**Mount Carmel Institutional Review Board**

Date Received:

IRB Protocol #:

Determination:

[ ] Qualifies for Exemption

[ ] Does not qualify for Exemption

Chairperson Date

Mount Carmel Institutional Review Board

**For Office** **Use Only**

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| **Office of Research Affairs/IRB Office****Mount Carmel Corporate Services Center****6150 East Broad Street / Columbus, OH 43213****Phone: 614-546-4325 | Fax: 614-546-4328** **Email: irb@mchs.com** |

**Request for Exemption**

**If the ONLY involvement of human subjects will be in one or more of the following categories AND all the answers in one or more categories is ‘Yes’ (or not applicable), the research may be eligible for exemption. However, the research must be declared exempt by the IRB on the basis of the following answers, and responses on the IRB submission form. Check only the categories which apply to the research being reviewed.**

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| **Category 1: For Educational Settings:**  |
| [ ]  Yes [ ]  No | The research will only be conducted in established or commonly-accepted educational settings including but not limited to schools and colleges. (May include other sites where educational activities regularly occur.) |
| [ ]  Yes [ ]  No | The research will involve only 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. |
| [ ]  Yes [ ]  No | The research will not involve individuals as participants who are known to be prisoners. |
| [ ]  Yes [ ]  No | The research is not subject to FDA regulations. |
| **Category 2: For Educational Tests, Surveys, Interviews, Public Behavior Observation:**  |
| [ ]  Yes [ ]  No | The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. |
| [ ]  Yes [ ]  No[ ]  N/A | ***Address this statement only if the research will involve children as participants. If children will NOT participate, check N/A and continue to the next statement.***The procedures will be limited to the use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior where the investigator will NOT participate in the activities being observed. |
| [ ]  Yes [ ]  No | **\***The information obtained from educational tests, survey procedures, interview procedures or observation of public behavior will be recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects.  |
| [ ]  Yes [ ]  No | **\*** Any disclosure of the human subjects' responses outside the research could NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. |
| ***\*‘Yes’ to either of these statements will qualify for exemption provided that BOTH of the following statements are true.***  |
| [ ]  Yes [ ]  No | The research will not involve individuals as participants who are known to be prisoners. |
| [ ]  Yes [ ]  No | The research is not subject to FDA regulations. |
| **Category 3: For Educational Tests, Surveys, Interviews, Public Behavior Observation of Public Officials:** |
| [ ]  Yes [ ]  No | **\*\***The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND the human subjects are elected or appointed public officials or candidates for public office. (Applies to senior officials such as mayor or school superintendent rather than a police officer or teacher.)  |
| [ ]  Yes [ ]  No | **\*\***The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. |
| ***\*\*‘Yes’ to either of these statements will qualify for exemption provided that BOTH of the following statements are true.*** |
| [ ]  Yes [ ]  No | The research will not involve individuals as participants who are known to be prisoners. |
| [ ]  Yes [ ]  No | The research is not subject to FDA regulations. |
| **Category 4: For the Secondary use of Data, Documents and Specimens:**  |
| [ ]  Yes [ ]  No | The research will involve only the study of **private, individually identifiable** data, documents, records, pathological specimens, or diagnostic specimens collected for clinical purposes.  |
| [ ]  Yes [ ]  No | The information will be recorded by the investigator in such a manner that participants cannot be readily identified either directly or through identifiers (such as a code) linked to them. The investigator will not attempt to re-identify or contact the research subjects.  |
| [ ]  Yes [ ]  No | The research will not involve individuals as participants who are known to be prisoners. |
| [ ]  Yes [ ]  No | The research is not subject to FDA regulations. |
| **Category 5: For Public Benefit or Service Programs (Federal):**  |
| [ ]  Yes [ ]  No | The project is a research or demonstration project conducted by or subject to the approval of a (federal) Department or Agency head and which is 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 public benefit or service programs. |
| [ ]  Yes [ ]  No | The research will not involve individuals as participants who are known to be prisoners. |
| [ ]  Yes [ ]  No | The research is not subject to FDA regulations. |
| [ ]  Yes [ ]  No | The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act). |
| [ ]  Yes [ ]  No | The research or demonstration project will be conducted pursuant to specific federal statutory authority. |
| [ ]  Yes [ ]  No | There is no statutory requirement that the project be reviewed by an IRB. |
| [ ]  Yes [ ]  No | The project does not involve significant physical invasions or intrusions upon the privacy of participants. |
| [ ]  Yes [ ]  No | The exemption has authorization or concurrence by the funding agency. |
| **Category 6: For Taste and Food Quality and Consumer Acceptance Studies:**  |
| [ ]  Yes [ ]  No | The research involves only a taste and food quality evaluation or a food consumer acceptance study in which (i) wholesome foods without additives will be consumed OR (ii) food will be consumed that contains a food ingredient, agricultural chemical or environmental contaminant that is at or below the level found to be safe by the Food and Drug Administration or is approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. |
| [ ]  Yes [ ]  No | The research will not involve individuals as participants who are known to be prisoners. |

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| Administrative Information |
| Study Title: |       |
| Proposed length of research study | Estimated Start Date: |       | Projected Completion Date: |       |
| **Principal Investigator Information** |
| Name: |       |
|  | [ ]  M.D. [ ]  D.O. [ ]  Ph.D. [ ]  R.N. [ ]  Other, specify:  |
|  | Human Subject Protection Training Completed. [ ]  Yes [ ]  No |
| Address: |       |
| Telephone: |       | Fax: |       | E-mail: |       |
| **Study Contact Information (if other than PI):**  |
| Name: |       |
|  | [ ]  M.D. [ ]  D.O. [ ]  Ph.D. [ ]  R.N. [ ]  Other, specify:  |
|  | Human Subject Protection Training Completed. [ ]  Yes [ ]  No |
| Address: |       |
| Telephone: |       | Fax: |       | E-mail: |       |
| **Co-Investigator(s):** |
|  (1) Name: |       |
| Address: |       |
| Telephone: |       | Fax: |       | E-mail: |       |
|  |
| (2) Name: |       |
| Address: |       |
| Telephone: |       | Fax: |       | E-mail: |       |
| **Additional Research Personnel not listed above****Note: Research personnel includes all individuals responsible for the design or conduct of the study who have access to confidential and identifying information, e.g. principal investigators, co-investigators, research nurses, study coordinators, students, and other support staff or persons assisting with the research.** |
| **Name** | **Title** | **Role** |
| Example: Jane Doe, RN | Study Coordinator | Data Collection |
|       |       |       |
|       |       |       |
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| **Attach additional page if necessary.** |
| Have all research personnel listed above taken the Human Subject Protection Training at the site listed below?  [www.citiprogram.org](http://www.citiprogram.org)/  | **[ ]** Yes[ ]  No🢂 **All research personnel must complete the training program prior to initiation of this research study.** |
| **Research Site(s):** |
| [ ]  Mount Carmel West [ ]  Mount Carmel East [ ]  Mount Carmel Grove City[ ]  Mount Carmel St. Ann’s [ ]  Mount Carmel New Albany [ ]  Fairfield Medical Center[ ]  Physician’s Office [ ]  Other, specify:      |

**EXEMPT CATEGORY RATIONALE**

**Describe the proposed project.** Attach a (type written) Protocol or Protocol Summary, a data collection sheet and any materials distributed as a part of this project.

The information **must** include a brief specific description of the procedure(s) involving the human subjects in **sufficient detail** to demonstrate that the research protocol meets the requirements for each Category of exemption claimed in this human subject research protocol.

**Information to be included in the Protocol Summary for EXEMPT applications:**

1. Objective of the study

2. A paragraph providing a brief background and significance of the study

3. Description of the Procedures and information to be collected

4. Population to be studied

5. Number of participants to be enrolled, charts to be reviewed, samples to be obtained

6. How will consent be obtained, if applicable? (Describe in detail when subjects will be approached, who will present

the consent form, etc.)

7. Provide a list of sites where the study will be performed

8. Provide a detail of the risks involved

9. Detailed­ account of how confidentiality will be maintained. How will you ensure that confidentiality will be

 maintained?

10. Any cost to the subject?

11. Any compensation to the subject?

In addition, for studies involving medical record reviews, answer the following questions:

1. Will you have ongoing contact with the subjects?

2. Will you be recording identifiers?

3. What is the timeframe of charts that you plan to review (for example, 2/1/1999 - 2/1/2001) \*\*Retrospective chart

 review can only occur on charts that were in place BEFORE you received IRB approval.

 **PRINCIPAL INVESTIGATOR'S ASSURANCE STATEMENT:**

I certify that the information provided in this application is complete and correct.

I understand that as Principal Investigator, I have the ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the Mount Carmel IRB.

I agree to comply with all IRB and Institutional policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

1. to accept responsibility for the scientific and ethical conduct of this research study,
2. to obtain prior review from the Institutional Review Board before amending or altering the research protocol to ensure the designation of Exempt remains appropriate,
3. to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study,
4. to train study personnel in the proper conduct of human subjects research.

Signature of Principal Investigator Date

Typed/Printed Name of Principal Investigator