GUIDELINES FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS

APPENDIX

Please read the Guidelines (pages 1 through 15) carefully and submit pages A-2 through A-7 and all required forms and safeguards, including questionnaires, research instruments, letters of consent, and approvals from authorized officials to the Human Subjects Review Board.

As of January 1st, 2014 all investigators must complete NIH or CITI training to conduct research at Ashland University. Certification must be completed within the last five years and verification must be attached to HSRB application. Print and attach to application verification of human subject protections in research training.

To be typed or word-processed

SEQUENCE OF RESEARCH PROTOCOL REVIEW

Student Directed Research *(Students work closely with your advisor)*

A. **NIH or CITI training in human subject protections in research within 5 years (Attach both student and faculty advisor certificate of proof to application)**
B. Discuss project with advisor and receive approval to proceed.
C. Complete Human Subjects Review Board Application: Part I, Part II, Part III (Investigator must sign application.)
D. Obtain advisor's signed approval and forward to:

Dr. Larry Bunce
Executive Director of Institutional Effectiveness
100 Founders Hall
Ashland University
Ashland, OH 44805
(Signed applications may be scanned to hsrb-au@ashland.edu, this is our preferred method of submission.)

After Proposal is received:

A. Director assigns the proposal to the appropriate reviewer(s).
B. Proposal is reviewed and returned to the Director.
C. HSRB Chair reviews, signs letter and forwards status of research proposal to the student's advisor.

Faculty Research

A. **NIH or CITI training in human subject protections in research within 5 years (Attach certificate of proof to application)**
B. Complete Human Subjects Review Board Application (Part I, Part II, Part III)
C. Forward proposal to Graduate School Office, 100 Founders Hall (or scan to hsrb-au@ashland.edu).

After Proposal is received by Graduate School Office:

A. Director assigns the proposal to the appropriate reviewer(s).
B. HSRB or review members review proposal and return proposal to Graduate School Office.
C. HSRB Chair reviews, signs letter and forwards status of research proposal to faculty member.

If you have any questions, please contact:

Dr. Christopher R. Chartier, Chair
Human Subjects Review Board
Phone: (419) 289.5342
E-Mail: cchartie@ashland.edu

HUMAN SUBJECTS REVIEW BOARD
PART I
APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH

Return the original typewritten application including Parts II and III to:
Director of the Graduate School
119 Andrews Hall
OR
(Signed applications may be scanned to hsrb-au@ashland.edu, this is our preferred method of submission.)

PRINCIPAL INVESTIGATOR _Jennifer L. Groman_ DEPARTMENT COE/Doctoral Studies & Advanced Programs
(typed name)

ADDRESS _257 College of Education_____EMAIL__jgroman@ashland.edu_____

CITY _Ashland_____ STATE _OH___ ZIP _4469___ PHONE (419) 651-2586_____

CO-INVESTIGATOR(S) _____ _____
(typed name) (signature)

_____ _____
(typed name) (signature)

PROJECT TITLE __The Creativity Project – Preliminary Survey_____

BEGINNING DATE OF RESEARCH (MONTH/YEAR) _October, 2018_____

ANTICIPATED ENDING DATE OF RESEARCH (MONTH/YEAR) __January, 2019_____

IS THIS RESEARCH RELATED TO A GRANT? Y/N ___N__ IF YES, GRANT NUMBER: _____

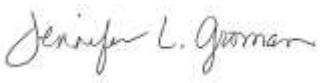
****

TYPE OF PROJECT

■ **FACULTY RESEARCH:**
EXTERNALLY FUNDED YES _____ AGENCY _____
NO ___X_____

☐ **STUDENT DIRECTED RESEARCH:**
ADVISOR_____
THESIS _____ DISSERTATION _____ COURSE REQUIREMENT _____
COURSE # _____ PRACTICUM _____ OTHER (Please Specify) _____

I agree to follow the procedures outlined in this summary description and any attachments to ensure that the rights and welfare of human subjects in my project are properly protected. ***I understand that no contact may be initiated with subjects until I have received approval of these procedures from the HSRB and complied with any required modifications in connection with that approval.***



___ _____ Date _September 11, 2018_____
(Signature of Principal Investigator)

APPROVAL OF FACULTY ADVISOR: ***Required for all students***

_____ Date _____
(Signature of Advisor)

PRINTED NAME OF ADVISOR __Dr. James Olive_____
ADDRESS/AFFILIATION _130 Schar College of Education/Doctoral Studies and Advanced Programs_____
CITY _Ashland_____STATE___OH_____ZIP___44805_____
PHONE (w) 419.207.6643 | (c) 614.285.5466 E-MAIL_jolive@ashland.edu

HUMAN SUBJECTS REVIEW BOARD
PART II: RESEARCH PROTOCOL

TYPE OF REVIEW REQUESTED *(Choose One)*

NOTE: Regardless of type of review, all of Part II and Part III must be completed and submitted to the HSRB. Research may begin only after written approval of HSRB is obtained.

_____ EXEMPTED I (We) believe the current project is **EXEMPTED**. It meets category(ies) _____ from the list of six categories on pages 4-6 of the Guidelines.

In the space below, explain why you feel your research project meets the **EXEMPTED** provisions. Briefly detail all the categories that apply to your research. (Refer to the six categories that define exempt status).

__X_____ EXPEDITED I (We) believe the current project meets the **EXPEDITED** classification. It meets category(ies) _(1)____ from the list of thirteen categories on pages 6-8 of the Guidelines.

In the space below, explain why you feel your research project meets the **EXPEDITED** provisions. Briefly detail all the categories that apply to your research. (Refer to the thirteen categories that define expedited status).

I am gathering information about identification and service of gifted students in Creative Thinking Ability. This study asks school personnel (teachers, administrators, school counselors, school psychologists, and other district staff) about their protocol for identification and service in a simple survey format. Topics in each part of the survey are listed below.

Part I – Non-identifying demographic information (home district type, their role in the district, no district names are requested)
Part II – Survey information regarding identification and service of Creative Thinking Ability gifted individuals in their district.
Part III – Opinion questions about the nature of Ohio's identification for Creative Thinking Ability, their own creativity and their students' creativity.

The data will be compiled and analyzed for themes and trends and the results used to design a research and grant proposal to further investigate students gifted in Creative Thinking Ability in

districts throughout Ohio and work alongside a cadre of teachers to create lessons, strategies, and practical ideas for meeting the needs of this unique and underserved population.

This proposal is the preliminary work for a larger proposal and request to be made in January, 2019.

_____ FULL BOARD I (We) believe that this project exceeds the requirements for the **EXEMPTED** and **EXPEDITED** classifications, and therefore, must be reviewed by the **FULL BOARD** of the HSRB.

HUMAN SUBJECTS REVIEW BOARD
PART II: RESEARCH PROTOCOL

Continued
(Please answer the questions below.)

YES NO		
_____ ____X___	A.	Human subjects in the proposed research are involved in activities that exceed those described as exempt categories.
_____ ___X____ ⇨ ⇨ ⇨ ⇨ (please circle appropriate classes of subjects)	B.	The proposed research activity will involve a special class of subjects. Examples would include: children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Further examples may include: individuals with psychiatric, cognitive, or developmental disorders, substance abuses, and any other special category of individual who may not have the capacity to make a reasoned decision about participation.
_____ ___X____	C.	The proposed research activity will involve an element of deception.
_____ _____X__	D.	The proposed research activity will expose subjects to discomfort or harassment beyond levels encountered in daily life.
_____ ____X___	E.	The subjects will be identifiable to anyone other than the researchers through records, responses or identifiers linked to the subjects.
_____ ____X__	F.	The subjects could be at risk of criminal or civil liability, damage to employability or to financial standing, or undue embarrassment, if responses became known outside this research project.
_____ ____X__	G.	The research deals with sensitive aspects of subjects' behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

_____ _____X_	H.	The research involves the collection or study of existing data from sources not publicly available. (Existing data can be documents, records, pathological specimens or diagnostic specimens).
_____ _____X__	I.	The subjects will be video/audio taped.
__X_____ _____	J.	The subjects are free to withdraw at any time without penalty.
_____ _____ ____X___ N/A	K.	The research activities outlined in Part III have the written approval of the authorized official(s) in the school district and/or other agencies involved with this research (if applicable). (Attach copy).
___X____ _____	L.	All required forms and safeguards are included with Part III: Summary of Proposal. This includes questionnaires, research instruments, letters of consent, approvals from authorized officials, etc. *Included in this proposal:* *Survey Questions/Research Instrument* *Consent Statement*

HUMAN SUBJECTS REVIEW BOARD
PART III: SUMMARY OF PROPOSAL

Summarize the proposed project and procedures to which humans will be subjected. **Consent form(s), questionnaires, etc. must be attached**. The summary should include purpose(s), solicitation and number of subjects, data collection procedures, an explanation of how consent is obtained, procedures for maintaining confidentiality and any potential risks involved for the subjects. Explain the nature of any deception if it is part of the design.

(Attach separate sheets if additional space is required.)

1. Project Description

Describe the specifications and objectives of your research, the data collection procedures, and any features of the research design that involve special conditions or procedures for subjects.

Start Here

2. Subject Recruitment

A. Explain how subjects will be recruited. Include sources from which they are recruited, where and how subjects will be first contacted, and recruitment techniques to be utilized.

B. Describe the sample size and characteristics of the subjects. Include age, gender, and/or racial/ethnic affiliations causing them to be included in the study population, institution status (i.e., patients or prisoners), and their general state of mental and physical health. Explain why it is necessary to use these particular population subgroups or special populations.

3. Confidentiality of Data

Explain how data will be secured and/or stored to safeguard the identifiable records of individuals. Include how long the data will be stored beyond the required 36 months and how the data will be destroyed.

4. Informed Consent Procedures

A. How will the subject be informed of the nature of the investigation, the reasonably foreseeable risks, and the voluntary nature of his/her participation?

_____ In writing (attach a written copy of this explanation)

_____ Orally (attach a written copy of this explanation)

B. Once the above information has been presented, will you obtain written consent from the subject (i.e., their signature) prior to their participation?

_____ Yes (attach a copy of the written consent form)

_____ No (attach a detailed justification for requesting waiver of written consent)

C. Are the subjects: (Check all that apply)

_____ children
_____ prisoners
_____ pregnant women
_____ other (please specify)_____

_____ mentally disabled
_____ economically disadvantaged
_____ educationally disadvantaged

Describe from whom consent will be sought and by whom permission will be granted.

5. Risks to Subjects

A. Describe in detail any immediate or long range risks to subjects that may arise from the procedures used in the study. Risks may be physical, psychological, social, legal, or economic. Indicate the precautions you have taken to minimize these risks.

B. Explain the nature of any deception if it is part of the research design.

6. Benefits

Describe the anticipated benefits to subjects, field of study, and to society, from knowledge that may be obtained in this study.

EXAMPLE OF TYPICAL CONSENT FORM
(Parental Consent)
"Title of Research Study"

Dear _____:

The Department of _____ at Ashland University supports the practice of informed consent and protection for human subjects participating in research. The following information is provided for you to decide whether you will allow _____ to participate in the present study. You are free to withdraw _____ at any time.

Your child will be asked to play a game with another child with a disability in a room that has toys and books, and your child's behavior will be observed. One session will last approximately 25 minutes. We are interested in studying the interaction between children who develop methods for increasing the effectiveness of efforts to integrate children with disabilities into the regular education classroom.

Your child's participation is solicited but strictly voluntary. We assure you that your child's name will not in any way be associated with the research findings. The information will be identified only through a code number.

If you would like additional information concerning this study before or after it is completed, or have any issues or concerns, please contact one of us by phone or mail. Thank you very much for your time, and we appreciate your interest and cooperation.

Sincerely,

Name of investigator	Name of Faculty Member
Graduate Student	Professor
Phone No. (____)_____	Phone No. (____)_____
Address _____	Address _____
City, State, Zip _____	City, State, Zip_____

****

I have read and understand the information about "Title of Research Study." I give consent for my child to participate in this study. I understand that this consent is voluntary and can be withdrawn without penalty at any time.

_____
Signature of parent or legal guardian

_____
Date

EXAMPLE OF TYPICAL CONSENT FORM
(Participant Consent)

"Gender Differences in Communication Strategies of
Pleasant and Unpleasant Feelings"

A. PURPOSE AND BACKGROUND

Messrs. Smith and Jones in Ashland University's Psychology Department are conducting a research study to help understand how men and women communicate pleasant and unpleasant feelings. You are being asked to participate in this study because…

B. PROCEDURES

If you agree to be in the study, the following will occur:

1. You will view two 15-minute videotapes; one will be of pleasant and the other of unpleasant content.

2. After viewing both videotapes, you will be asked to take part in a focus group discussion led by Smith and Jones. Everyone in this focus group will have viewed the tapes. During the focus group, you and other group members will be asked to discuss reactions to scenes in both tapes. An audiotape will be made of this discussion. This discussion is expected to last about thirty minutes.

3. You will respond to a questionnaire about your reaction to the videotapes. It should take approximately fifteen minutes to complete the questionnaire.

4. You will answer questions on a standard paper and pencil personality test. It should take about an hour to complete this test.

These procedures will be done…and will take a total time of about two and one-half hours.

C. RISKS/DISCOMFORTS

1. Some of the videotapes are likely to produce unpleasant feelings, but you will be able to stop watching at any time if you feel too uncomfortable

2. Some of the focus group discussion questions may make you uncomfortable or upset but you are free to decline to answer any questions you do not wish to answer or to leave the group at any time.

3. Confidentiality: Participation in research will involve a loss of privacy; however, your records will be handled as confidentially as possible. The researchers will ask you and the other people in the focus group to use only first names during the

group session. They will also ask group members not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussion private. Only Smith and Jones and their assistant will have access to your study records and audiotapes. After the group discussion has been transcribed from the tapes, the tapes will be destroyed. No individual identities will be used in any reports or publications that may result from this study.

D. BENEFITS

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand how the differences in how males and females communicate pleasant and unpleasant feelings.

E. COSTS

There will be no costs to you as a result of taking part in this study.

F. PAYMENT

You will be paid $20 for your participation in this study. If you decide to withdraw prior to study completion, you will receive $10. You will be paid in cash immediately after you complete your participation in the study.

G. QUESTIONS

You have talked to Messrs. Smith and Jones, or the person who signed below, about this study and have had your questions answered. If you have further questions, you may call him/her at….

If you have any comments or concerns about participation in this study, you should first talk with the researchers. If for some reason you do not wish to do this, you may contact the Human Subjects Review Board, which is concerned with the protection of volunteers in research projects. You may reach the board office between 8:00 and 5:00, Monday through Friday, by calling or writing….

H. CONSENT

You will be given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You are free to decline to be in this study, or to withdraw from it at any point. Your decision as to whether or not to participate in this study will have no influence on your present or future status as a [patient, student or employee].

If you agree to participate, you should sign below.

_____ _____

Date Signature of Study Participant

_____ _____

Date Signature of Person Obtaining Consent

Notes to Researcher:

1. Research involving sensitive aspects of the subject's own behavior: The Procedures section should discuss in detail the kinds of sensitive questions that will be asked during interviews, in questionnaires, or in focus groups (i.e., you should specify that questions about sexual activity, drug or alcohol use, domestic violence or child abuse, or other illegal activities will be asked).

In studies in which you think it is likely that subjects will reveal actions that you are legally or morally obligated to report to authorities (e.g., when child, spousal, or elderly abuse is suspected), a statement should be added to the consent form's discussion of confidentiality, briefly saying that such circumstances may arise.

When questions about drug use or other illegal activities are involved, research subjects are placed at risk since research discussions and records do not enjoy the same legal privilege as medical records. In order to protect your subjects better, you may wish to obtain a Federal Certificate of Confidentiality through your funding agency. This Certificate prevents courts from compelling researchers to reveal information about their subjects. Whether or not you obtain a Certificate, subjects should be warned in the consent form about the risk of loss of confidentiality. Wording like the following is recommended:

> Participation in research will cause a loss of privacy. In this study you will be asked about drug use and other possibly illegal activities. The researchers will keep information about you as confidential as possible, but complete

confidentiality cannot be guaranteed. On rare occasions, a court has subpoenaed research records.

If you obtain a Certificate of Confidentiality for the study, the end of the statement can be revised as follows:

> ….On rare occasions, research records have been subpoenaed by a court, but the National Institute on Drug Abuse [or other issuing agency] has given the researchers a Federal Certificate of confidentiality which says courts cannot force the researchers to reveal information about your participation in the study.

2. **Collecting long-term tracking information:** If relatives, neighbors, co-workers, employers, or government agencies will be contacted during the study to provide information on subjects' whereabouts, you should explain so in Procedures. Subjects should be reminded that they could ask to have these tracking procedures stopped at any time.

RESEARCH PROPOSAL SUBMISSION CHECKLIST

The *Guidelines for the Conduct of Research Involving Human Subjects* outlines definitions and processes and should be reviewed in depth **prior** to submitting the research proposal. The Appendix in the Guidelines contains the forms to be submitted to the Human Subjects Review Board.

All proposals will be screened using the following checklist. Incomplete proposals will be returned to the principal investigator, and the proposal will not be examined further. **Please examine the proposal carefully before submitting two copies of the proposal.**

- ☐ Complete information/signatures on page A-2

- ☐ Complete information on page A-3 including:

  - ❖ Type of review
  - ❖ Category(ies)
  - ❖ Explanation

- ❑ Written authorization attached (indicated by “yes” on item K on page A-4)

- ❑ Questionnaire(s) attached (indicated by “yes” on item L on page A-4)

- ❑ Project description included (item 1 on page A-5)

- ❑ Explanation of how subjects will be informed attached (see 4A. on page A-6)

- ❑ Written consent form or justification attached (see 4B. on page A-6)

- ❑ Verification of NIH or CITI training within 5 years from all investigators/faculty advisors attached (page A-1)