DALLAS COUNTY JUVENILE DEPARTMENT	Application to Conduct Research (External)
	Research and Statistics Henry Wade Juvenile Justice Center * 2600 Lone Star Drive, Dallas, TX 75212 www.dallascounty.org

Please submit this completed form with finalized copies of all recruitment materials (e.g., flyers, telephone scripts, etc.), tests, experiments, survey/questionnaires/interview documents including individual questions to dcjd_research@dallascounty.org. Also include both **consent** and **assent** forms. Copies of human subjects training certificates are also required for all personnel who will be participating in the research project. If you require assistance in completing this form or you need additional information, please contact Dr. Daniel Pacheco by email at daniel.pacheco@dallascounty.org.

According to **45 CFR 46.102**, a human subject is a "living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information through intervention or interaction with the individual, and uses, studies, or analyzes the information; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information.

Please indicate whether the project being proposed in this application is
☐ Primary Research
☐ Secondary Research (Data Analysis)

Project Title:		
Principal Investigator (PI)		
Name (Last Name, First Name):		
Highest Earned Degree:		
University Name & Address (Affiliation):		
Department/School/College/Program:		
☐ Faculty	☐ Staff	☐ Student
If PI is a student, who is the faculty sponsor?		
Email Address:		
Will the PI be the primary contact? ☐ Yes ☐ No		
If PI will not be the primary contact, indicate primary contact here:		

Other Study Personnel:

Name (Last Name, First Name)	Role in Study	Human Subjects Protection Training Completed?

How is the study funded (explain)?

Has the study received IRB approval (Attach)?
If yes, IRB#
If no, explain:

Have all PIs, Co-PIs, Faculty Sponsors, research assistants, graduate assistants completed human subjects training in accordance with grant funder requirements, university rules?

☐ Yes ☐ No

Note: Approval cannot be granted if any individual associated with the research project in a capacity of collecting, managing, and safeguarding data, interacting with youth, has not completed human subjects training. Please provide the names of all personnel who will be associated with the project along with their human subjects training certificates.

Indicate the methods to be used for the study. (Check all that apply)

☐ Descriptive
☐ Qualitative
☐ Quantitative
☐ Field Work
☐ Oral History
☐ Experimental (with control group)
☐ Participant Observation
☐ Longitudinal
☐ Other, specify:

Estimated Study Duration
Please indicate the estimated duration of the proposed research project. Include all time needed for recruitment, procedures, data collection/management.

Publication/Reporting of Results
Please identify all methods in which you may publicly disseminate the results of your study:

☐ Academic journal
☐ Academic conference poster
☐ Thesis
☐ Book or book chapter
☐ Other:
☐ Public poster session
☐ Academic conference paper
☐ Dissertation
☐ Class project

PROTOCOL SUMMARY

Instructions: Use non-technical language (refrain from using jargon) to address each element below. **DO NOT** attach sections from a grant application, screen shots, or links to supplemental information. You are discouraged from copying/ pasting from other documents (e.g., a grant application). Provide sufficient information for effective review by all Research Review Committee. Define abbreviations and terms that are not considered common language.

Describe the objectives of the proposed research:
Descriptively explain the importance of the proposed research project. Clearly identify and state the objectives, specific aims, hypotheses, research questions, and rationale for conducting the study.

Describe prior studies (i.e., scholarship) that form the basis for the proposed research:

Describe what you expect to obtain from this study.

How will the obtained knowledge be applied?

USE OF TECHNOLOGY

If the research proposal is secondary research, then skip to STUDY POPULATION.

Various uses of technology cannot be escaped. Desktop and laptop computers with analytical and statistical software are the mainstay of research, generally, and data analysis, specifically. The objective for this section is to distinguish and isolate the technology to be used for data collection (e.g., the Dimensional Change Card Sort task administered using an iPad) from the day-to-day machinations of data management, storage, cleaning, and analysis.

Will this study require hardware and/or software; or a combination of both; or other device (i.e., apparatus, mechanical, or electronic equipment such as a tablet or iPad; laptop; or smartphone) for data collection?

☐ Yes ☐ No

Is the device intended solely for use in research?

☐ Yes ☐ No

STUDY POPULATION

The youth under the authority of the Dallas County Juvenile Department represent unique populations. Not only are they youth who have been detained or under probation and the authority of a court, but they may also have clinical symptomology and environmental challenges, among other things, that make them a particularly interesting population for study. When responding to the following, please provide specific, detailed responses.

Number of Participants
Indicate the maximum number of participants that will be involved in the research project: _____

Characteristics of Participants

Describe the target population as represented in the research proposal to the Institutional Review Board. The Dallas County Juvenile Department requires a high level of detail regarding the characteristics of the individuals (e.g., the youth, adults, staff). Below are some common descriptors that can be helpful in describing the target population:

Adults (age 18-64)	College Students (age 18+)
Babies/Toddlers (age 0-3)	Children in daycare
Young children (4-10)	Children in School
Youth (age 11-12)	Children or youth in drug/alcohol treatment
Families (parents & children)	Institutional residents
Detained youth/adolescents	Youth/adolescents on probation
Children/youth w/disabilities	Non-English speakers

Children, Youth, and Adolescents

The Dallas County Juvenile Department Criminal Background Check Policy requires that all individuals who interact, or who could potentially interact with children, youth, and/or adolescents complete a criminal background check through the Dallas County Juvenile Department. Check the appropriate box:

☐ All study personnel will have a criminal background check completed with the DCJD prior to any performing any study procedures.
☐ Other, explain:

Non-English Speakers

If non-English speaking participants will be included in the proposed research, please indicate the communication strategy with either the participant or their parents/caregivers.

☐ Use of interpreters ☐ Translated recruitment and informed consent/assent documents
☐ All participants will be English-speakers
☐ Other

Selection Procedures

The eligibility criteria to be included in the proposed research has different implications depending on whether the research is primary or secondary. If the research is **secondary**, participants will not be informed but the PI/co-PIs must provide an explanation of the eligibility criteria for inclusion. If the research is **primary**, participants will be informed and the PI/co-PIs must provide an explanation of the strategy to inform participants of the eligibility criteria for inclusion.

Will participants be fully informed of the selection criteria and the selection procedure?
☐ Yes ☐ No
If "No," explain:

Will a control or comparison group be included in the research?
☐ Yes ☐ No
☐ Participants will be informed that they may be a member of a control or comparison group along with an explanation of the implications of being assigned or not assigned to such a group.
☐ Participants **WILL NOT** be informed that they may be part of a control or comparison group.
Explain:

If random assignment will **NOT** be an element of the research design, will there be a "comparison group" or other "reference group" classification?

☐ Yes ☐ No

Explain the classification process (e.g., youth referred to a program because they were eligible but never participated in the program).

RECRUITMENT OF PARTICIPANTS

If the research proposal is secondary research, then skip to METHODS AND PROCEDURES FOR THE USE OF ARCHIVAL DATA.

The identification and recruitment of participants must be ethically and legally acceptable and free of coercion. Procedures used to recruit participants should be designed to reach diverse populations. For example, vulnerable participants, such as detained youth, should not be recruited for the sake of convenience.

Recruitment Method(s) and Procedures

☐ Advertisement ☐ Referral
☐ Verbal/face-to-face ☐ Telephone
☐ Social media (Internet) ☐ Letter
☐ Other, explain:

1. **How will participants be identified?**

2. **Identify the steps for recruiting participants.** If recruiting by Internet or telephone, explain how contact information will be obtained.

3. **Who is responsible for the recruitment process?**

Describe the measures that will be taken to minimize the potential for undue influence or coercion. Potential participants should be duly informed of their election to participate, specifically, that they can choose to participate or not participate in the study.

INFORMED CONSENT

If the research proposal is secondary research, then skip to METHODS AND PROCEDURES FOR THE USE OF ARCHIVAL DATA.

In research involving more than minimal risk, when capacity to consent is unclear, the capacity to consent must be determined by a physician, clinical psychologist, or by another, qualified professional. Individuals who lack the capacity to consent may participate in research only if consent is given on their behalf by a legally authorized representative. **Attach copies of the IRB approved and stamped consent and assent forms to this application.**

Will written, signed consent/assent be obtained from each participant/representative?
☐ **Yes** ☐ **No** If "No," explain:

Will Informed Consent be obtained using a language other than English?
☐ **Yes** ☐ **No**
If "Yes," explain:

Will recruitment materials or data collection instruments be administered in a language other than English?
☐ **Yes** ☐ **No**
If "Yes," explain:

List all study personnel who will be authorized to obtain informed consent:

Who will provide written informed consent/permission/assent? (Provide copies of all version that will be used)
☐ Adult parent/guardians/caregivers ☐ Legally authorized representative
☐ Youth (Assent) ☐ Other, Explain:

Describe the procedure to be used to obtain assent in a manner that is sensitive to the developmental stage of the participants:

Process of Assent/Consent

Consider: a) the environment where informed consent will be solicited; b) the timing of the process (for instance, the stress that may be associated with the situation); c) the involvement of someone other than the investigators to help explain the research; and d) opportunity for prospective participants or their legal representatives to discuss participation in the research with family, friends, or their advisors before signing the consent form.
Note: Federal regulation requires that participants be provided with a copy of the consent form.

Where will the assent/consent process take place?

How – and by whom – will it be determined whether the participants, or their legally authorized representatives, understand the information provided? Clearly document that the PI has an adequate plan in place to assure an acceptable level of comprehension by the prospective participant before assent/consent is documented.

Please provide at least three (3) questions each participant will be asked during the informed assent/consent process to confirm the prospective participant's understanding of the consent form and the study procedures. For research conducted in person, the questions *should* be open-ended, not allowing a simple "yes/no" response to ensure that they can describe the important aspects of the study (i.e., purpose, procedures, etc.). For research not conducted face-to-face, the questions can be multiple choice (i.e., for web-based assessments, surveys), but they **MUST** precede any screening questions or items that will be used for analysis.

Describe the process if a prospective participant provides an incorrect response to the assent/consent comprehension questions for the proposed research.

Waiver of Informed Assent/Consent Process

Informed assent/consent can be waived by the Institutional Review Board of record (the IRB with jurisdiction/authority over the research project). The Code of Federal Regulations (CFR) under the U.S. Department of Health and Human Services identifies four (4) provisions for which a waiver is appropriate. Indicate the source from the HHS regulations under which a waiver was requested and granted.

☐ No Waiver Requested
☐ 45 CFR 46.116(c)
☐ 45 CFR 46.116(d)
☐ 45 CFR 46.408(c)
☐ 45 CFR 46.101(i)

Is there a Waiver of Assent/Consent on record for this project?

☐ Yes ☐ No

Explain why a Waiver of Assent/Consent presents no more than minimal risk to participants:

Explain why a Waiver of Assent/Consent will not adversely affect the rights and welfare of participants:

Explain why the project cannot be practicably pursued with an informed assent/consent from participants:

METHODS AND PROCEDURES FOR THE COLLECTION OF NEW DATA

If the research proposal is secondary research, then skip to METHODS AND PROCEDURES FOR THE USE OF ARCHIVAL DATA.

Indicate all proposed sources of new data to be employed by the proposed study.

☐ Interviews
☐ Surveys/Questionnaires
☐ Behavioral observation
☐ Task administration/Reassessment
☐ Standardized assessments
☐ Deception
☐ Audio/Video recording
☐ Questions regarding suicidal ideation (of any kind)

Describe the activity or activities in which participants will be involved.

Describe the frequency and duration of procedures, psychological tests or instruments to be used; educational assessments; experiments and interventions; follow-up or scenario resolution, etc.

METHODS AND PROCEDURES FOR THE USE OF ARCHIVAL DATA

If the proposed project will use only archival data, then completing this section of the application should necessarily preclude the completion of a large proportion of prior sections as indicated by the instructions for each section. Contact the IRB at your institution if you have any questions regarding this distinction.

Will archival data be used? ☐ **Yes** ☐ **No**

If "Yes," indicate all that apply:

☐ Only some archival data will be used (i.e., identifiers such as the PID or SID for follow-up analyses)

☐ A blend of both archival and new data will be collected for this project (i.e., a prior dataset merged with new data residing in a new dataset)

☐ Only archival data will be used (i.e., **NO** new data will be collected, no interaction with participants of any kind)

☐ Other, Explain:

Describe the records to be used in the analyses (e.g., clinical, educational, employment, institutional):

Has the appropriate permission to access the records been granted by the appropriate authority?

☐ Yes Identify the source:

☐ No

Number of records to be used:

Explain the deidentification process of the records for the proposed research project:

Will identifying information of any kind be accessible or available during any part of the process to obtain, manage, store, manipulate, secure, transfer, or archive the data?

☐ Yes ☐ No

If "Yes," explain:

If any of the archived records data became publicly available, could such an incident result in negative psychological, physical, economic, sociological, or legal consequences to the participant from which the data originated?

☐ Yes ☐ No

If "Yes," describe the potential negative consequences:

Consider the question above in relation to negative consequences for the participant's relatives, family, friends, coworkers, peers, or any other individual who had, has or could have any contact with the participant.

☐ Yes ☐ No

If "Yes," describe the potential negative consequences and identify the potential:

Confirm that study personnel, including the PI(s) will not have access, or create a link or links of any kind, which could make it possible to identify participants in the proposed research project.

☐ No access will exist and no link(s) will be created. **Initials** _____

☐ Access or a link is possible. Explain:

RISK/BENEFIT ASSESSMENT

If the research proposal is secondary research, then skip, only respond to the "Potential benefits" items in this section.

A reasonable individual, including a minor or youth who has reached the age of reason would consider it important to know the risk of harm or discomfort when deciding whether or not to participate in the research project.

Potential Risks

Is there any risk of physical harm or discomfort associated with the research (i.e., pain, discomfort, dizziness, swelling, bruising, etc.)?

☐ Yes ☐ No

If "Yes," describe:

Is there any risk of psychological harm or discomfort associated with the research procedure(s) (i.e., boredom, frustration, reaction to sensitive questions – depression or suicidal ideation; embarrassment, etc.)?

☐ Yes ☐ No

If "Yes," describe:

Is there any risk of social harm to participants associated with the research (i.e., discrimination, loss of privacy/confidentiality, being charged with a crime, etc.)?

☐ Yes ☐ No

If "Yes," describe:

Is there any economic risk associated with the research (i.e., loss of current or future employment, inability to find housing, being denied insurance, etc.)?

☐ Yes ☐ No

If "Yes," describe:

Minimizing Risks

Strategies to be used to minimize risk.

☐ Participants can elect to skip or stop responding to questions that make them uncomfortable.
☐ Data will be coded and all identifying information will be stored in a separate place from the data.
☐ Data will be coded anonymously.
☐ Unique identification numbers and or keys will be coded in the original data (i.e., the secondary ID number link strategy).
☐ Monitor experiments by professional staff.
☐ Provide opportunities to rest or take breaks.
☐ Withdrawal of a participant based on specific criteria. Explain:
☐ Remind participant that she/he can elect to stop or withdraw from the study.
☐ Modification of the data collection process. Explain:
☐ Other, describe:

Describe other precautions and strategies to minimize the risk or harm of the research process:

In an effort to mitigate the risk associated with suicidal ideation questions often administered during human subjects research procedures, the DCJD must confirm that any study personnel who will be administering any instrument that assesses suicidal ideation (i.e., Beck Depression Inventory; Child Behavior Checklist) has the appropriate training for managing sensitive situations.

☐ The proposed research includes an assessment of suicidal ideation. The PI confirms that all study personnel will or have completed the appropriate training for managing any sensitive situations that may arise because of the nature of the assessment. Initials: _____

☐ The proposed research **DOES NOT** include an assessment of suicidal ideation and specialized training is not required.

Potential Benefits

Describe any direct benefits anticipated for the individual participants in this study. If there are not direct benefits to participants, explain:

Describe potential benefits to society (at large) or to the community:

Describe any direct or indirect benefits anticipated for the Dallas County Juvenile Department (DCJD) from this study. If there are no direct or indirect benefits to DCJD, explain:

PARTICIPANT PRIVACY AND DATA CONFIDENTIALITY

The items below can be relevant to both primary and secondary research proposals. Respond to each appropriately based on the type of research being proposed.

Privacy

In a research context, privacy is understood as a participant's ability to control how, when, and to what degree others view, access, or learn the research participant's personal information. From the list below, select the steps proposed to protect participants' privacy during screening, consenting, and conducting the research (check all that apply):

☐ Research procedures will be conducted in person in a private setting.
☐ Data will be collected and reviewed in a private setting.
☐ Only authorized study personnel will be present during research related activities.
☐ The collection of participant data is limited to what is necessary to achieve the aims of the research.
☐ Participants will not be approached in a setting or location that may constitute an invasion of privacy or could potentially stigmatize them.
☐ The project is secondary research and privacy in this context is **not applicable**.
☐ Other:

Confidentiality

The PI is responsible for taking any and all necessary measures to maintain confidentiality of the data. This includes all relevant properties of good data management practices, coding data, and choosing appropriate and secure ways to store data to prevent unauthorized access.

Will personally identifying information be obtained from research participants?

☐ Yes: Data will be directly labeled with personally identifying information (Identifiable)
☐ Yes: Data will be labeled and coded with a link to personally identifying information (Coded)
☐ No: Data will not be labeled with any personally identifying information, nor with a code that the research team can link to personally identifying information (Anonymous)
☐ Other:

Indicate how research data will be protected from inappropriate use or disclosure (check all that apply)

☐ Stored in a locked office/room
☐ Restricted access to authorized study personnel
☐ Use of a secure computer
☐ Encryption of digital data
☐ Network restrictions
☐ Password protections (HIPAA compliance measures such as those by Box cloud storage)
☐ Security software (e.g., firewall) installed on servers, laptops, tablets, etc.
☐ Restrictions on copying study-related materials
☐ Destruction of source data immediately after collection (preserving anonymity of participants)
☐ Audio/video recording will be transcribed and then destroyed
☐ Audio/video recordings will be modified to eliminate the possibility that research participants can be identified
☐ Photographs or other images will be modified to eliminate the possibility that research participants can be identified.
☐ Access rights are terminated when authorized study personnel leave the study
☐ Other:

Will coded or identifiable data be released to a third party?

☐ Yes ☐ No

If "Yes," specify the type of data that will be released, to whom it will be released, and the reason(s):

Will the proposed study involve obtaining individually identifiable health information from a healthcare provider?

☐ Yes ☐ No

If "Yes," describe the procedures in place to comply with the HIPAA Privacy Rule:

Where and what format (i.e., digital, audio, etc.) will data be kept?

Where will signed participant assent/consent forms be stored? Signed assent/consent forms must be stored in a separate place from the data and from personally identifiable information.

If audio/video recordings, images, or other media will be collected, will they be anonymized or de-identified? If so, describe the procedures and include a timeline:

How will the data be archived once all data analysis is complete? A typical university record retention policy requires all study materials to be stored for three (3) years after the study is considered "closed" for IRB purposes.

☐ Direct identifiers and/or the key to participant codes (i.e., links) will be destroyed (all data will be stripped of identifiers) and/or the key to codes destroyed, paper documents shredded, electronic files purged, and electronic media deleted and scrubbed.
☐ The data will be safeguarded and retained for study record-keeping (typical university policy)
☐ The data will be safeguarded and retained by PI(s) for future research use
☐ The data will be safeguarded and retained for future research use
☐ Restricted use data will be destroyed or returned to the source
☐ No direct or indirect identifiers will be collected for the proposed research project. The anonymous data will be retained at the discretion of the PI(s)
☐ Other:

RESEARCH REVIEW CATEGORY

The Department of Health and Human Services (DHHS) with other Federal Regulations require IRBs to be responsible for determining whether the proposed data collection meets the federal definition of research. By completing this application, this designation is presumed to have been completed. The DCJD is aware of the criteria for each IRB review category. Indicate the IRB category that corresponds with the proposed research project. Inasmuch as the target population covered by this application includes youth under the authority of the DCJD, *Minimal Review* is not a typical category for these purposes. **ATTACH THE IRB APPROVAL LETTER**.

☐ Full Board Review	IRB#	Date Approved:
☐ Expedited Review	IRB#	Date Approved:
☐ Minimal Review	IRB#	Date Approved:

ASSURANCES

Signature certification.

My signature below certifies that:

1. **I, all of my assigns, and all study personnel will adhere to and comply with all ethical principles and regulations regarding the protection of human subjects in research, and**

2. **The information provided herein, and any and all other supporting documents are accurate and complete.**

Principal Investigator's **Printed Name:**
Date:

_____
Signature

Co-Principal Investigator's **Printed Name:**
Date:

_____
Signature