Waynesburg University
Checklist for IRB Protocol Submission

Criterion	Faculty Member/PI	IRB designee approval/comments
Approval of course faculty member or capstone chair		
All principal investigators (PI) and all sub-investigators (SI) have read Waynesburg University's IRB guidelines **AND** completed NIH Protection of Human Subjects education OR the Social and Behavioral Science Module of CITI training		
Consent form: • Copied on department letterhead of principal investigators • Written at 6th grade reading level of lower (Limit the use of 3+ syllable words) • Includes contact information for: ✓ Principal investigator **and** ✓ IRB chair: Dr. Sara Clutter, 724-852-3236 or sclutter@waynesburg.edu • Includes statement of confidentiality/anonymity • Includes statement that not all questions must be answered • Includes statement that participation is voluntary • Includes statement that human subject can terminate participation at any time without consequence • Includes an explanation of alternative options • If an intervention study, includes language related to assignment to control or experimental group		

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• Includes language related to risks and benefits • Includes language related to compensation and/or cost to participant • Include same elements on Assent Form – at comprehension level of intended children		
Includes permission to use or freedom from copyright for **ALL** measurement tools/ surveys/ questionnaires intended to be used		
Includes abstract (**BRIEF** summary of the purpose and procedures, written in language which can be understood by someone who is not a specialist in your field).		
Includes detailed description of research methodology or quality improvement plan (includes specific aims of the project, complete but concise description of the procedures, including nature and location of ALL contacts with human subjects). This should be written in language easily understood by someone who is not a specialist in your field. If it is necessary to include terminology specific to your specialty/discipline, you may include a glossary of terms for reviewers to reference as needed.		
Includes all advertisements intended to be used (paper, electronic, e-mail, media, etc.) to recruit subjects		
Includes description of how both paper and electronic data will be stored, secured, and destroyed.		

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All sections of the protocol application are complete – including signatures, descriptions of settings, and attachments, as requested		
Are **ANY** element of protected health information being used/accessed? If yes, access to these elements must be include in informed consent or a HIPAA waiver form must accompany the IRB protocol or QI application (please refer to HIPAA waiver form for a list of the elements of protected health information)		
If the proposed study involves deception, the principal investigator has addressed why deception is necessary and discussed alternatives to the research methodology if deception of human subjects is not approved		