

SOP: FO 302 Version No: 2 Effective Date: 03/27/06	RESEARCH EXEMPT FROM IRB REVIEW	Supercedes Document Dated: 10/01/04
---	--	--

1. POLICY

Research activities in which the only involvement of human subjects will be in one or more specific categories, which are listed in section 1.1 of this policy, may be exempt from IRB review. Determination of exemption must be based on regulatory and institutional criteria and documented. Project may be re-reviewed by the IRB at anytime to determine whether the study continues to meet the exempt status.

Specific Policies

1.1 Exempt Research Activities

A research project is identified as **exempt from full IRB review** if it involves no more than minimal risk¹ **and** only involves human subjects (or materials of human origin) in one or more of the following categories:

- 1. Research conducted in **established or commonly accepted educational settings, involving normal educational practices**, such as:
 - i. Research on regular and special education instructional strategies,
 - ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2. Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures or observation of public behavior², unless:**
 - i. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
 - ii. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. *(Also see Expedited category #7).*
- 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt, **if:**
 - i. **The human subjects are elected or appointed public officials or candidates for public office;** or
 - ii. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4. Research involving the **collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens**, if these sources are publicly available or if the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. *(Also see RR 401 - Expedited category #5.)*

- 5. Research and demonstration **projects which are conducted by or subject to the approval of Department of Health and Human Services**, and which are designed to study, evaluate, or otherwise examine:
 - i. Public benefit or service programs;
 - ii. Procedures for obtaining benefits or services under those programs;
 - iii. Possible changes in or alternatives to those programs or procedures; or
 - iv. Possible changes in methods or levels of payment for benefits or services under those programs.
- 6. **Taste and food quality evaluation and consumer acceptance studies:**
 - i. If wholesome foods without additives are consumed, or
 - ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- 7. Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review (*Also see SC 502 – Emergency Use*).

1.2 Special Considerations

These exempt categories do not apply to research involving:

- a. Deception of subjects where the Investigator does not disclose the true purpose of the research and/or the results of the subject's participation in the study,
- b. Sensitive behavioral research, or research involving pregnant women, in vitro fertilization, prisoners, the mentally disabled, or other "vulnerable" populations).

The use of voice, video, digital, or image recordings automatically raises the status of a project to Expedited (*See RR 401 – Expedited category #6*). This is one of the most common misclassification errors found in applications.

Categories #1 through #6 **cannot** be used for classified research or research involving prisoners. **Note:** The IRB does not currently allow for use of prisoners in research involving human subjects at Sparrow Health System facilities.

Categories #1 through #5 **cannot** be used for research to which FDA regulations and policies apply.

¹Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

² The exemption for research involving survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

- Children are defined in the HHS regulations as “persons who have not yet attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.”

2. SCOPE

These policies and procedures apply to Investigator claims for exemption from IRB review.

3. RESPONSIBILITY

IRB Administrator is responsible for evaluating submissions that claim exemption from IRB review, maintaining follow-up status to assure project continues to meet the criteria for Exemption.

IRB Chairperson (or designee) is responsible for providing consultation in the review of claims of exemption.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.101

45 CFR 46.102

21 CFR 56. 104, 105

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs

6. ATTACHMENTS

FO 302-A	Exemption Screening Questions
FO 302-B	Claim of Exemption
FO 302-C	Claim of Exemption Checklist for Staff
CO 601-M	Exempt Determination Letter

7. PROCESS OVERVIEW

The IRB Administrator, IRB Chairperson, or designee, shall review the protocol to determine if the study is eligible for exemption, is of minimal risk, and is consistent with the Exemption Checklist (FO 302-C). This checklist shall be completed and signed by the reviewer. If study is ineligible for exemption, it will be reviewed for expedited or full board review, and the investigator will be so informed. The Principal Investigator is to be notified using the Exemption Disqualification Notice (CO 601-L) if the study is determined to be ineligible for Exempt status. If the protocol is non-exempt, the IRB Administrator, Chairperson, or designee will determine its eligibility for expedited or full board review.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Coordinator</i>	Maintain and make available submission information regarding research that is exempt from IRB review.	Claim of Exemption
<i>IRB Administrator</i>	Review claims of exemption, confirm by signature and route to IRB Coordinator for processing, announcing in agenda and for filing.	Claim of Exemption Checklist for Staff CO 601-M – Exempt Determination Letter
<i>IRB Administrator and/or IRB Coordinator</i>	If project is disqualified for Exemption from IRB Review, an Exemption Disqualification Notice to be sent to Principal Investigator	CO 601-L – Exemption Disqualification Notice
<i>IRB Chairperson</i>	Provide guidance to IRB Administrator on Claims of Exemption as needed and requested.	