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| --- | --- | --- | --- |
| Date: |       | **IRB Log No.:** |       |
| **Study Title:** |       |
| **Principal Investigator:** |       |
| Hospital / Center / University: |       | Email Address: |       |
| Department: |       | Telephone: |       |
|  |  |
| **Current Approval (or Renewal) Date:** |       | Approval Terminates: |       |
| **Study Status:** | [ ] Active | [ ] Completed |
| **Type of Report:** | [ ] 6-Monthly Progress Report | [ ] Annual Progress Report |
| ***NOTE:*** A study cannot be “completed” if subjects are in follow-up. |
|  |
| What is the expected end date for this study? |       |
| Is the current statement of work the same as originally approved by the IRB? | Yes: [ ]  | No: [ ]  |
| If NO, explain: |       |
| Have any changes been made to the protocol, project management, or supporting documents since the last approval? | Yes: [ ]  | No: [ ]  |
| If YES, explain: |       |
| Are any changes to the protocol planned in the future? | Yes: [ ]  | No: [ ]  |
| If YES, explain: |       |
| Record the category number(s) on page 2 that continue to apply for this study: |       |
|  |  |  |  |
| **Brief Statement of Work:** |
|       |
| **Reason for Study Renewal: *(Please write brief progress of the study.)*** |
|       |
|  |
| **Statement of Investigator:** |
|  |
| I certify that any changes to the protocol, including addition or deletion of study personnel, have been reported to the KFMC IRB within specified timelines. |
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| **Principal Investigator’s Signature** |  | **Date** |

**Exempt Categories for Research:**

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, or (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 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.
3. 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.
4. Research and demonstration projects which 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; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
5. 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.

**NOTE:** Research that is determined to be Exempt from IRB review is not Exempt from protection of the human subjects. The following criteria to protect human subjects must be met:

* + - * The investigator assures that all investigators and co-investigators are trained in the ethical principles, and relevant regulations and institutional policies governing human subject research;
			* The investigator assures that human subjects will voluntarily consent to participate in the research when appropriate (e.g., surveys, interviews) and will provide subjects with pertinent information, e.g. risks and benefits, contact information for investigators, and IRB chair, etc.;
			* The investigator assures that human subjects will be selected equitably, so that the risks and benefits of the research are justly distributed;
			* The investigator assures that the IRB will be immediately informed of any information, unexpected or adverse events that would increase the risk to the human subjects and cause the category of review to be upgraded to Expedited or Full Review;
			* The investigator assures that the IRB will be immediately informed of any complaints from participants regarding their risks and benefits; and
			* The investigator assures that confidentiality and privacy of the subjects and the research data will be maintained appropriately to ensure minimal risk to subjects.