INSTRUCTIONS

Use this form to request a determination for activities that involve **prospective collection** of data only, including:

- O Use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior¹
- o **Educational Research:** conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.²
- Program evaluation or demonstration project designed to study, evaluate, or otherwise examine:
 - O Public benefit or service programs;
 - o procedures for obtaining benefits or services under those programs;
 - o possible changes in or alternatives to those programs or procedures; or
 - o possible changes in methods or levels of payment for benefits or services under those programs,
 - O Quality assurance activities

Please attach the survey, questionnaire, interview script or test to the completed form together with the consent language that will be administered before the subject participates in the activity.

For assistance completing the form, call OHSRP at (301) 402-3444. Submit a PDF of the completed form with required signatures and attachments to:

PDF and E-mail: ohsr-nih-ddir@od.nih.gov

¹ The following activities involving educational tests, survey, interviews or observation of public behavior **are not** eligible for exemption and must be reviewed by an IRB if:

the information obtained is recorded such that human subjects can be identified, directly or through identifiers linked to the subjects; and

[•] any disclosure of the 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; **or**

[•] the research involves children, unless it involves observation of public behavior and the investigator will not participate in the activities being involved.

² Note that educational research may include children and use identifiable information, however other local or federal regulations may apply such as The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) and/or The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98); however OHSRP cannot provide advice on these regulations.

Fax: 301-402-3443 Interoffice mail: Building 10, Room 2C146

Date of Request:
Requestor's name: e-mail:
Role:Administrative supportInvestigatorOther, explain:
Name of NIH Senior Investigator:(The investigator <u>must</u> be an NIH employee)
ICLaboratory/Branch
Building & Room No Tel. No FAX No
Is the NIH Senior Investigator an NIH employee(FTE)?YesNo
Senior Investigator Signature: (Signature of Investigator who will conduct research) Supervisor Signature: (Signature of official for IC, e.g., Lab/Branch Chief)
Name of NIH investigator conducting research if not the NIH Senior Investigator: (i.e., junior investigator, contractor investigator, fellow, student)
Please provide the name and e-mail of any others who should receive a copy of the OHSRP determination:
 What role will the NIH investigator(s) have in this research project? (check all that apply) Conduct research activity Analyze samples/data only Consultant/advisor to collaborator(s) Author on publication(s)/manuscript(s) pertaining to this research Other, please describe:
2. Title:
4. Proposed start date// Proposed completion date//

5. Specify the nature of the dat	ta: (select all that apply)	
Interview procedure Survey		
Educational Testing		
Educational Research		
Research on public benefi	it or service programs	
other, describe:		
6. What kind of human data (e., test results, recordings) will be	g., private information, responses collected in your research?	to questionnaires,
7. Will human data be? (select a	all that apply)	
Collected Yes No		
Received Yes No		
Sent Yes No		
8. If receiving or sending, list the Name Institution/IC		FWA number*
Where are the subjects of the description or complete the institution:		·
Address:	Phone:	
	re direct contact or intervention witerviewing, surveying or recording	_
If yes, what is the age rar Children aged < 18 ye	nge of subjects involved in the rese	arch?
Adults aged \geq 18 yea		
11. Who will collect the data or	r information?	
(a) NIH Investigator		
(b) non-NIH Collaborator	r	
(c) NIH Contractor		
(d) Other, specify		

	If b or c, will an Honest Broker or data use agreement be used? Yes No			
	If yes, complete and attach the Honest Broker Assurance or data-use agreement to this submission; e-mail ohsr_nih_ddir@od.nih.gov to request a form.			
12.	 Select the best description that applies to the human data or information: Data or information will not contain any identifiable information, nor can it be linked to individual subjects by you or your collaborators. Data or information will be recorded in such a manner that subjects can be identified directly or through identifiers linked to the subjects 			
	Per NIH guidance, are all conflicts of interest by NIH employees (sender or seiver), if any, resolved?YesNo**			

*A Federalwide Assurance (FWA) is issued by the U.S. Department of Health and Human Services (DHHS)/ Office of Human Research Protections (OHRP) to institutions which receive Federal funds/support to conduct human subjects research. To search for the FWA# for domestic or international institutions go to http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc

^{**}If the answer is "No", note that OHSRP will be unable to make a determination and research <u>may not proceed</u> until all conflicts are resolved. For more information, see the October 2011, <u>A Guide to Preventing Financial and Non-Financial Conflict of Interest in Human Subjects Research at NIH</u>. For assistance review the list of Ethics Coordinators and find the contact for your IC: http://ethics.od.nih.gov/coord.pdf