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| **DSU IRB**  **INITIAL RESEARCH SUBMISSION FORM** | |
| **INSTRUCTIONS:**   1. ***The IRB does not accept handwritten versions of this form. You must submit typed versions to prevent errors and delays due to legibility problems.*** 2. ***All questions must be answered. N/A is only an option where indicated.*** 3. ***If PI changes during life of the research study, provide updated information.*** 4. ***Your review may be delayed if we need to obtain clarification from you because information listed below differs from the information listed in supporting documents.*** 5. ***Please check the DeSales IRB website to ensure you are completing the most current version of this form.*** 6. **PRINCIPAL INVESTIGATOR (PI) INFORMATION:**   The PI is the person legally responsible for the conduct of this research and through whom all communication with the IRB occurs. The IRB must be assured that the PI can personally oversee the conduct of research and protection of human subjects.  Working under the general direction of a Principal Investigator, the research coordinator provides overall coordination of a significant multi-funded and/or multi-site research project(s), participates in developing research designs, data collection methods and strategies for data management. Coordinates multiple data collection efforts which may include other collaborating agencies or institutions. They may recruit or oversee recruitment of human subjects, write and edit reports and manuscripts, develop and monitor reports and work with funding agencies.  **CO- PRINCIPAL INVESTIGATOR (CO-PI) INFORMATION:**  The CO-PI is the person who works collaboratively with the PI on the conduction of the research. The IRB must be assured that the CO-PI is a graduate student; undergraduate students can not serve as a CO-PI. | |
| PRINCIPAL INVESTIGATOR (PI): |  |
| DSU Email: |  |
| DSU Department: |  |
| Phone #: |  |
| CO-PRINCIPAL INVESTIGATOR (CO-PI) |  |
| DSU Email: |  |
| RESEARCH COORDINATOR (if applicable): |  |
| **DSU Email:** |  |

1. **RESEARCHERS & TEAM MEMBERS:**

Please list all individuals that will be involved in overseeing the research process, consent process, report generation, data collection and/or data analysis in this research study.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Department or External Location** | **Title**  **(PI, Co-PI, faculty investigator, student investigator, research coordinator, external consultant)** | **Contributions to the Research Study**  **(responsible for student investigators, subjects, data analysis, consent process, data collection, etc.)** |
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* The PI must ensure each member of this research study has completed CITI training in the protection of human subjects. Training must be current and completed prior to submission of this application and copies must be submitted to the IRB. Has each member of the team completed this training?

YES

NO

* For this research study, how many of the following will the PI supervise:

Sites:\_\_     \_\_\_ Student Investigators:\_\_     \_\_\_ Research Coordinators:\_\_\_     \_\_

Projected # Subjects:\_\_     \_\_\_

1. **RESEARCH STUDY INFORMATION**
2. Research study Title: \_     \_\_
3. Date of submission:\_\_     \_\_\_\_
4. Briefly describe the purpose of the research study and include study aims or research questions:

\_\_     \_\_\_

1. Provide background to support your research study aims and methods. (For ex. a critical review of peer reviewed literature or evidence based practice.)

\_\_     \_\_\_

1. Identify your research study design, including all experimental procedures, and describe how the data collected will provide evidence to answer your research questions and build upon previous research findings.

\_\_     \_\_\_

1. Please explain the funding for this research study. For example, are you receiving any grants from other parties to conduct this research or will the research be completely funded by the University?

N/A

\_\_\_\_\_     \_\_\_\_

1. Is this research federally funded entirely or in part?

YES

NO

Name the federal agency.

N/A

\_\_\_\_\_     \_\_\_\_

Provide a copy of the grant.

N/A

1. Have you submitted this IRB proposal to another IRB?

YES

NO

Has another IRB approved, declined to review, tabled, deferred, disapproved, or terminated this research study?

YES

NO

Currently Under Review

Provide IRB correspondence.

N/A

1. **RESEARCH SITE LOCATION INFORMATION**

Please identify where the research will take place by completing this section for each site. If you or your research team members will be conducting the research at more than one site, complete and attach the Additional Site form at the end of this document for each additional site.

*If site information changes during the course of this research study, you will need to notify the DSU IRB. Please request the necessary changes using the Change in Research Submission Form available on the DSU IRB website.*

1. Name of research location: \_\_\_\_\_      \_\_\_\_
2. Physical address: \_\_\_\_\_      \_\_\_\_
3. Phone number: \_\_\_\_\_      \_\_\_\_
4. What type of facility is this site:

University/College  Hospital  Medical office

K-12 School System  Long term care facility  Other (specify): \_

1. What resources are available at this site to treat emergencies resulting from research study-related procedures?

Basic Life Support trained personnel

Advanced Cardiac Life Support trained personnel and a crash cart

Emergency drugs and supplies to stabilize subject until emergency personnel arrive

Emergency response team within the facility

Other: \_\_\_\_\_      \_\_\_\_

N/A: explain \_\_\_\_\_      \_\_\_\_

1. If this site is not a hospital, please name the closest medical facility to be used in an emergency.

\_\_\_\_\_      \_\_\_\_

How far is this medical facility from the site? \_\_\_\_\_      \_\_\_\_

N/A

1. Is this research study location a non-DeSales institution?

NO. ***Please proceed to question #8***

YES – ***Please complete the following:***

1. Describe the non-DeSales institution’s overall role in this research study. \_\_\_\_\_      \_\_\_\_
2. Describe your understanding of the local research context of the non-Desales institution or how the knowledge will be obtained (i.e. statistical consultants). \_\_\_\_\_      \_\_\_\_
3. Describe the adequacy of the non-DeSales insititution to support the research study.

\_\_\_\_\_      \_\_\_\_

1. Describe the responsibilities of the non-DeSales institution employees. \_\_\_\_\_      \_\_\_\_
2. Describe the oversight provided by the DeSales investigators in order to ensure adequate and ongoing protection of the human subjects. \_\_\_\_\_      \_\_\_
3. If the research is ongoing at this non-DeSales institution (such as a multi-center study) provide a report on research results to date and a summary of all unanticipated problems and/or serious adverse events and other reportable adverse events.

\_\_\_\_\_      \_\_\_

N/A

1. If a DeSales investigator is the lead researcher of a multi-site study, please describe how you will manage research study modifications, interium results and other aspects of the protection of human subjects in this study.

\_\_\_\_\_      \_\_\_

N/A

1. Does the non-DeSales institution meet the definition of “Engagement in Research”. *(For guidance, please review the Non-DeSales Institution policy located on the DeSales IRB website).*

YES

NO

1. Do you request that the DeSales IRB review on behalf of this non-DeSales institution?

YES – *Please provide a written letter of permission from an authorized individual (on the institution letterhead) that authorizes the PI to perform activities at the location.*

NO

1. Do you request that DeSales rely on the IRB of this non-DeSales institution?

YES

NO– *Please provide a written letter of permission from an authorized individual (on the institution letterhead) that authorizes the PI to perform activities at the location.*

Privacy and Confidentiality

1. **Privacy Protections:** Privacy is a subject’s ability to control how other people see, touch, or obtain information about the subject. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about HIV status, illegal drug use, etc.

What precautions will be used to ensure subject privacy is protected? (check all that apply).

Use of drapes or other barriers for subjects who are required to disrobe.

Research intervention is conducted in a private room.

The collection of sensitive information about subjects is limited to the amount necessary to achieve the

aims of the research, so that no unneeded information is being collected.

Other (specify): \_\_\_\_\_      \_\_\_\_

1. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy. It refers to the subject’s understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be any printed information, electronic information, or visual information such as photographs which could allow anyone to identify subjects in this study. This applies to both screening data and research data in your study.

a. What precautions will be used to maintain the confidentiality of identifiable information? (check all that

apply).

Paper-based records will be kept in a secure place as determined by the PI and only be accessible to

personnel involved in the research study.

Computer-based files will only be made available to personnel involved in the research study through the use of access privileges and passwords, for example, protecting a laptop or cloud based files.

Prior to access to any research study-related information, personnel will be required to sign statements

agreeing to protect the security and confidentiality of identifiable information.

Whenever feasible, identifiers will be removed from research study-related information.

When the research involves third party data collection tools, for example, web-based surveys, precautions are in place to ensure the data is secure by using passwords and encryption.

Audio and/or video recordings of subjects will be transcribed and then destroyed to eliminate audible

identification of subjects.

Audio and/or video recordings of subjects will be will be kept in a secure place as determined by the PI and only be accessible to personnel involved in the research study.

Other (specify): \_\_\_\_\_      \_\_\_\_

b. Who will perform the screening examination of subjects to determine if they are eligible for the research study for this site?

\_\_\_\_\_      \_\_\_\_

N/A

1. **RECRUITMENT, CONSENT AND SUBJECT PAYMENT INFORMATION:**

Please provide information about how subjects will be recruited, the consent form subjects will be asked to sign, and what type of incentive or compensation subjects will receive. Any recruitment interactions with subjects must be scripted and the scripts must be attached to this application.

* 1. Do you intend to enroll any subjects from the following “vulnerable categories? (check all that apply)

Prisoners

Minors (anyone under 18yo.)

Pregnant women

Students of PI or research study staff

Students to be recruited in an educational setting

Employees directly supervised by PI

Employees of research site

Poor/underinsured

Limited or non-readers

Cognitively impaired

Requires translation

Others who may be vulnerable due to their situation (specify): \_\_\_\_\_      \_\_\_\_

* 1. Please describe the population from which you will recruit for this research. (For example, race,ethnicity, gender, educational level, etc). \_\_\_\_\_      \_\_\_
  2. Describe in detail the process by which subjects will be invited to participate in the research study including:
     1. how you will contact them;
     2. how you will invite them to participate in the research study;
     3. how they will express their desire to participate.

\_\_\_\_\_      \_\_\_\_

* 1. Are you using any written or verbal materials to screen volunteers prior to enrollment in the research to determine their eligibility to participate (such as telephone call scripts, written or web-based questionnaires or pre-screening forms)?

YES. Please include for review and describe the screening plan.

\_\_\_\_\_      \_\_\_\_

NO

* 1. Do you anticipate any difficulties in recruiting/retaining a sufficient number of participants for this research?

YES Please explain: \_\_\_\_\_      \_\_\_\_

NO.

* 1. Who will conduct the consent discussion with the subject? (check all that apply).

PI

Co-PI

Faculty investigator

Research coordinator

Student investigator

Other (specify): \_\_\_\_\_      \_\_\_\_

* 1. Please describe the circumstances and location of the consent process: (check all that apply).

In a private room. The process is as follows:

\_\_\_\_\_      \_\_\_\_

In a waiting room. The process is as follows:

\_\_\_\_\_      \_\_\_\_

In an open hospital ward setting. The process is as follows:

\_\_\_\_\_      \_\_\_\_

In a group setting. The process is as follows:

\_\_\_\_\_      \_\_\_\_

In a group setting with follow up in a private room. The process is as follows:

\_\_\_\_\_      \_\_\_\_

In an emergency situation. The process is as follows:

\_\_\_\_\_      \_\_\_\_

Online, in public, or over the phone. The process is as follows:

\_\_\_\_\_      \_\_\_\_

Other (specify):

\_\_\_\_\_      \_\_\_\_

N/A, waiver of consent is requested. Please provide documentation of the following

* The research involves no more than minimal risk to the subjects;
* The waiver or alteration will not adversely affect the rights and welfare of the subjects;
* The research could not practicably be carried out without the waiver or alteration; AND
* Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
  1. How will you be sure there is sufficient opportunity for the subject to consider whether to consent?

Subjects will be allowed to take home the unsigned consent form for consideration prior to signing it.

Subjects will be allowed a waiting period to consider their decision.

Subjects will be required to wait \_\_\_       \_\_\_ hours after participating in the consent process before signing the consent form.

Other, please specify: \_\_\_\_\_      \_\_\_\_

* 1. Describe steps taken to minimize the possibility of coercion or undue influence: (check all that apply).

There will not be any threat of harm or adverse consequences if the subject does not agree to participate

in the research study, and the information provided during the consent process will be presented in a

balanced way with equal emphasis on all elements of consent. (i.e. there will not be over-emphasis of

benefits or under-emphasis of risks).

Other (specify): \_\_\_\_\_      \_\_\_\_

* 1. How will you show that the consent process is comprehensible to the research subjects? (Check all that apply)

The consent process will be:

conducted at an appropriate reading level

conducted with a translator available

presented in a language known to the subject

presented with minimal, well defined technical jargon

presented by someone who can answer questions about the research study

Other (specify): \_\_\_\_\_      \_\_\_\_

* 1. Mark one of the following regarding waiver of rights during the consent process:

The consent process will not involve the use of any language that requires or appears to require the subject and/or their representative to waive legal rights, and the consent process will not involve the use of any language that releases or appears to release the sponsor, institution, or any of their agents from liability

for negligence.

Other (specify): \_\_\_\_\_      \_\_\_\_

* 1. Subject compensation or incentive: If subjects are to be compensated, state specifically for which visits subjects will receive compensation and when it will be provided. For example, *“payment will be made at the end of each research study visit,”* or *“participants will be involved in a raffle at the conclusion of the study.”* Please be as specific as possible to minimize confusion.

Subjects will not be paid/compensated/incentivized.

Provide a statement explaining the payment plan (amounts, visits not paid, when payment will be made).

For example, *You will be paid $\_\_\_ for each completed research study visit. If you do not complete the research study, you will be paid for the visits you have completed. You will be paid at the end of each research study visit OR you will be paid within 30 days of the end of your participation in the research study, etc.*

\_\_\_\_\_      \_\_\_\_

Provide a statement explaining any other compensation method.

\_\_\_\_\_      \_\_\_\_

1. Select the item that best describes the risk level for this research:

*Minimal risk definition: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.*

Greater than minimal risk

Minimal or no known risks. Please indicate the applicable description(s) of the research:

**Data or specimens**:

* Research using **records/materials** that have been collected or will be collected for **nonresearch purposes**.
* Prospective collection **of specimens of data** for research purposes through non-invasive means
* **Blood samples** from **healthy, non-pregnant adults** who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 mg in an 8 week period and collection may not occur more frequently than 2 times per week.
* **Blood samples** from **other adults and children**. The amount does not exceed the lesser of 50 ml or 3ml/kg in an 8 week period and collection does not occur more than 2 times/week.

**Behavior/Individual Characteristics:**

* Collection of **data from recordings** made for research purposes.
* Research on individual or group characteristics or behavior using methods such as, but not limited to **surveys, interviews, focus groups, and program evaluation.**

**Clinical Studies** of drugs or medical devices when:

* Drugs: An Investigational New Drug (IND) Application is not required and does not significantly increase risk. (An IND means a new drug or biologic drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms investigational drug and investigational new drug are deemed to be synonymous. [21 CFR 312.3(b)])
* Devices: An IDE Application is not required or the device is cleared for marketing and is being used in accordance with its cleared/approved labeling.

**None of the above.**

1. Proposed Review Categories

Exempt

Expedited

Full Board Review

1. **PRINCIPAL INVESTIGATOR CONFIRMATION OF IRB REQUIREMENTS**

The PI must assure that IRB of the following by signing in the space provided below:

* The answers in this form are accurate.
* I will read and abide by all of the DSU IRB requirements and correspondence I receive.
* If one or more of the IRB requirements are not acceptable, I understand that I may ask the IRB to reconsider its requirements, but may not enroll subjects until the issue is resolved in a manner acceptable to the IRB.
* Confirm that you have included all of the following by checking the boxes:

Consent form (required unless waived)

Assent form (if applicable)

Recruitment materials

Screening materials (if applicable)

Data collection instruments (interview flow sheets, surveys, web-based questionnaires, etc.)

Grant submission materials (if applicable)

Research protocol (if applicable)

Conflict of Interest (COI) Forms for each research team member

CITI Training Certificate for each research team member

Current healthcare professional license showing expiration date (if applicable)

Letter of Permission for non-DeSales institution (if applicable)

For each additional site, please copy, complete and attach the Additional Site Listing form at the end of this document.

Print Name of PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**To submit your application to the IRB for review:**

* Obtain PI’s signature on this form.
  + Scan the entire application with all attachments and create ONE file in pdf format with the following filename structure:

PI last name followed by 3-4 key words from the title of the research study

*Ex. Starling\_ReadingScrambledWords.pdf*

* + The PI must email the application to [IRB@desales.edu](mailto:IRB@desales.edu)
* In the email subject line write the filename:

*Ex. Starling\_ReadingScrambledWords*

* In the email text write the full title of the research study:

*Ex. Effects of Context Cues on Reading Scrambled Words*

* Attach the application in ONE file in pdf format.

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| --- |
| **DSU IRB**  **ADDITIONAL RESEARCH SITE FORM** |

Please identify additional sites where the research will take place by completing a separate form for each additional site. *If site information changes during the course of this research study, you will need to notify the DSU IRB. Please request the necessary changes using the Change in Research Submission Form available on the DSU IRB website.*

1. Name of research location: \_\_\_\_\_      \_\_\_\_
2. Physical address: \_\_\_\_\_      \_\_\_\_
3. Phone number: \_\_\_\_\_      \_\_\_\_
4. What type of facility is this site:

University/College  Hospital  Medical office

K-12 School System  Long term care facility  Other (specify): \_

1. What resources are available at this site to treat emergencies resulting from research study-related procedures?

Basic Life Support trained personnel

Advanced Cardiac Life Support trained personnel and a crash cart

Emergency drugs and supplies to stabilize subject until emergency personnel arrive

Emergency response team within the facility

Other: \_\_\_\_\_      \_\_\_\_

N/A: explain \_\_\_\_\_      \_\_\_\_

1. If this site is not a hospital, please name the closest medical facility to be used in an emergency.

\_\_\_\_\_      \_\_\_\_

How far is this medical facility from the site? \_\_\_\_\_      \_\_\_\_

N/A

1. Is this research study location a non-DeSales institution?

NO. ***Please proceed to question #8***

YES – ***Please complete the following:***

1. Describe the non-DeSales institution’s overall role in this research study. \_\_\_\_\_      \_\_\_\_
2. Describe your understanding of the local research context of the non-Desales institution or how the knowledge will be obtained (i.e. statistical consultants). \_\_\_\_\_      \_\_\_\_
3. Describe the adequacy of the non-DeSales insititution to support the research study.

\_\_\_\_\_      \_\_\_\_

1. Describe the responsibilities of the non-DeSales institution employees. \_\_\_\_\_      \_\_\_\_
2. Describe the oversight provided by the DeSales investigators in order to ensure adequate and ongoing protection of the human subjects. \_\_\_\_\_      \_\_\_
3. If the research is ongoing at this non-DeSales institution (such as a multi-center study) provide a report on research results to date and a summary of all unanticipated problems and/or serious adverse events and other reportable adverse events.

\_\_\_\_\_      \_\_\_

N/A

1. If a DeSales investigator is the lead researcher of a multi-site study, please describe how you will manage research study modifications, interium results and other aspects of the protection of human subjects in this study.

\_\_\_\_\_      \_\_\_

N/A

1. Does the non-DeSales institution meet the definition of “Engagement in Research”. *(For guidance, please review the Non-DeSales Institution policy located on the DeSales IRB website).*

YES

NO

1. Do you request that the DeSales IRB review on behalf of this non-DeSales institution?

YES – *Please provide a written letter of permission from an authorized individual (on the institution letterhead) that authorizes the PI to perform activities at the location.*

NO

1. Do you request that DeSales rely on the IRB of this non-DeSales institution?

YES

NO– *Please provide a written letter of permission from an authorized individual (on the institution letterhead) that authorizes the PI to perform activities at the location.*

Privacy and Confidentiality

1. **Privacy Protections:** Privacy is a subject’s ability to control how other people see, touch, or obtain information about the subject. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about HIV status, illegal drug use, etc.

What precautions will be used to ensure subject privacy is protected? (check all that apply).

Use of drapes or other barriers for subjects who are required to disrobe.

Research intervention is conducted in a private room.

The collection of sensitive information about subjects is limited to the amount necessary to achieve the

aims of the research, so that no unneeded information is being collected.

Other (specify): \_\_\_\_\_      \_\_\_\_

1. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy. It refers to the subject’s understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be any printed information, electronic information, or visual information such as photographs which could allow anyone to identify subjects in this study. This applies to both screening data and research data in your study.

a. What precautions will be used to maintain the confidentiality of identifiable information? (check all that

apply).

Paper-based records will be kept in a secure place as determined by the PI and only be accessible to

personnel involved in the research study.

Computer-based files will only be made available to personnel involved in the research study through the use of access privileges and passwords, for example, protecting a laptop or cloud based files.

Prior to access to any research study-related information, personnel will be required to sign statements

agreeing to protect the security and confidentiality of identifiable information.

Whenever feasible, identifiers will be removed from research study-related information.

When the research involves third party data collection tools, for example, web-based surveys, precautions are in place to ensure the data is secure by using passwords and encryption.

Audio and/or video recordings of subjects will be transcribed and then destroyed to eliminate audible

identification of subjects.

Audio and/or video recordings of subjects will be will be kept in a secure place as determined by the PI and only be accessible to personnel involved in the research study.

Other (specify): \_\_\_\_\_      \_\_\_\_

b. Who will perform the screening examination of subjects to determine if they are eligible for the research study for this site?

\_\_\_\_\_      \_\_\_\_

N/A