***Human Subjects Research Review (HSR-1):***

## **Cover Sheet**

IRB# \_\_\_\_\_\_\_\_\_\_\_

 Date Logged: \_\_\_\_\_\_\_\_\_\_\_

Application Status: (*Check one*.)

Exempt       (no more than Minimal Risk - fits one of the 6 federally designated exempt review categories)

Expedited       (no more than Minimal Risk - fits one of the 9 federally designated expedited review categories)

Full IRB Review       (more than Minimal Risk – does not qualify for Exempt or Expedited)

Principal Investigator/Researcher’s Name: \_\_\_\_\_\_ Student ID Number: \_\_\_\_\_\_

Type of Research Project (Capstone, Dissertation, describe other) \_\_\_\_\_\_

Title of Research Project: \_\_\_\_\_\_

Principal Investigator/Researcher’s Address: \_\_\_\_\_\_

Telephone Number: \_\_\_\_\_\_ Email: \_\_\_\_\_\_

Faculty Research Supervisor’s Name (if applicable): \_\_\_\_\_\_

College: [ ]  Business [ ]  Tech [ ]  Health [ ]  Arts & Science [ ]  OTHER:\_\_\_\_\_\_\_\_\_\_\_

Project Proposed Start Date:       Project Proposed Completion Date:

As the principal investigator, I attest that all of the information on this form is accurate, and that every effort has been made to provide the reviewers with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in participant(s), selection process, change in faculty research supervisor, adverse incidents, or final completion date of project. I also attest that I will treat human participants ethically and in compliance with all applicable state and federal rules and regulations that apply to this study, particularly as they apply to research work conducted in countries other than the United States.

Signature of Principal Investigator/Researcher \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_

 Date

Approval Signature – Faculty Research Supervisor (for students):

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date

IRB Certification Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_

###### *The above named research project is certified for compliance with Davenport University’s requirements for the protection of human research participants with the following conditions:*

1. *Research must be conducted according to the research project that was certified by the IRB.*
2. *Any changes to the research project, such as procedures, consent or assent forms, addition of participants, or study design must be reported to and certified by the IRB.*
3. *Any adverse events or reactions must be reported to the IRB immediately.*
4. *The research project is certified for the specific time period noted in this application; any collection of data from human participants after this time period is in violation of IRB policy.*
5. *When the study is complete, the investigator must complete a Completion of Research form.*
6. *Any future correspondence should be through the principal investigator/faculty research supervisor and include the assigned IRB research project number and the project title.*

###### \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

NOTES:

* *Attach the appropriate documents and submit the entire application materials under the cover of a completed Application Checklist to the CRP or Dissertation Chairperson.*
* *Do not proceed with any research work with participants until IRB Certification is obtained.*
* *If any change occurs in the procedure, sample size, research focus, or other element of the project impacts participants, the IRB must be notified in writing with the Amendment to Original IRB Certification (HSR -4) form.*
* *Please allow 30 days after receipt of a complete application for processing.*
* DO NOT COLLECT DATA PRIOR TO RECEIVING IRB CERTIFICATION

***Human Subjects Research Review (HSR-1)***

***Form***

*Please completely answer the requested information (NA is not acceptable for any question).*

1. Purpose of the Study: \_\_\_\_\_\_
2. Summary of the Study. (Provide a brief description of the research, the role of human subjects, and the overall goals of this project in lay language. Include a brief description of the research procedures, paying special attention to what will happen to participants and what they will be told about the research - 500 words or less).

 \_\_\_\_\_\_

1. Participant Demographics:

a. Anticipated Sample Size:

b. Special Ethnic Groups (describe):

c. Institutionalized Y N Protected Group (describe):

d. Age group:

e. General State of Health:

1. f. Other details to describe sample group.

4. Will deception be used in the study? Y N (please describe) \_\_\_\_\_\_

5. Will electric recording such as audio or videotapes be used in the study? Y N (please explain) \_\_\_\_\_\_

6. Confidentiality protection issues (pertains to audio and video as well as written documents.)

a. What precautions will be taken to insure the privacy and anonymity of the participants? (i.e. closed doors, private rooms, handling of materials where participant’s identify could be discovered, etc.). \_\_\_\_\_\_

b. What specific precautions will be taken to safeguard and protect participant’s confidentiality while handling the data (audio/video/paper) both in principal investigator’s possession and in reporting the findings? (i.e., coding, removal of identifying data). \_\_\_\_\_\_

c. Describe procedures where confidentiality may be broken by law (e.g., child abuse, suicidal intent). \_\_\_\_\_\_

7. Review by institutions outside of Davenport University (Attach copies of permission letters, IRB certifications, and any other relevant documents). \_\_\_\_\_\_

8. Informed Consent and Assent (Attach copies of all relevant forms). If consent is not necessary (e.g., anonymous interview), describe how you will inform all participants of the elements of consent (see instructions). \_\_\_\_\_\_

* 1. If written or oral informed consent is required, describe the manner in which consent and/or assent was obtained for each level).
1. Adult Participants (18 years and older – written consent required). \_\_\_\_\_\_
2. Child Participants (under 18 – parent/guardian permission and participant assent required). \_\_\_\_\_\_
3. Institutionalized participants (parent/guardian/conservator permission with appropriate participant assent). \_\_\_\_\_\_

1. Describe any possible physical, psychological, social, legal, economic or other risks to participants. \_\_\_\_\_\_
2. Describe the precautions taken to minimize risk to participants. \_\_\_\_\_\_
3. Describe procedures implemented for correcting harm caused by participating in the study (e.g., follow up calls, referral to appropriate agencies). \_\_\_\_\_\_
4. Potential benefit of the study:
5. Assess the potential benefit(s) of the study for the participants: \_\_\_\_\_\_
6. Assess the potential benefits(s) to the professional community: \_\_\_\_\_\_

12. Discuss any sources of funding/grants for this research, if any. \_\_\_\_\_\_

a. Has the DU Grants office been included/notified through the process of obtaining funding/grants? \_\_\_\_\_\_

b. Is there an obligation to present/publish results of the research as a stipulation to accepting funding/grants? \_\_\_\_\_\_

13. Conflicts of interest:

a. Identify any conflicts of interest for the researcher(s) and the anticipated participants in the research: \_\_\_\_\_\_

b. Identify any conflicts of interests for the researcher(s) and any anticipated sources of funding for the research: \_\_\_\_\_\_

Attach any other required forms, including the principal investigator and faculty research supervisors’ NIH or NIH approved Human Subjects research Training forms, the principal investigator’s Informed Consent form, tests, institutional permission slips, etc, related to this study. **Failure to do so will result in delayed processing of the application.**

\_\_\_\_\_\_ NIH (or equivalent) certificate(s) for researcher(s)/research supervisor(s)

\_\_\_\_\_\_ Statement of Institutional Permission or Letter of Support

\_\_\_\_\_\_ IRB Approval from other institution(s) (if any)

\_\_\_\_\_\_ Informed Consent documentation

\_\_\_\_\_\_ Survey Instrument

\_\_\_\_\_\_ Permission to Use Survey Instrument

\_\_\_\_\_\_ List of researchers (if more than listed on Cover Sheet)