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| MSUTLL2CfutureTM-short | | **APPLICATION FOR APPROVAL OF INVESTIGATION INVOLVING HUMAN PARTICIPANTS** | | | | | | | |
|  | | (Application must be typed) | | | | | | | |
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| 1. **Principal Investigator:** | |  | | | | | | | |
| **Mailing Address:** | |  | | | | | | | |
| **Contact Phone:** | |  | | | | | | | |
| **Email Address:** | |  | | | | | | | |
|  | |  | | | | | | | |
| **Co-Investigator(s):** | |  | | | | | | | |
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| (Include affiliation if not from Morgan): | | | | |  | | | | |
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| 1. **If you are a student, provide the following:** | | | | | | | | | |
| **Faculty Sponsor:** | |  | | | | | | | |
| **Department:** | |  | | | | | | | |
| **Campus Phone:** | |  | | | | | | | |
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| 1. **Project Title:** | |  | | | | | | | |
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| **NOTE: NO CONTACT WITH HUMAN SUBJECTS MAY OCCUR**  **UNTIL THIS APPLICATION HAS BEEN APPROVED.** | | | | | | | | | |
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| 1. Dates during which research with human participants will take place (including all contact with human participants and until analysis of subject identifiable data and records are complete or access to identifiable data and records is no longer necessary): | | | | | | | | | |
| Date research with human participants will begin: | | | | |  | | | | |
| Date research with human participants will end: | | | | |  | | | | |
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| 1. Has this project been previously considered by Morgan State’s Institutional Review Board? | | | | | | | | | |
| Yes  No | | | | | | | | | |
| If yes, give IRB # & approval date: | | | | # |  | | Approval Date: | |  |
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| 1. Is a proposal for external support being submitted? | | | | | | Yes  No | | | |
| If yes, you must submit one complete copy of that proposal as soon as it becomes available and complete the following: | | | | | | | | | |
| 1. Name of Grant Program: | | | | |  | | | | |
| 1. Name of Grant Agency: | | | | |  | | | | |
| 1. Is notification of human subjects approval required:  Yes  No | | | | | | | | | |
|  | | | | | | | | | |
| 1. Description of Human Participants: | | | | Number: |  | | | Age: |  |
| Male: |  | | | Female: |  |
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| 1. In your judgment, does your research fall under one of the eight exempt categories? | | | | | | | | | |
| Yes  No | | | | | | | | | |
| If you believe it does, indicate the category under which you are claiming exemption. A listing of exempt categories is included in Morgan State University’s *Policies and Procedures for Research Involving Human Participants*, found on the Office of Research Administration website. | | | | | | | | | |
| Exemption: |  | | | | | | | | |
| Category: |  | | | | | | | | |
| **IF YOU ARE CLAIMING AN EXEMPTION, SKIP NUMBERS 15-16** | | | | | | | | | |
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| 1. STUDENT PROJECTS ONLY | | | | | | | | | |
| Is this project an independent research project?  Yes  No | | | | | | | | | |
| Master’s thesis?  Yes  No | | | | | | | | | |
| Doctoral dissertation?  Yes  No | | | | | | | | | |
| If **no**, is your project a supervised student project that was assigned as part of the requirements for a course?  Yes  No | | | | | | | | | |
| Course No. and Name: | | | |  | | | | | |
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| 1. Describe the source(s) of participants and the selection criteria. Specifically, where did you obtain the names of potential participants (i.e. agency files, hospital records, local organizations, etc.)? Where and how will you contact them? | | | | | | | | | |
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| 1. A) Is any of the information being gathered Protected Health Information covered by the Health Insurance Portability and Accountability Act (HIPAA)?  Yes  No | | | | | | | | | |
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| B) If yes, are you using an informed consent document that is consistent with HIPAA regulations? (Please attach a sample.)  Yes  No | | | | | | | | | |
| **If the response to 11b is no, you must attach an *Addendum to Application for Approval of Investigation Involving Human Participants*, *Request for Waiver* or *Alteration of Patient Authorization Requirements* to this application.** | | | | | | | | | |
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| 1. **Procedures:** Provide a step-by-step description of each procedure, including the frequency, duration and location of each procedure. | | | | | | | | | |
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| 1. **Description:** Briefly describe the proposed research: Include major hypotheses and research design. | | | | | | | | | |
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| 1. **Consent:** Describe the informed consent process and attach all **consent** documents. For projects involving minors: describe the process through which assent will be obtained and attach copies of **assent forms.** If you have not indicated that the project is exempt and consent and/or assent will not be obtained, explain why a waiver is requested. | | | | | | | | | |
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| 1. **Expertise:** Cite your experience with this kind of research. List any assistants who will be working with you, and cite their experience also | | | | | | | | | |
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| 1. **Benefits:** Describe the anticipated benefits to participants and the importance of the knowledge that may reasonably be expected to result. | | | | | | | | | |
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| 1. **Risks:** Describe the risks involved with these procedures (physical, psychological and/or social) and the precautions you have taken to minimize these risks. | | | | | | | | | |
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| 1. **Data Retention:** How will research data (written or otherwise recorded) be maintained securely for the 3-year Data Retention requirement? At the end of the 3 years of required Data Retention will research data be destroyed? If not, where and in what format and for how long will they be stored? To what uses – such as research, demonstration, public performance, archiving, etc. – might they be put in future? How will subjects’ permission for further use of their data be obtained.   *STUDY DATA MUST BE RETAINED SECURELY FOR AT LEAST 3 YEARS AFTER THE STUDY END DATE.* | | | | | | | | | |
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| 1. Principal Investigators must submit a Request for Amendment form when seeking to make a change to a study that has already been approved. | | | | | | | | | |
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| Committee approvals for expedited and full review applications are for one-year periods. If the research activity extends past one year, applications must submit a Request for Renewal form at least **three weeks** prior to the expiration of the initial approval period. | | | | | | | | | |
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| Any problems connected with the use of human participants once the project has begun must be reported to the Office of Sponsored Programs and Research and/or the Institutional Review Board immediately. | | | | | | | | | |
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| **I agree to provide whatever surveillance is necessary to ensure that the rights and welfare of the human participants are properly protected. I understand that I cannot initiate any contact with human participants before I have received approval and/or complied with all contingencies made in connection with that approval.** | | | | | | | | | |
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| **Signature of Principal Investigator/Project Director** | | | | | **Date** | | | | |
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| 1. Approval by Faculty Sponsor (required for all students): | | | | | | | | | |
| **I affirm the accuracy of this application, and I accept responsibility for supervising the conduct of this research project and the protection of human participants as required by law.** | | | | | | | | | |
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| **Signature of Faculty Sponsor** | | | | | **Date** | | | | |
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| **Please submit the completed and SIGNED application, together with copies of ALL the following relevant documents to** [**irb.research@morgan.edu**](mailto:irb.research@morgan.edu)**:** | | | | | | | | | |
| Application for Approval of Investigation Involving Human Participants, including minimum 3-Year Data Retention Plan  Project Abstract/Executive Summary | | | | | | | | | |
| Survey Instruments or Protocol | | | | | | | | | |
| Informed Consent Form (or Script), Assent Form \* | | | | | | | | | |
| Subjects Information Sheets or Debriefing Materials | | | | | | | | | |
| Recruitment Letter, Poster, Advertisement | | | | | | | | | |
| Human Subjects Education Certificate (CITI or NIH) – REQUIRED | | | | | | | | | |
| Other *(specify)*: | | |  | | | | | | |
| \* A sample informed consent form is attached on the following page. | | | | | | | | | |
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| **Submit all to:** [**irb.research@morgan.edu**](mailto:irb.research@morgan.edu) | | | | | | | | | |
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| **For more information CONTACT:** | | | | | | | | | |
| **Division of Research and Economic Development (D-RED)** | | | | | | | | | |
| **Office of Research Administration** | | | | | | | | | |
| **Tyler Hall, Room D-304** | | | | | | | | | |
| **(443) 885-4340** | | | | | | | | | |
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| For further information on Morgan State University’s Institutional Review Board please visit: | | | | | | | | | |
| <https://www.morgan.edu/office-of-research-administration/research-compliance/human-subjects-research> | | | | | | | | | |
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**INFORMED CONSENT**

***(Sample Template: SEE INSTRUCTIONS BELOW)***

**INSTRUCTIONS*: DELETE THIS SECTION before sending to the IRB office with your application. The language should be modified as appropriate for your study. Provide relevant information in the sections below, replacing italicized directions/guidance (anything in the GREEN font color) with information specific to your study, and deleting sections that do not apply to your research.***

*I am/we are* asking you to participate in a research study titled *“TITLE”.* *I/We* will describe this study to you and answer any of your questions. This study is being led by *Name of PI, Department at Morgan State University. The* **Faculty Advisor for this study is** *(if PI is a student)**Name, Department at Morgan State University.*

**What the study is about**

The purpose of this research is to….

*Provide a clear, concise summary of Key Information in lay language of the purposes of the research, including prominent use of the term "research." (Note: the IRB can waive this element if the study requires deception. In such cases, a* ***Debriefing Statement*** *should also be used to inform participants at an appropriate time after their involvement in the study.)*

**What we will ask you to do**

*I/We* will ask you to…

*Explain in simple, non-scientific language what will happen to the participant or what s/he will be asked to do in the study. Describe the participant time commitment for each component. All procedures listed in the IRB application and funding proposal should be described, and any experimental procedures (interventions, manipulations, treatments) specifically noted.*

**Risks and discomforts**

*In simple, non-scientific language, describe any reasonably foreseeable risks or discomforts:*

* *Legal risks (e.g., possibility of discovering activities that may require reporting to authorities, possibility of being arrested)*
* *Physical risks (e.g., nausea, muscle aches, rashes, infection, discomfort)*
* *Social or economic risks (e.g., loss of confidentiality; effect on financial standing, employability, or insurability)*
* *Emotional risks (e.g., feelings of sadness or anxiety)*

***If there are no known risks****, state: I/We do not anticipate any risks from participating in this research.*

**Benefits**

*Describe any probable benefits of participation. Be sure to distinguish between a likely direct benefit (e.g., from therapeutic or intervention research) and a possible indirect benefit (e.g., reflecting on an experience may lead to a better understanding of oneself).* ***If there are no direct benefits, indicate that there are none.***

***Describe the expected benefits to society or scientific knowledge: e.g., “…information from this study may benefit other people now or in the future…” or “…we hope to learn more about \_\_\_\_\_\_\_ …”***

*Note: Compensation, financial incentives, learning about how experiments are conducted, receiving a gift, or earning extra credit for being a research participant**are not “benefits” and should not be listed here.*

**Compensation for participation**

*Indicate whether the participant will receive compensation or extra credit for being in the study. If participants will not receive any compensation, state this. If students will receive course credit for participation, ways of earning credit without participating in the research should be mentioned here.*

**Audio/Video Recording**

*If audio and/or video recording devices will be used, explain why these are needed and what will be done with them upon completion of the research (kept indefinitely, archived after transcription, destroyed after X years).*

*ONLY IF USING A SIGNED CONSENT, provide a separate signature line for the participant to be audio/video recorded, if the recording is optional for participation. For example:*

Please sign below if you are willing to have this interview recorded *(specify audio or video)*. You may still participate in this study if you are not willing to have the interview recorded.

I do not want to have this interview recorded.

I am willing to have this interview recorded:

Signed:

Date:

*If you will take photographs or make audio, video, or other recordings that you want to use for activities beyond research analysis (publications, presentations, other promotional purposes), include a section that:*

* *Informs the participant that you are making a [type(s) of media used] recording in which the person’s name, likeness, image, and/or voice will be included;*
* *Asks the participant to grant you the right to make, use and publish recordings in whole or in part in media forms now known (such as film, slides, and digital audio) or developed in the future. This includes the right to edit or duplicate any images/recordings;*
* *Explains the limitations on reproduction, distribution, performance, or display of images/recordings;*
* *Explains that the participant does not have rights to inspect or approve the finished product or printed/published matter that uses the images/recordings or versions of the images/recordings; and*
* *Explains that the participant will not receive any financial compensation for commercial and/or non-commercial (as appropriate) uses of the images/recordings.*

*The same signature line above may be used for this performance release information.*

**Privacy/Confidentiality/Data Security**

*Explain briefly, and in lay terms,**how you will protect the participant’s privacy and/or confidentiality.*

* *De-identification of data*
* *If you will de-identify data with identifiers, or keep identifying information separate from research data ( e.g. signed consent forms kept separate from the survey data and the two will not be connected)*
* *If you plan to keep identifying information with the data, state this here*
* *If you are not planning to collect any identifying information at all (as in anonymous surveys).*
* *Physical security of data/research files*
* *Who will have access to identifying information*
* *How will sensitive data be kept secure in an electronic environment*

*If using a survey vendor to administer online surveys, include the following statement:*

Please note that the survey(s) [is/are] being conducted with the help of [company name], a company not affiliated with Morgan and with its own privacy and security policies that you can find at its website. We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.

*When the research involves e-mail communication, include the following statement:*

Please note that email communication is neither private nor secure. Though [I am/we are] taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

*For sensitive research data with identifiers, stored in the cloud or on servers, or transmitted via the internet, consider including the following statement:*

Data may exist on backups and server logs beyond the timeframe of this research project.

***OR***

Your confidentiality will be kept to the degree permitted by the technology being used. We cannot guarantee against interception of data sent via the internet by third parties.

**Sharing De-identified Data Collected in this Research**

*(****If you may share data without identifiers:*** *We strongly recommend that you include this section in your consent, to inform participants that you may share de-identified data you collect from them. Certain sponsors now require researchers to make available their de-identified data to the research community, as do a growing number of journals. If you choose not to include the following language and later wish to share de-identified data, you may not be able to do so without re-contacting participants to obtain consent.)*

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

**Future use of Identifiable Data or Specimens Collected in this Research**

***In addition to the recommended data sharing language, above, if you are collecting identifiable data or identifiable biospecimens, you must include one of the following:***

Identifiers might be removed and the de-identified information or biospecimens used for future research without additional consent.

**OR**

Identifiable information might be used for future research with obtaining your consent.

**OR**

Your information or biospecimens will not be used or distributed for future research studies.

**Information about use of your biospecimens**

***If you are collecting biospecimens, you must include the following:***

Specimens collected from you for this study and/or information derived from your specimens *will/may/will not* be used to generate commercial profit. You will/will not share in any commercial value or other compensation from products developed using these specimens.

***If clinically-relevant research results may be generated, you must include this statement:*** You *will/will not* receive any clinically relevant results discovered about you and/or the general subject population.

***If your study may involve whole genome sequencing, include this statement:*** This research *may/will* include whole genome sequencing.

**Clinical Trial**

***If the study is a “clinical trial,”*** *you must include language such as the following, identifying the study as a clinical trial and stating that the study will be listed on ClinicalTrials.gov. For NIH-funded trials this is required; for all others this is strongly suggested:* This study is classified as a clinical trial and will be registered online at http://www.ClinicalTrials.gov. The website will not include any information that can identify you, but will include a summary of results once the research is completed. You can search this publicly-available website at any time.

**Taking part is voluntary**

*Explain that the participant's involvement is voluntary, the participant may refuse to participate before the study begins, discontinue at any time, or skip any questions/procedures that may make him/her feel uncomfortable, with no penalty to him/her, and no effect on the compensation earned before withdrawing, or their academic standing, record, or relationship with the university or other organization or service that may be involved with the research.*

*If completing all research materials (e.g., answering all survey or interview questions; meeting a minimal requirement of entries in a weekly/monthly log) is required for participation, you must make this condition clear to them here. State that people can choose not to participate if they are uncomfortable with these conditions.*

**Follow up studies** *(Include this section if you will or might approach participants for a follow up study)*

We may contact you again to request your participation in a follow up study. As always, your participation will be voluntary and we will ask for your explicit consent to participate in any of the follow up studies.

*Explicit consent may not be necessary. Here is suggested language if you choose to ask for specific consent:*

May we contact you again to request your participation in a follow up study? Yes/No

**If you have questions**

*Explain how the participant can contact you with questions or concerns. A standard statement follows:*

The main researcher conducting this study is *[principal investigator’s name]*, a *[professor, graduate/undergraduate student, etc.]* at Morgan State University. Please ask any questions you have now. If you have questions later, you may contact *[principal investigator’s name/advisor’s name]* at *[email address]* or at *[phone number]*. If you have any administrative questions or concerns regarding your rights as a participant in this study, you may contact the MSU Institutional Review Board (IRB) at 443-885-4340. *If participants will be given a copy of this form, or some other information sheet, indicate that here.*

**Statement of Consent** *(Include only if you are using signed, written consent.* ***Signed consent*** *cannot be used if you tell participants that your study is anonymous. For online studies, asking participants to click on an “I approve” box is usually sufficient).*

I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Signature of Participant Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant (printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Signature of Legally Authorized Representative

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   
Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Printed Name of Legally Authorized Representative

Signature of person obtaining consent Date

Printed name of person obtaining consent \_\_\_\_\_\_