Tutorial and Template for Completing IRB Electronic Application

The following YouTube video tutorial will introduce the use of the IRB electronic application. Please review prior to completing the electronic application.

[Tutorial Video Link](https://drive.google.com/file/d/1y89MJReH91SXX-tkxHC3uItBDBXsMmMY/view?usp=drive_link)

The tutorial video encourages you to develop your application information and narratives prior to accessing the live application link. You only have 1 hour to complete the application link. After 1 hour it goes dormant and all your information will be lost.

You can view a ‘mock’ electronic IRB application at [Mock Practice Application](https://irb.umassglobal.edu/Lists/IRBApplication/Item/newifs.aspx?DefaultView=Immersion). If you use the following Word application template in this document to draft your application, you can then just copy the narratives off the template and paste into the electronic form.

To help illustrate typical language/narratives for the application the last document in this packet is the Word Application Template with Example Narrative.

If you are an EDD or DNP dissertation student, always check with your dissertation chair for permission prior to complete the live electronic application.

**When you are ready to submit to IRB the live link is posted on the IRB website at** [**https://irb.umassglobal.edu**](https://irb.umassglobal.edu/)**.**

Word application template is a replication of the electronic IRB official application. You can use this Word template to draft your application, save and then send to your chair for review prior to submitting the official electronic application. Review the previous video link before using this template.



**Institutional Review Board**

Practice Word Application

**Part 1 – Administrative Information**

This form is to be used for requesting IRB review of any new project. IRB approval is required before any research involving human subjects may be initiated.

Full details must be provided and all necessary documentation submitted. UMass Global is committed to safeguarding the rights and welfare of all people who participate in research conducted by UMass Global faculty and students. UMass Global supports responsible experimentation which promises to increase knowledge and understanding and encourages the highest ethical standards among UMass Global researchers.

The central aim of the IRB is to protect the rights of human participants in research studies, including their rights to give informed consent and to have their safety protected from undue risk. The IRB has the responsibility and authority to review and approve all research projects by UMass Global faculty and students involving human or animal participants. It will approve only research that conforms to the professional standards as understood within the relevant discipline.

The IRB Application becomes the researcher’s record of compliance with laws and regulations protecting the rights and welfare of human participants in research described in the Department of Health and Human Services (DHHS) regulations 45 CFR 46, as specified in the Office for Protection from Research Risks (OPRR) 1983 report on Protection of Human Subjects.

Submit an electronic copy of the Application for Exempt, Expedited, and Standard Review found within this form.

For questions, please contact irb@UMassGlobal.edu.

**Institutional Review Board Application**

IMPORTANT: Please respond to all the questions. Do not leave any items blank. Responding to each question on this application fulfills one of the requirements for the ethical conduct of researchers. If a question does not pertain to your study, indicate not applicable (NA) following the question. Do not delete or modify questions from this application. Please note that incomplete applications will be returned without review.

**Part 1A: Research Information**

**Research Information**

Researcher’s Assurance: I certify that the information provided in this application is complete and correct. I understand that as principal researcher, I have ultimate responsibility for the conduct of the study, adherence to ethical standards, and protection of the rights and welfare of human participants. I agree to:

(1) Conduct the study according to the approved protocol; (2) Make no changes to the approved study without prior IRB approval; (3) Use the approved procedure and form(s) for obtaining informed consent; and, (4) Promptly report any significant adverse events to the IRB within five working days of occurrence.

**Researcher's Name:**

**Date:**

**Student ID:** [pre-populated based on login]

**Phone Number:**

**Email Address:** [pre-populated based on login]

**Address:**

**Person Overseeing the Study** This section is completed by student.

**Name:**

**Department: Phone Number:**

**Email Address:**

**Address**

**Part 1B: Application Information**

**Title of proposed research study: Remember to insert title!!!**

**Type of Review Requested:**

[ ]  **Exempt Review:** As defined in 45 CFR 46, there are six exemptions to the regulatory requirements described in section 46.101(b) of 45 CFR 46. See IRB Research Review Policy for “exempt” review requirements.

[ ]  **Expedited Review:** Surveys considered minimal risk; research on individual or group behavior or characteristics where research does not cause stress to subject and confidentiality is maintained; research involving deception that poses no more than minimal risk; performance of non-invasive tests; collection of data using noninvasive procedures; collection of blood samples by finger stick or venipuncture by trained personnel; research using existing documents, records, pathological specimens, or diagnostic specimens.

[ ]  **Full IRB Review:** Research with greater than minimal risk; research of a sensitive nature; research with vulnerable populations (children, prisoners, pregnant women, mentally disabled, elderly individuals, non-English or English as second language speakers, or economically/educationally disadvantaged individuals); research involving invasive procedures; research inducing physical pain or potential injury.

**Type of Research:**

[ ]  Institutional Research

[ ]  Graduate Research

[ ]  Undergraduate Research

**Principal Researcher Position:**

[ ]  Faculty

[ ]  Doctoral Student

[ ]  Master's Student

[ ]  UMass Global Staff Member

[ ]  Non UMass Global Researcher

**Principal Researcher’s College Affiliation:**

[ ]  Arts and Sciences

[ ]  Business and Professional Studies

[ ]  Education

[ ]  Nursing and Health Professions

**Category that applies to your research:**

[ ]  Doctoral Dissertation

[ ]  Master's Thesis

[ ]  Faculty Professional/Academic Research

[ ]  Course Project

[ ]  DNP Clinical Scholarly Project

**Part 2 – Study Design, Methods and Procedures**

Provide a summary of the study, including the purpose and research questions:

Describe briefly how this study will contribute to existing knowledge in the field:

**Description of Human Subjects**

Target Population

Number of Participants or Sample Size

Characteristics of Population

Specify Age of Subjects

Do your subjects include any of the following:

[ ]  Pregnant women/neonates

[ ]  Minors ages seven through seventeen

[ ]  Infants or children younger than seven years of age

[ ]  Cognitively impaired

[ ]  Inmates or prisoners

[ ]  Elderly/aged persons

[ ]  Non-English speaking persons

[ ]  Economically or socially disadvantaged

[ ]  Adults with physical or mental disabilities

[ ]  Patients

[ ]  Other special populations targeted in the study protocol

[ ]  None of the Above

 **Recruitment**

Specify how you will gain access to, recruit and select your subjects? Describe when, where and how participants will be contacted. How will potential participants be initially identified? From what sources will participants be identified, i.e., school, business, health care, law enforcement, non-profit organization, etc. Attach letters or email from all organizations on official letterhead granting permission or IRB approval from the organization. Attach all recruitment documents i.e., flyers, brochures, bulletin boards, media, electronic media, social media, etc.

**Data Collection**

List all instruments, assessments, tests, questionnaires, interviews or other materials developed specifically for this research. If no special assessments were developed and used in this study, state “non- applicable” or NA . In Part 6 of this application, attach copies of any materials listed here, and attach verification of permission to use the materials in this research.

List the titles of all instruments, assessments, tests, questionnaires, interviews or other materials developed commercially or by a third party. If no commercially developed materials were used in this study, state “non-applicable” or NA. In Part 6 of this application, attach copies of any materials listed here, and attach verification of permission to use the materials in this research.

Describe in detail and in sequence the study procedures that involve human participants, including tests, treatments and research interventions

Are you offering payment or other inducements to participants in this study?

[ ]  No

[ ]  Yes Describe the amount of the payment or inducement and how it will be received.

Will participation in the study involve any cost to the participant?

[ ]  No

[ ]  Yes If yes, indicate the anticipated costs and rationale.

**Part 3 – Risks and Benefits**

Please select all the potential risks that are involved in your study.

[ ]  Use of private records (such as educational or medical records)

[ ]  Manipulation of psychological or social state such as sensory deprivation, social isolation, psychological stress

[ ]  Probing for personal or sensitive information in surveys or interviews such as private behaviors or employer assessments

[ ]  Presentation of materials which some participants may consider sensitive, offensive, threatening or degrading

[ ]  Possible invasion of privacy of subject’s family

[ ]  Social or economic risk (reputation, cultural, employability, etc.)

[ ]  Identification of child, spousal, or elder abuse

[ ]  Identification of illegal activity

[ ]  Risk of injury or bodily harm

[ ]  None of the Above

**Please indicate other risks in the field provided above.**

What level of risk does this research present to dignity, rights, health, welfare, or privacy of the participants?

[ ]  Less than Minimal Risk to Participants - Justify your rating below

[ ]  Minimal Risk to Participants - Justify your rating below

[ ]  More than Minimal Risk to Participants - Explain and specify risks below

Describe the steps that will be taken to minimize risks or harms and to protect the welfare of participants. Include a description of how you will handle an adverse or unexpected outcome that could be potentially harmful against any risk.

Describe any benefits that individuals may reasonably expect from participation. If there are none, state "None."

Describe any anticipated benefits of this study to society, academic knowledge or both.

**Part 4 – Privacy and Confidentiality**

Will you or any member of your research team collect or have access to any of the personal identifiers listed below? Select all that apply.

[ ]  Name

[ ]  Date of Birth

[ ]  Mailing or email address

[ ]  Phone numbers

[ ]  Social Security number

[ ]  Medical records

[ ]  License

[ ]  IP address

[ ]  Photos/images/audio recording

[ ]  Signatures, handwriting samples

[ ]  N/A

Any unique identifier not mentioned above:

Describe the procedures for how the subject’s privacy will be maintained during the study. What provisions have been made to protect the confidentiality of participants? Where will you securely store data and research records? How will you dispose of signed consent, data and research records after the research is completed? Note you need to indicate a 3 year timeline. For instance, *stored for 3 years after which point they will be securely shredded and discarded.*

**Part 5 *–* Consent Process**

Include any of the following attachments applicable to this application:

**Informed Consent**

The entire informed consent process involves giving a subject adequate information concerning the study, providing adequate opportunity for the subject to consider all options, responding to the subject's questions, ensuring that the subject has comprehended this information, obtaining the subject's voluntary agreement to participate, and continuing to provide information as the subject or situation requires. Identify and describe the procedures you will use to obtain Informed Consent. Attach a copy of the informed consent form in Part 6 (see UMass Global requirements and Sample Informed Consent form) and include the script of oral explanations. Include any Informed Consent forms required by other participating organizations.

[ ]  Consent Required: Participant informed consent required

[ ]  Consent Required: Written assent for children and individuals under 18

[ ]  Consent Required: Parent/Guardian permission for children and individuals under 18

[ ]  Consent not required

**Write Informed Consent Procedures**

**Part 6 – Attachments**

**Include your NIH or Citi Certificate and any of the following attachments applicable to this application:** Have all your documents saved in one folder and ready to upload when you are going to complete the ‘live’ application.

* Consent/Assent Forms (All parental/guardian consent forms, Information sheets for Waiver of Consent, Internet Consents, Verbal Consent scripts, etc.)
* Screening Materials (Demographic questionnaires or measures used in screening subjects for inclusion or exclusion)
* Site Permission/Support Letters (Letters form agency or organization granting permission – on official letterhead)
* Recruitment Materials
* Data Collection Instruments (Questionnaires, copyrighted tests, focus group questions, interview questions, scripts, etc.)

**Part 7 – Assurance**

I agree:

* To comply with all IRB policies, decisions, conditions and requirements.
* This study protocol has been designed, to the best of my knowledge, to protect human participants engaged in research in accordance with the applicable principles, policies, regulations, and laws governing the protection of human subjects in research.
* To obtain prior approval from the IRB before amending the research protocol or the approved consent/assent form.
* To report to IRB any adverse event(s) and/or unanticipated problem(s) involving risks to participants.
* To submit the Annual Review Form as needed.

[ ]  I have completed the NIH or Citi Certificate and included a copy with the proposal.

[Please Check NIH/Citi Certificate box.]

Researcher's Typed Signature:

Date:

**Part 8 – ONLY for FULL IRB REVIEW**

Full IRB review is required for all research involving greater than minimal risk to subjects. This responsibility cannot be delegated. Full review is required for research involving any protected subject population. Protected groups include: fetuses, pregnant women, human in vitro fertilization, prisoners, children, elderly, and psychiatric patients. Depending on the type of research or target population, some groups may be vulnerable to coercion or undue influence or have impaired capacity to make decisions and require additional safeguards. The researcher shall design subject selection and consent procedures that will protect the rights and welfare of all subjects. In addition, a study may be referred to the full board by an expediting reviewer. For example, a reviewer may seek guidance from the full board in determining whether a study meets the regulatory definition of minimal risk or when the scientific question posed exceeds the expertise of the identified expediting reviewer.

Describe how your protocol mitigates or accommodates possible risks to the research participants.

Describe the professional experiences and special training you have that qualifies you to conduct the proposed study involving more than minimal risk to participants.



**Institutional Review Board**

**Word application template with example narratives/suggestions**

**Part 1 – Administrative Information**

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The central aim of the IRB is to protect the rights of human participants in research studies, including their rights to give informed consent and to have their safety protected from undue risk. The IRB has the responsibility and authority to review and approve all research projects by UMass Global faculty and students involving human or animal participants. It will approve only research that conforms to the professional standards as understood within the relevant discipline.

The IRB Application becomes the researcher’s record of compliance with laws and regulations protecting the rights and welfare of human participants in research described in the Department of Health and Human Services (DHHS) regulations 45 CFR 46, as specified in the Office for Protection from Research Risks (OPRR) 1983 report on Protection of Human Subjects.

Submit an electronic copy of the Application for Exempt, Expedited, and Standard Review found within this form.

For questions, please contact irb@UMassGlobal.edu.

**Institutional Review Board Application**

IMPORTANT: Please respond to all the questions. Do not leave any items blank. Responding to each question on this application fulfills one of the requirements for the ethical conduct of researchers. If a question does not pertain to your study, indicate not applicable (NA) following the question. Do not delete or modify questions from this application. Please note that incomplete applications will be returned without review.

**Part 1A: Research Information**

Research Information

Researcher’s Assurance: I certify that the information provided in this application is complete and correct. I understand that as principal researcher, I have ultimate responsibility for the conduct of the study, adherence to ethical standards, and protection of the rights and welfare of human participants. I agree to:

(1) Conduct the study according to the approved protocol; (2) Make no changes to the approved study without prior IRB approval; (3) Use the approved procedure and form(s) for obtaining informed consent; and, (4) Promptly report any significant adverse events to the IRB within five working days of occurrence.

**Researcher's Name:**

**Date:**

**Student ID:** [pre-populated based on login]

**Phone Number:**

**Email Address:** [pre-populated based on login]

**Address:**

**Person Overseeing the Study** This section is completed by student.

**Name:**

**Department: Phone Number:**

**Email Address:**

**Address**

**Part 1B: Application Information**

**Title of proposed research study: Remember to insert title!!!**

*Supporting a Growth Mindset in High School Classroom Teachers*

**Type of Review Requested:**

[ ]  **Exempt Review:** As defined in 45 CFR 46, there are six exemptions to the regulatory requirements described in section 46.101(b) of 45 CFR 46. See IRB Research Review Policy for “exempt” review requirements.

[x]  **Expedited Review:** Surveys considered minimal risk; research on individual or group behavior or characteristics where research does not cause stress to subject and confidentiality is maintained; research involving deception that poses no more than minimal risk; performance of non-invasive tests; collection of data using noninvasive procedures; collection of blood samples by finger stick or venipuncture by trained personnel; research using existing documents, records, pathological specimens, or diagnostic specimens.

[ ]  **Full IRB Review:** Research with greater than minimal risk; research of a sensitive nature; research with vulnerable populations (children, prisoners, pregnant women, mentally disabled, elderly individuals, non-English or English as second language speakers, or economically/educationally disadvantaged individuals); research involving invasive procedures; research inducing physical pain or potential injury.

**Type of Research:**

[ ]  Institutional Research

[x]  Graduate Research

[ ]  Undergraduate Research

**Principal Researcher Position:**

[ ]  Faculty

[x]  Doctoral Student

[ ]  Master's Student

[ ]  UMass Global Staff Member

[ ]  Non UMass Global Researcher

**Principal Researcher’s College Affiliation:**

[ ]  Arts and Sciences

[ ]  Business and Professional Studies

[x]  Education

[ ]  Nursing and Health Professions

**Category that applies to your research:**

[x]  Doctoral Dissertation

[ ]  Master's Thesis

[ ]  Faculty Professional/Academic Research

[ ]  Course Project

[ ]  DNP Clinical Scholarly Project

**Part 2 – Study Design, Methods and Procedures**

Provide a summary of the study, including the purpose and research questions:

*There is a lot of research on how to develop and support a growth mindset in students, but there is less research on how to do that in adults, and even less research on how to do that in classroom teachers. This study will attempt to learn more about how high school principals develop a growth mindset in their teachers.*

*Purpose Statement*

*The purpose of this qualitative case study is to identify and describe the strategies that California public high school principals utilize to develop a growth mindset in classroom teachers.*

*Research Question*

*1. How do California public high school principals perceive the importance of developing a growth mindset in classroom teachers?*

*2. What strategies do California public high school principals use to develop a growth mindset in their classroom teachers?*

*3. What strategies do California public high school principals use to sustain a growth mindset in their classroom teachers?*

Describe briefly how this study will contribute to existing knowledge in the field:

*This study will add to the body of knowledge on how to support a growth mindset in classroom teachers. This will better support principals and other school leaders in planning and facilitating effective professional development that will support teachers in their learning.*

**Description of Human Subjects**

Target Population

 *Northern California public high school principals*

Number of Participants or Sample Size

*12 high school principals*

Characteristics of Population

*The population for this study is California public high school principals. Principals are defined as the highest level administrator at a school site. Public high schools are defined as schools which teach grade levels 9 through 12, inclusive, and are overseen by the California Department of Education. There are 1,312 public high schools in the State of California.*

Specify Age of Subjects

 *All subjects are adults age 18 or older*

Do your subjects include any of the following:

[ ]  Pregnant women/neonates

[ ]  Minors ages seven through seventeen

[ ]  Infants or children younger than seven years of age

[ ]  Cognitively impaired

[ ]  Inmates or prisoners

[ ]  Elderly/aged persons

[ ]  Non-English speaking persons

[ ]  Economically or socially disadvantaged

[ ]  Adults with physical or mental disabilities

[ ]  Patients

[ ]  Other special populations targeted in the study protocol

[x]  None of the Above

 **Recruitment**

Specify how you will gain access to, recruit and select your subjects? Describe when, where and how participants will be contacted. How will potential participants be initially identified? From what sources will participants be identified, i.e., school, business, health care, law enforcement, non-profit organization, etc. Attach letters or email from all organizations on official letterhead granting permission or IRB approval from the organization. Attach all recruitment documents i.e., flyers, brochures, bulletin

boards, media, electronic media, social media, etc.

*Subjects will come from high schools in Napa, Sonoma, Marin, and Solano counties in California. A nonprobability purposive convenience sampling will be used. The principal investigator will contact principals that he knows in the selected counties and use snowball sampling to connect with potential subjects. Potential subjects will be contacted by email, phone, and/or in person and asked to participate in the study as long as they meet the selection criteria. These criteria require the principal to be working at a high school with a WASC accreditation of six years with a one day visit or better, the principal needed to have been the principal at the school at the time of the WASC accreditation visit, and the principal needs to have been in his/her third year or greater as principal at the time of the study.*

**Data Collection**

List all instruments, assessments, tests, questionnaires, interviews or other materials developed specifically for this research. If no special assessments were developed and used in this study, state “non- applicable” or NA . In Part 6 of this application, attach copies of any materials listed here, and attach verification of permission to use the materials in this research.

 *The investigator will use an interview protocol that was developed after conducting a thorough literature review of the subject matter and was reviewed by the dissertation chair and two additional qualitative research experts with doctoral degrees. See attached.*

List the titles of all instruments, assessments, tests, questionnaires, interviews or other materials developed commercially or by a third party. If no commercially developed materials were used in this study, state “non-applicable” or NA. In Part 6 of this application, attach copies of any materials listed here, and attach verification of permission to use the materials in this research.

*N/A Only use when you have commercial, copyrighted and third party instruments that require permission to use.*

Describe in detail and in sequence the study procedures that involve human participants, including tests, treatments and research interventions

1. *Potential subjects will be identified and approached by the principal researcher per the recruitment instructions above.*
2. *The principal investigator will share with the potential subjects the purpose of the study and the research questions. He will explain to the potential subjects that they will be asked to participate in a 30 to 45 minute interview.*
3. *If subjects agree, they will be provided with the standard UMass Global Bill of Rights and an informed consent form. These documents outline the subjects’ rights and explains the risk that is involved, that their participation is voluntary and that they may opt out at any time, and procedures and protocols for maintaining confidentiality during the study.*
4. *The principal investigator will schedule the interview. The interview will not begin until the subject has signed the informed consent form and had an opportunity to have any questions answered by the investigator.*
5. *The principal investigator will follow the interview protocol that was developed (see attached). During the interview, the investigator will take some notes, but will record the interview using two devices. The recordings will be kept confidential to protect the subjects and will be transcribed.*
6. *The transcripts of the interviews will later be shared with the subjects so that they can review them for accuracy and provide any clarifications or additional information.*

Are you offering payment or other inducements to participants in this study?

[x]  No

[ ]  Yes - Describe the amount of the payment or inducement and how it will be received.

Will participation in the study involve any cost to the participant?

[x]  No

[ ]  Yes If yes, indicate the anticipated costs and rationale.

**Part 3 – Risks and Benefits**

Please select all the potential risks that are involved in your study.

[ ]  Use of private records (such as educational or medical records)

[ ]  Manipulation of psychological or social state such as sensory deprivation, social isolation, psychological stress

[ ]  Probing for personal or sensitive information in surveys or interviews such as private behaviors or employer assessments

[ ]  Presentation of materials which some participants may consider sensitive, offensive, threatening or degrading

[ ]  Possible invasion of privacy of subject’s family

[ ]  Social or economic risk (reputation, cultural, employability, etc.)

[ ]  Identification of child, spousal, or elder abuse

[ ]  Identification of illegal activity

[ ]  Risk of injury or bodily harm

[x]  None of the Above

**Please indicate other risks in the field provided above.**

*Subjects will be asked to reflect and share information about their leadership style and strategies that they use in their work leading their classroom teachers. It is possible that there would be some minimal discomfort in sharing some of this information.*

What level of risk does this research present to dignity, rights, health, welfare, or privacy of the participants?

[ ]  Less than Minimal Risk to Participants - Justify your rating below

[x]  Minimal Risk to Participants - Justify your rating below

[ ]  More than Minimal Risk to Participants - Explain and specify risks below

Describe the steps that will be taken to minimize risks or harms and to protect the welfare of participants. Include a description of how you will handle an adverse or unexpected outcome that could be potentially harmful against any risk.

 *The principal investigator will take steps to make sure that participants feel comfortable in the interview. Questions will be structured and asked in such a way that they are as nonthreatening as possible. The investigator will be cognizant of his body language and reactions during the interview so that they encourage the subject to share and engage in conversation and make them feel comfortable. Should the investigator feel as though the interview is becoming contentious or that the subject is feeling overly uncomfortable*

Describe any benefits that individuals may reasonably expect from participation. If there are none, state "None."

*One possible benefit is that the interviewee will have contributed to the body of knowledge on how school leaders support a growth mindset in classroom teachers. Aside from assisting in this research, there are no other expected benefits from participating in this study.*

Describe any anticipated benefits of this study to society, academic knowledge or both.

*The results of this study will add to the body of research and knowledge about how school leaders support a growth mindset in classroom teachers. This will better support leaders in planning and facilitating effective professional learning that results in teachers improving their practice which will ultimately result in increased student learning.*

**Part 4 – Privacy and Confidentiality**

Will you or any member of your research team collect or have access to any of the personal identifiers listed below? Select all that apply.

[x]  Name

[ ]  Date of Birth

[x]  Mailing or email address

[x]  Phone numbers

[ ]  Social Security number

[ ]  Medical records

[ ]  License

[ ]  IP address

[x]  Photos/images/audio recording

[ ]  Signatures, handwriting samples

[ ]  N/A

Any unique identifier not mentioned above:

 *None*

Describe the procedures for how the subject’s privacy will be maintained during the study. What provisions have been made to protect the confidentiality of participants? Where will you securely store data and research records? How will you dispose of signed consent, data and research records after the research is completed?

*The published dissertation will not include any identifying information on the principals or their schools. Instead, pseudonyms and/or codes like “Principal #1” or “School 1” will be used. All identifying information, recordings, and notes which are in electronic format will be stored on a password protected computer or on password secured online applications such as Google Drive. Only the principal investigator will have the passwords to these files. Any hard copy notes or identifying information will be stored in a locking filing cabinet which only the principal investigator will have access to. All electronic and hardcopy information, including signed consent forms, will be stored for 3 years after which point they will be securely shredded and discarded.* Note you need to indicate a 3 year timeline. Digital interview recordings and signed inform consents are to be securely stored and then destroyed at end of study. Transcripts of recordings fall under the 3 year rule.

**Part 5 *–* Consent Process**

Include any of the following attachments applicable to this application:

**Informed Consent**

The entire informed consent process involves giving a subject adequate information concerning the study, providing adequate opportunity for the subject to consider all options, responding to the subject's questions, ensuring that the subject has comprehended this information, obtaining the subject's voluntary agreement to participate, and continuing to provide information as the subject or situation requires. Identify and describe the procedures you will use to obtain Informed Consent. Attach a copy of the informed consent form in Part 6 (see UMass Global requirements and Sample Informed Consent form) and include the script of oral explanations. Include any Informed Consent forms required by other participating organizations.

[x]  Consent Required: Participant informed consent required

[ ]  Consent Required: Written assent for children and individuals under 18

[ ]  Consent Required: Parent/Guardian permission for children and individuals under 18

[ ]  Consent not required

**Write Informed Consent Procedures**

*Subjects will be provided with the UMass Global Bill of Rights as well as an informed consent form outlining the details of the study. The informed consent form will include the role of subjects in the study (engaging in a 30-45 minute interview and possible providing artifacts to the investigator which support what was shared in the interview), the risks and benefits involved in the study, confidentiality procedures/protocols, and their rights throughout the study. These include the choice to opt out of the study at any time without consequences, the choice to not answer particular interview questions, and to ask questions before, during, and after the study. It also provides contact information for the principal investigator, the dissertation chair, and UMass Global’s office of Academic Affairs should questions or concerns about the study arise.*

**Part 6 – Attachments**

**Include your NIH or Citi Certificate and any of the following attachments applicable to this application:**

* *Informed Consent Form*
* *NIH or Citi Certificate*
* *Interview Protocol and Questions*
* *Recruitment Email*

**Part 7 – Assurance**

I agree:

* To comply with all IRB policies, decisions, conditions and requirements.
* This study protocol has been designed, to the best of my knowledge, to protect human participants engaged in research in accordance with the applicable principles, policies, regulations, and laws governing the protection of human subjects in research.
* To obtain prior approval from the IRB before amending the research protocol or the approved consent/assent form.
* To report to IRB any adverse event(s) and/or unanticipated problem(s) involving risks to participants.
* To submit the Annual Review Form as needed.

[ ]  I have completed the NIH or Citi Certificate and included a copy with the proposal.

[Please Check NIH/Citi Certificate box.]

Researcher's Typed Signature:

Date: