**VCU IRB EXEMPT REVIEW SHEET**

PI:  VCU IRB #

1. **EXCLUSIONS:**Research involving the following may NOT be approved under the Exempt Review process:

* Greater than minimal risk
* Prisoner population

***II.* REVIEW CRITERIA:**The following 2 general conditions must be met:

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| **(1)** Does this research activity meet the applicable definitions of ***‘human subjects’ and ‘research’*** or ***‘human subject’ and ‘clinical investigation’***? | |
| **No ►** STOP! Not human subjects research. Exempt review not required. | |
| **Yes** | |
| **(2)** Does the research activity qualify as no greater than ***minimal risk*** to the research participants? | |
| **No ►** STOP! §46.102(i) **NOT** met. |
| **Yes** |

***III.* EXEMPT CATEGORY:**One or more of the following categories must be identified:

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| **(1)** Educational strategies, curricula, or classroom management methods [[§46.101(b)(1)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101)].  **(2)** Educational tests, surveys, interviews, or observations of public behavior [[§46.101(b)(2)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101)]. ***Restrictions****-* Category 2 does not apply if: ***(a)*** information obtained is recorded so that subjects can be identified directly (or indirectly through identifiers and disclosure of the subjects’ responses could reasonably place the subjects at increased risk, or if ***(b)*** the research allows for the inclusion of data on children and involves surveys/interview procedures, or observation of public behavior where the investigator participates in the activities being observed.  **(3)** Educational tests, surveys, interviews, or observations of public behavior not approvable under Category2 *(if publicly elected/appointed public officials/candidate or if federal statutes require confidentiality)* [[§46.101(b)(3)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101)].  **(4)** Existing data, documents, records, specimens - secondary data analysis [[§46.101(b)(4)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101)]. ***Restriction****-* Category 4 does not apply if the sources are not publicly available or if the investigator intends to record information in such a manner that subjects can be identified directly or through identifiers linked to the subjects.  **(5)** Federal department or agency research and demonstration projects for evaluation of public benefits/services [§46.101(b)(5)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101)].  **(6)** Taste and food quality/consumer acceptance studies (no additives or safety questions) [[§46.101(b)(6)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101)].  **No Categories Apply ►** STOP! §46.101(b) **NOT** met. |

***IV.* OTHER CONSIDERATIONS:**Verify all of the following:

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| **(1)** A mechanism exists for disclosing that the activity involves research and participation is voluntary (not applicable if Category 4 is selected above).  **(2)** PI is qualified.  **(3)** Plans to protect the privacy of the subject and maintain confidentiality of the data are adequate.  **(4)** No conflict of interest issues are pending.  **(5)** No issues are pending regarding Non-VCU institutions/Sites (foreign or domestic).  **(6)** Funding proposal is congruent with protocol (if submitted for review).  **(7)** All required documents have been included.  **(8)** Any other outstanding issues or concerns (of the reviewer) have been resolved. |

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| **Reviewer Information:**  Reviewed By:  Date: | **Exempt Review Result:**  Exemption Determination Granted  Not H.S. Research  Requires IRB Review:  Expedited *or*  Full |