MCMURRY UNIVERSITY INSTITUTIONAL REVIEW BOARD
HUMAN SUBJECTS RESEARCH PROPOSAL FORM

McMurry University IRB proposal and committee review process follows Office for Human Research Protections regulations. ALL researchers are required to affirm familiar	Reviewed Yes	Reviewed No
THE BELMONT REPORT		
TITLE 45: Public Welfare Department of Health & Human Services PART 46: PROTECTION OF HUMAN SUBJECTS		
COOPERATIVE RESEARCH		
RESEARCH INTEGRITY		

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Principal Investigator (PI) _____

Project Title _____

PI's telephone: cell/office _____

PI's e-mail _____

PI's Department/Agency _____

Principal Investigator's Status

_____ McMurry University Faculty/Staff _____ External Agency/University

BELMONT REPORT Confirmation Statement

I have read the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" and subscribe to the principles therein. In light of this declaration, I present for the McMurry University Institutional Review Board's (IRB) consideration the following information that will assist the IRB in its decision.

Primary Investigator Affirmation Signature: _____ **Date:** _____

Conflict of Interest Statement

Is the primary investigator (&/or faculty supervisor)

Investigator Status	No	Yes	If Yes, *identify source of conflict*
Primary Investigator			
Faculty Supervisor			

External Funding Statement

Source of external or internal funding for project: _____

Duration

Is this project expected to continue for more than one year? YES NO

Data Collection Start Date: _____ Data Collection End Date: _____

Investigative or Research Study Required Information

The following information **is required for all projects**.

1. **Research Proposal Information – Explanations – Questions – Rationale**: Provide concise, yet, detailed information to enable IRB members understand exactly the investigate purpose of and how the study will be conducted (design). (minimum 250-word description)

   As required by Federal Human Study Research – a quality IRB proposal review necessitates members understand: the rationale for study related to advancing discipline knowledge, recruitment through protection of subjects, participation consent, safeguards for vulnerable groups, and data collection, management, and storage of the proposed study.

WITHIN THE APPENDIX: Attach copies of ALL supporting documents used to gather data from or with human subjects. Documents include, but are not limited to: questionnaires, informed consents, training of research personnel, measurement/testing instruments &/or protocols: interview, exercise, training, etc.; include any cover letters or instructions to participants or research personnel (attach as an appendix).

HUMAN SUBJECTS (SAMPLE) INFORMATION

Proposed Number of Subjects _____

Subject Population (check all that apply)

_____ Adult _____ Vulnerable Populations (VP)

___ Minor ___ Children Specify Other VP: _____

Project Data Collection Method – Description and Procedures:

Method (check all that applies): Must include a copy of instrument within the Appendix of IRB proposal.

_____ Questionnaire(s) _____ Interview _____ Treatment _____ Task

_____ Observation(s) _____ Files (Portfolios, etc.) _____ Test _____ Survey(s)

_____ Other Specify other method or tool:

HUMAN SUBJECTS STUDY CONSIDERATIONS: In the sections below,

1. ***Research Study Objective***: Provide a **thorough description** of the proposed research study's purpose (hypothesis) and the rationale (need) for this research study.

   A. ***Explain the purpose (hypothesis) of the research study.***

   B. ***Provide a detailed rationale of why there is a need for this study.*** Base rationale on review of literature that demonstrates need for further human subject research is warranted.

2. ***Human Subject Interaction***: **EXPLAIN all information** related to human subject recruitment, selection for &/or exclusion from study participation, & intervention interactions (if applicable) proposed by this study:

   A. ***Recruitment & Selection*** procedures of individual participants for this study (sample, assistants, group leaders, teams, classroom, etc.).

   Additional information to include:

   - If applicable, provide rationale for the study's use of deceptive **and/or** coercive (enticer) tactics (+ or -) with subjects.

   B. ***Study Protocols***: **FULLY EXPLAIN** protocol/procedure descriptions for all aspects of the study. (**APPENDIX**: SUBMIT a copy of all data collection scripts, instruments, surveys, questionnaire scripts, research team training, data collection worksheets & protocols, informed consents, etc.).
   EXPLAIN exactly how data collection with human subjects will be conducted &/or administered.

   Additional information to include - IF:

   - If assistants or experimental interventions are used, **SUBMIT** the training protocols for study administrators, testing protocols, etc. in the APPENDIX.

C. ***Potential Risks***: Please select the level of risk associated with subjects participating in this study.

If selecting the ****HIGH RISK*** category **OR** if working with any **vulnerable population**s, **FULLY EXPLAIN** a research based or supported risk-to-benefit analysis statement addressing why a subject would consider participating.

CIRCLE or HIGHLIGHT the level of potential or known risk(s) for subjects electing to participate in this study.
Does the content or practices associated with this research study pose any foreseeable physical, emotional, psychological, etc. risks **and/or** benefits to or for the study's subjects?

Risk Category	**Yes**	**No**	**Briefly explain potential or known risk** (i.e. discomfort, stress, anxiety, etc.)
Minimal Risk			
Average Risk			
**High Risk*			*Fully Explain Risk-to-Benefit

3. ***Human Subject Understanding and Care of Information***:

A. ***Rationale for providing or withholding information*** **about the study's purpose, use, findings, etc. to the following**:

1. Study's sample and/or study assistant(s)

2. Will you tell the subject the purpose of the study at the beginning?
   - If no, SUBMIT a research/literature base rationale for withholding this information

3. Will you debrief sample at the conclusion of the study?
   - If no, SUBMIT a literature base rationale as to why you will withhold this information.
   - If yes, explain debriefing protocol

B. ***Human Subjects' Data management/use protocols*** (who has access to data, when is data destroyed, etc.). Human subject data collection, storage, use, and destruction must be addressed and included in proposal submission.

High priority is placed on data collection and storage security. Subject identities must not be decipherable to anyone but the PI or other researchers – be sure to address how the data will be stored securely during the course of the study (i.e. on a laptop with a password is not sufficient). Subject data coding is expected to be explained and must demonstrate know of and planning for data security and maintaining subject anonymity.

Who has access to the raw data?

Data Collection Protocols – explain exactly how data will be gathered.

Data Storage Protocols – explain exactly how the raw data will be stored to ensure confidentiality.

Data Destruction Plan – explain when raw data will be destroyed. Provide the name of the responsible Party, relationship to the study/institution, & contact information.

PRIMARY INVESTIGATOR:

The Principal Investigator must sign this form.

I hereby certify that

a) the **information provided is complete and accurate**,
b) **no other procedures will be used in this project**, and
c) **the study will be conducted exactly as approved and that I will not *modify, in any form (includes every aspect: process, protocol, procedure, etc.) the approved study**.
d) if any modification is needed, I will submit a modification request to the McMurry University IRB Chairperson to **notify, seek, and gain modification approval PRIOR TO CHANGING any aspect of the approved project**.

Signature of Primary Investigator **Date**

ADDITIONAL INVESTIGATOR:

Each investigator must provide the following information and sign this form.

I certify that

- I have read the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," and subscribe to the principles therein.

Belmont Report Statement: Additional Investigator's initials

I certify that

- I agree to follow Federal Guidelines for human subject research and abide by McMurry IRB Research proposal and summary protocols. .

Compliance Statement: Additional Investigator's initials

I hereby certify that

a) the **information provided is complete and accurate**,
b) **no other procedures will be used in this project**, and
c) **the study will be conducted exactly as approved and that I will not *modify, in any form (includes every aspect: process, protocol, procedure, etc.) the approved study**.
d) if any modification is needed, I will submit a modification request to the McMurry University IRB Chairperson to **notify, seek, and gain modification approval PRIOR TO CHANGING any aspect of the approved project**.

Signature of Additional Investigator **Date**

Additional Investigator's Phone Number **Additional Investigator's e-mail**

Additional Investigator's Address

Attach relevant Appendix Documents – possible examples include:

Appendix Document	***Resource/Explanation***	***Included with Proposal?***		
		Yes	***No***	***NA***
Research Objectivity: Title 42 Part 50.605	Conflict of Interest Statement (addressed within proposal)			
Informed Consent Forms	http://www.hhs.gov/ohrp/policy/consent/index.html			
Research Protocols	Scripts, Research Personnel Training, Measurement/Testing Protocols, etc.			
Research Instruments	Surveys, Questionnaires, Evaluation, etc.			
Data Use Agreements	Submit If data result sharing occurs with outside agencies or other group not directly associated with this study.			
Research Summary Statement ***Date due to IRB Chair:*** _____ *(maximum: 21 days following completion of data collection).*	At the completion of the *human subjects data collection* phase, PI will submit a written statement acknowledging the completion of human subject interaction. The ***Research Summary Statement*** should address the following: • adherence to proposed: ○ sampling techniques & number of subjects, data collection ○ data collection protocols ○ data storage/management ○ proposed date of data destruction ○ individual responsible for data destruction			
Human Research Protection Training	Click here for the HHS-Office for *Human Research Protections Training*			
Other:				