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| This is NOT a commonly utilized form. It is recommended that you contact [askirb@pitt.edu](mailto:askirb@pitt.edu)to determine whether your study meets the exempt criteria for this new category. Please read Question #4 carefully as this is a new requirement of this exemption. | |
| **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. | |
|  | |
| 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](mailto:askirb@pitt.edu) for assistance. | Yes  No |
| 1. Is the research or demonstration project conducted or supported by a Federal Department or Agency Head or otherwise subject to the approval of department or agency heads (or approval of heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects)?   If No, contact us at [askirb@pitt.edu](mailto:askirb@pitt.edu).  If Yes, provide the name, department, and title of the individual conducting the project or providing approval: | Yes  No |
| 1. Is the program designed to study, evaluate, improve or otherwise examine a public benefit or service programs including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs?   Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects should also include waivers of otherwise mandatory requirements using authorities such as sections 1115 (https://[www.ssa.gov/OP\_Home/ssact/title11/1115.htm)](file:///C:\Users\dad85\Box%20Sync\IRB%20Workspace%20(M%20Drive)\2018%20Common%20Rule%20Changes%20-%20Exempt%20Categories\PittPRO%20forms\www.ssa.gov\OP_Home\ssact\title11\1115.htm)) and 1115A (https://[www.ssa.gov/OP\_Home/ssact/title11/1115A.htm](file:///C:\Users\dad85\Box%20Sync\IRB%20Workspace%20(M%20Drive)\2018%20Common%20Rule%20Changes%20-%20Exempt%20Categories\PittPRO%20forms\www.ssa.gov\OP_Home\ssact\title11\1115A.htm)) of the Social Security Act, as amended.  If No, contact us at [askirb@pitt.edu](mailto:askirb@pitt.edu).  If Yes, name and describe the program and the public benefit it delivers: | Yes  No |
| 1. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision.   *The research or demonstration project MUST be published on a publicly accessible Federal web-site or in such other manner as the department or agency head determined prior to commencing the research involving human subjects. (REQUIRED)*  Has this research and/or demonstration project been published to a publicly accessible Federal web-site or in such other manner as the department or agency head determined prior to commencing the project?  If No, contact us at [askirb@pitt.edu](mailto:askirb@pitt.edu).  If Yes, please provide the link or location of this website: | Yes  No |
| 1. Please provide information about how the project will be conducted using the appropriate exempt form. Depending on the Research Activity, complete the most appropriate form and upload OR contact [askirb@pitt.edu](mailto:askirb@pitt.edu).   Exempt Category – Tests, Surveys, Interviews, or Observations of Public Behavior  Exempt Category – Secondary Research with Data and/or Specimens |  |
| 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 all 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**