (PHI) and/or specimens?				
Does the protocol describe Protected Health Information (PHI) to be collected prior and/or after consent and why? Is it explained who PHI will be disclosed to?				
Informed Consent				
Does the consent form contain a reason for approaching potential subjects?				
Is it clear that participation in the study is voluntary?				
Dose the consent form contain the name(s) of invesitigator(s)?				
Is contact information provided for subjects who have questions during the course of the research or after the research? Is the contact information provided in an appropriate manner (i.e., contact cards in the absence of writtten consent)?				
Is contact information for the appropriate IRB included should subjects have study concerns?				
Does the consent provide a pupose for the study and a description of activities?				
Does the consent provide a duration of subject's participation?				
Are anticipated risks and potential benefits described? If none are anticipated, is that described?				
If applicable, are available alternative therapies/treatments provieded?				
If applicable, is treatment of injuries resulting in participation described?				
If applicable, is a clear description provided of costs that would be the responsibility of the subject and/or the subjects' insurer?				
Is there sufficient information for a potential participant to make an informed decision about whether to participate?				
Are there any other factors that would unduly influence the decision of participants?				
Are subjects offered their right to withdraw from the study at any time?				
Is there a clear mechanism for how data will be handled should subjects decide to withdraw?				

Does the consent describe use and disclosure of study data, to whom and for what purposes?				
Does the consent describe any compensation to subjects?				
Consent Process				
Is the consent process consistent with the protocol?				
Does the consent process allow subjects to ask questions before making a decision to participate?				
Is the informed consent process respectful and culturally appropriate?				
Will the subjects understand the terminology used? Is the reading level appropriate?				
If there is more than one subject population, is more than one consent form needed?				
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 translation needed?				
Is there a plan in place to consent illerate individuals?				
If child assent is required, is it appropriate to the children's developmental stage and situation?				
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 researcher has requested a waiver of consent documentation, can the waiver be approved in accordance with the federal regulations (are risks minimal)?				
When research will take place on-line (survey tool, etc), does the protocol request a waiver to document consent?				
If waiver of consent documentation is requested, is a copy of the consent elements available for subjects?				
Deception				
If the resesarch involves deception, is the deception justified?				
Are the subjects appropriately debriefed about the deception?				
If the debriefing is given at a time other than immediately following participation, is this justified?				