



Mercy Medical Center – Des Moines Institutional Review Board

Exemption Status Application

Preparing Exemption Status Application

1. Please submit a typewritten and completed application.
2. In order for Exemption Status to be granted, there must not be any way to identify subjects. If a master list of subjects is kept, Exemption status does not apply.
3. There are six categories of exemption. In order to be granted Exemption Status your proposed protocol must meet criteria for any one **WHOLE** exemption. (not just part of it)
4. This application will not be processed if not completed. This could result in your trial being tabled.

To move through this document, please keep document “locked” and use “Tab” key.

Please forward documents

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Institutional Review Board
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Institutional Review Board
Exemption Status Application

1. Project Information

PLEASE PROVIDE ALL REQUESTED INFORMATION

Principal Investigator: _____

Site: _____

Name of Study: _____

Duration of Study: _____

Purpose of the Study: _____

2. Determination of Exemption Status

CHECK ALL THAT APPLY

| | |
|--------------------------|---|
| <input type="checkbox"/> | <p><u>Exemption #1: Normal Educational Practices and Settings</u> Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</p> |
| <input type="checkbox"/> | <p><u>Exemption #2: Anonymous Educational Tests, Surveys, Interviews, or Observations</u> Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, 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.</p> |
| <input type="checkbox"/> | <p><u>Exemption #3: Identifiable Subjects in Special Circumstances</u> Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Exemption #2 if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) the federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.</p> |
| <input type="checkbox"/> | <p><u>Exemption #4: Collection or Study of Existing Data</u> 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 CAN NOT be identified, directly or through identifiers linked to the subjects.</p> |
| <input type="checkbox"/> | <p><u>Exemption #5: Public Benefit or Service Programs</u> Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, 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, and (iv) possible changes in methods or levels of payment for benefits or services under those programs.</p> |
| <input type="checkbox"/> | <p><u>Exemption #6: Taste and Food Evaluation and Acceptance Studies</u> Taste and food quality evaluation studies that do not involve consumption by the subject of any type or volume of food that has any potential risks such as indigestion or vitamin deficiencies.</p> |

If one or more of these exemptions is marked, you will need to complete this application.

If none of these exemptions are marked then your proposed research does not meet the criteria for an exempt status study. You will need to either fill out the IRB's Waiver of Consent and use of PHI Application or the Application for Human Research form.

3. Data Collection

PLEASE PROVIDE ALL REQUESTED INFORMATION

| | | Yes | No |
|----|--|--------------------------|--------------------------|
| 1. | Are you applying for exemption status in order to conduct research on subject's medical records? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. | Will anyone involved with this research be maintaining a "Master List" that would be able to link the subject to the data. <i>If answer is, "Yes" DO NOT COMPLETE THE REST OF THIS APPLICATION. CALL THE IRB OFFICE.</i> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. | Approximately how many subject's will be used to collect data | | |
| 4. | Give in detail the information that will be collected (<i>i.e. Age, Lab Value, Type of Procedure, etc.</i>) | | |

4. Risk

PLEASE PROVIDE ALL REQUESTED INFORMATION

| | | Yes | No |
|----|---|--------------------------|--------------------------|
| 5. | Does this research involve more than minimal risk to the subjects? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. | Will granting exemption status adversely effect the rights and welfare of the subjects? | <input type="checkbox"/> | <input type="checkbox"/> |

6. Required Documentation

PLEASE SUBMIT ALL DOCUMENTATION WITH APPLICATION

| | |
|----|---|
| 7. | Summary of proposed data collection. Please include scientific rationale, purpose, and hypothesis |
| 8. | Any form or tool to be used to help collect data. This includes checklists and/or case forms. |
| 9. | Any additional forms, tools or summaries to be used in conjunction with this study |

7. Signatures

As Primary Investigator of the study being submitted for review, I make the following assurances:

- I will notify the IRB should there be any changes of status to this waiver.
- There will be no Personal Health Information (PHI) maintained that would be linked to the subject or the subject's medical records
- The data collected in this research will not have any subject identifiers recorded

Primary Investigator Name (Printed)

Primary Investigator Signature

Date