APPENDIX B

Requesting ‘Exemption from IRB Review’

The IRB guidelines describe the IRB policies, as implemented at the University of the South. These guidelines provide details about requesting an exemption from IRB review. If you would like to request an exemption, please complete this checklist and submit it with the IRB Cover Sheet, a one-page summary of your research to the IRB Chair. If only portions of your project are exempt, please submit an application for full review (see IRB Review Guidelines page 3), and indicate which portions you think are exempt. Contact the IRB Chair if you have any questions.

Note: Protocols that have been granted exemption from the University of the South IRB Review may still be subjected to review mandated by study sites, schools, or collaborating institutions.

Protocol Name: ____________________________________________

Circle all that are true for your research:

a. Exemption 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. This exemption can apply to adults or children.

b. Exemption 2 (adults). Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior with adults, 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.

*If (i) and (ii) are true, exemption will not be granted.

c. Exemption 2 (children). Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), or observation of public behavior when the observer does not interact with the children, 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.
*If (i) and (ii) are true, you will not be granted the exemption. Moreover, research with children that involves survey procedures or interview procedures with the children is not exempt.

d. **Exemption 3.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior 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. Exemption 3 (ii) applies to children as well as adults.

e. **Exemption 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. “Existing data” means that the data was collected prior to the start of this study, for example, court records that were on file before the initiation of a research study of court records. “Information recorded by the investigator…” would include secondary analysis of datasets without identifiers linked to subjects. It also includes studies, such as the court record review, in which the investigator records data from identified files, but does not include the identifiable information in the research dataset – that is, the investigator uses IDs that are random and unrelated to the primary data.

f. **Exemption 5.** 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. This exemption applies to research with children as well as adults.

g. **Exemption 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. This exemption applies to research with children as well as adults.

*Note the following are not necessarily grounds for an exemption:*

1. The work is not supported by a federal department or agency. Federal regulations require that that non-federal research that meets eligibility requirements for review must be reviewed and approved.

2. The work is conducted outside of the United States. See source document for more details.

Source: [http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.110](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.110)

Principal Investigator Signature: ____________________________ Date: __________________

Print Name: ____________________________