

<b>PARKVIEW HEALTH</b>	<b>INSTITUTIONAL REVIEW BOARD MANUAL</b>
Policy & Procedure Title: Exempt Research Protocols Category: IRB Review P&P	

## I. Policy Statement

The regulatory guidelines under which the PH IRB operates permit certain types of Protocols to be pursued without the necessity of full PH IRB review.

Refer to PH IRB Exempt Research List of Categories of Research. Also see Checklist for Exempt Research.

## II. Definition of Terms

Existing Data: Data that is in existence at the time of proposal to the PH IRB.

## III. Procedure

- A. To apply for an Exempt Research Protocol review, an Investigator must submit a PH IRB Protocol Submission Form to the PH IRB.
- B. The PH IRB Office may determine if the research Protocol qualifies for an Exempt category.
- C. If the Protocol is found to be Exempt from review, the Investigator will be notified in writing.
- D. If the Protocol does not qualify for the Exempt category, the Investigator will be contacted and a complete Protocol must be submitted for full Board review.
- E. If an Investigator is not sure whether the research qualifies for one of the Exempt categories, the Investigator may contact the PH IRB Office for clarifications.

## IV. References

- A. [21 CFR 56.104](#)
- B. [45 CFR 46.101\(b\)](#)
- C. OHRP Guidance: Exempt Research and Research That May Undergo Expedited Review (05-05-1995) at:  
<http://www.hhs.gov/ohrp/humansubjects/guidance/hsd95-02.htm>

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