Requirements for a script

By definition, "exempt" research is exempt from the requirement for a signed consent form. Nevertheless, the ethical principles listed in the Belmont Report, particularly the discussion of the first principle, respect for persons, emphasizes the importance of ensuring that subjects are fully informed about the nature of the research project so that they can make an informed decision to participate or not. An "informational script," provides that kind of information. Such a script should be used in all exempt research that involves interaction with subjects.

This script can be presented in a number of ways, depending on the research design, but should be presented to all potential subjects before they are asked whether they are willing to participate. For example, it could be presented in recruitment material, such as a letter or email, can be read aloud, or can be presented as the first screen of an online survey. Include this script only once, in the recruitment section, and be clear in your protocol how it will be presented.

Ensure that the form is in layman terminology (an 8th grade reading level is preferred). Guidance on plain language can be found here: Home | plainlanguage.gov. When presented in text, ensure that the script is in a clear font. Some experts say simple fonts, called "san serif", like Arial, Calibri, Tahoma are better for reading than Times New Roman, and size 12 is recommended.

Below are the elements that should be considered, but they must be revised to be protocol-specific. Do not use text that is not consistent with your study design.

Topic / Issue	Sample text
State the purpose of the study, consistent with the Study Aims section of your protocol. Note that if the purpose is presented in a way in which you intentionally choose to exclude some information, it is likely that your study includes a planned deception. [link to guidance once it is created]. Be sure to include the word "research".	*The purpose of this research study is to _____.*
Describe the study population and procedures, consistent with the Study Design and Research Activities sections. If you may be audio and/or video recording any study procedures, this must be explained.	*We will be asking _____[number and type of subjects] to _____[description of tasks, topics of any surveys/interviews/focus groups, duration and location].*
Describe risks and benefits, consistent with the Risk and Benefits section. Risks in an exempt study are typically limited to the potential for breach of confidentiality and/or discomfort answering questions. Be very careful that you do not refer to the study being anonymous unless you will not know the subject's identity at any time (for recruitment, scheduling, payment, etc.). Note that it is extremely rare that there is direct benefit to subjects.	*There are no foreseeable risks associated with this project.* Or *Risks of this study include _____. To minimize this risk, we will ____ .* *There are no direct benefits to you.* Or *Potential benefits include _____.*
Describe any incentives, consistent with the Recruitment section:	*Participants will receive _____ as a token of our appreciation.*
Include a statement that participation is voluntary.	*Your participation is voluntary.*
Include a withdrawal statement. Note that if the study is truly anonymous (you	*You can withdraw from this study at any time. To do so, _____ [include instructions, such as contacting the PI].*

will not have identifiers for any reason such as recruitment, scheduling, payment, linking two timepoints, etc.), the study team would not be able to withdraw data because they would not be able to identify the data belonging to the specific subject. In this case, they can stop participating.	Or *You can stop participating at any time by _____ [include instructions, such as closing the web browser, informing an interviewer, etc.]*
Include a statement of consequences.	*If you choose not to participate, or if you do not complete the study, this will have no effect on your relationship with _____ [list applicable entities associated with the study team that the subject population could potentially have other affiliations with, such as the University of Pittsburgh, UPMC, their specific doctor(s), a specific instructor /course /supervisor /department, etc.]*
Include contact information Include only Pitt / UPMC phone numbers and/or email addresses – no personal contact methods can be used. If fitting, you should also include the advocate phone number	*This study is being conducted by _____ [PI], who can be reached at _____, if you have any questions.* And possibly *You may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss concerns.*
Include an assessment of agreement and necessary further instruction as to how to participate.	*Would you like to participate? (if speaking with the potential subject)* Or *If you would like to participate, _____. [Include instruction such as "click here to proceed to the online survey."]*
Address sharing for future research Restrictive language is not recommended	*At some point, your identifiers might be removed from the private information and/or biospecimens. This de-identified information and/or biospecimens may be used by other researchers or for-profit companies for future research studies. If this happens, we will not contact you for additional consent*
<u>The following are elements that should be included only if applicable to your particular study:</u>	
If data is collected online (by email, through videoconferencing, through an online questionnaire, etc.) and information could potentially be of a sensitive nature:	*Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.*
In the rare case that data collection could result in reportable information, such as risk of harm to self or others:	*In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.*
If your study involves compensation, include the amount as well as any other relevant information such as the timing or method of payment	*You will be compensated $_____ for your time.*