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| **Always ensure that you have reviewed the most current guidance** for this category on the [HRPO website](http://www.hrpo.pitt.edu) (see “Exempt” review) and that you are using the most current version of this exempt form. Ensure that you have reviewed the guidance. **This form should rarely be used. Projects that are not human subjects research should not be submitted for IRB review, with rare exception.** |
|  |
| Name of Principal Investigator:  |
| Study Title:  |
| Study Number: STUDY |
|  |
| 1. Will any information from this project be submitted to the Food and Drug Administration (FDA)? If Yes,  and contact us at askirb@pitt.edu for assistance.
 | [ ]  Yes [ ]  No |
| 1. Are the data being studied in this project obtained in a systematic manner?
 | [ ]  Yes [ ]  No |
| 1. Is the intent of this data collection to contribute to ‘generalizable knowledge’ - that is the findings are applicable to sites outside the University of Pittsburgh / UPMC?

If No, explain:      * + If No, and if this project is being conducted at a UPMC facility, has it been submitted to the UPMC QA/QI committee? [ ]  Yes [ ]  No

Note: If you are submitting this project to the UPMC QA/QI committee, or a similar review committee, you need not complete this form. | [ ]  Yes [ ]  No |
| 1. Does your study meet the following conditions?

i. No member of the research team has interacted or intervened, for research purposes, with the individuals whose data/specimens will be studied (note: if any members of this study team are/were affiliated with a project you will obtain data/specimens from, you may not qualify for this determination), ANDii. No identifiable private information will be reviewed or recordedIf No to either, this project does not qualify for a “no human subjects” determination.  and contact us at askirb@pitt.edu for assistance. | [ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| 1. Will the planned activity involve accessing or using data and/or specimens?

If Yes, complete the “Secondary Research with Data/Specimens” form instead of this form. | [ ]  Yes [ ]  No |
| Additional information, clarification, or comments for IRB review:  |

Reminders:

* After completing this document, save it to your computer and then upload into PittPRO, **Basic Information page, item 8**.
* For External (non Pitt/UPMC) sites, upload site permission letters in PittPRO, **on the Research Sites page, select “External Sites/Other, and attach the permission letter in item 2.**
* If applicable, upload the introductory script in PittPRO, **on the Recruitment Methods page, item 5.**
* Upload any interview questions, questionnaires/surveys, focus groups guides, etc. into PittPRO, **on the Research Activities page, item 2.**
* If data will come from, or will be sent to, another institution, you must consult with the University of Pittsburgh [Office of Research](http://www.research.pitt.edu/) regarding any necessary transfer agreements.
	+ If you intend to share electronic data, this must be addressed in PittPRO, **Electronic Data Management page**.
	+ If you intend to share data in a paper format, this must be addressed in PittPRO, **Data Safety and Monitoring page**.