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| --- | --- |
| In some cases, individuals under 18 years of age can be evaluated with educational tests (not surveys or interviews). They can also be passively observed in public places, but only so long as researchers do not participate in the activities being observed or interact with the children. | |
| **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. Does this study involve any intervention?   If Yes or Unsure,  and contact us at [askirb@pitt.edu](mailto:askirb@pitt.edu) for assistance  \*Note: ‘Intervention’ includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes. | Yes  No |
| 1. Will participants under 18 years of age be studied?  * If Yes, is this study limited to passive observation of public behavior and/or educational tests?  Yes  No   + If No, as this exempt category is not applicable. Contact us at [askirb@pitt.edu](mailto:askirb@pitt.edu) for assistance. * If Yes, also address the following:  1. Provide a rationale for the specific age ranges of the children to be studied: 2. Describe the expertise of the study team for dealing with children of that age range: 3. Describe the adequacy of the research facilities to accommodate children of that age range: 4. If applicable, describe how the parents will be informed or involved in this project: | Yes  No |
| 1. Will information be recorded anonymously (no participant identifiers or codes that can be used to re-identify subjects will be recorded, even temporarily)?   If No, provide a justification for recording identifiers: | Yes  No |
| 1. Will sensitive information be recorded that could damage participants’ reputation or employability, financial standing, educational advancement, etc. or place them at risk for criminal or civil liability?   If Yes, describe the sensitive data that will be collected and justify the need for this data: | Yes  No |
| 1. Upload the introductory script in PittPRO, on the Recruitment Methods page, item 5. An [Introductory Script Sample](http://www.hrpo.pitt.edu/guidance#i) is available on the HRPO website. An introductory script should be used unless this study is limited to passive observation of public behavior.   If not applicable, explain: |  |
| 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**.