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| UNCC_Logo_4c.jpg  **PROTOCOL APPROVAL APPLICATION**  **Institutional Review Board (IRB) for Research with Human Subjects** | | | | |
| **Easy to Use Template Instructions:**  Simply tab to the gray blocks and type in your information. The box will expand as you type.  To select a box, simply point the mouse to the box and click! | | | | |
| **PROJECT TITLE** |  | | | |
| **INVESTIGATOR**  **INFORMATION** | **Name:** |  | **Dept.:** |  |
| **Title:** |  | **Status:**  Select one: | Student  Faculty/Staff  *(If student, provide information for responsible faculty below)* |
| **Degree(s):**  *(If student: state degree being sought)* |  | **Phone:** |  |
| **Complete Mailing Address:** |  | **Email:** |  |
| **Responsible**  **Faculty** | **Name** |  | **Dept.:** |  |
| **Title:** |  | **Phone:** |  |
| **Degree(s)** |  | **Email:** |  |
| **List all co-investigators below, including those from other institutions.**  Simply tab to the gray blocks and type in your information. The box will expand as you type. | | | | |

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| **Name** | **Degree(s)** | **Responsibility on Research Project** | **Department**  (provide address if off-campus) | **Contact Information** |
|  |  |  |  | **Ph:** |
| **Email:** |
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| **Email:** |
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| **Email:** |

**Investigator’s Agreement:**

I certify that myself as well as all co-investigators have completed the required UNC Charlotte Human Subjects On-Line Training Tutorial located at **http://research.uncc.edu/compliance-ethics/human-subjects** and that each of the co-investigators has accepted their role in this study I agree to a continuing exchange of information with the Institutional Review Board (IRB). I agree to obtain approval before making any changes or additions to the project. I will provide progress reports at least annually, or as requested. I agree to report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. A copy of the informed consent will be given to each subject if applicable and a signed original will be retained in my files.

Signature of Investigator Date

**Responsible Faculty Member’s Agreement:** (If the Investigator is a student)

I certify that, as the student’s responsible faculty, I have:

* read and endorsed the materials submitted; and
* completed the required UNC Charlotte Human subjects On-Line Training Tutorial.

Signature of Responsible Faculty Date

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| 1. **Completion of required Human Subjects Training Tutorial**   **NOTE:** Co-investigators from institutions or organizations not affiliated with UNC Charlotte must either complete UNC Charlotte’s required on-line IRB tutorial or provide documentation that similar training has been completed elsewhere. |

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| **2. Current or Planned Funding Source (Internal or External)**  **NOTE:** Please submit a copy of methodology section of grant application with protocol application (if applicable). |

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| **P.I. of Grant or Contract**: |  | |
| **Name of Funding Source**: |  | |
| **Grant/Contract No. (if available)**: |  | |
| **Grant/Contract or Project Title**: |  | |
| **Attached**: **Grant Methodology Section** | Yes | No If “NO”, please provide explanation in text box below. (Text box will expand.) |
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| **No Funding** |  | |

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| **3. Conflict of Interest**  Will members of the research team have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this study or otherwise have a potential conflict of interest regarding the conduct of this study? If so, please provide explanation below. |

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| **4. Student Investigators**  Indicate if research is for any of the following and provide explanation in the text box below, if needed: |

Class project Undergraduate Master Doctoral

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| **5. Purpose of Project**  Provide a **brief summary (i.e. 300 words or less)** of the purpose of the project in layman’s terms including: background information as necessary, research question(s), and explanation of why the study is needed. Provide the full name/title at least once when using acronyms. |

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| **6. Enrollment Information** |

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| **Expected number of participants:** |  |
| **Expected gender representation:** |  |
| **Expected minority representation:** |  |
| **Expected age of participants:** |  |

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| **7. Vulnerable Populations** | Yes  (Target Population) | No  (Incidental Inclusion) |

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| **Children:** |  |  |
| **Non-English speaking:** |  |  |
| **Decisionally impaired or mentally incompetent :** |  |  |
| **Prisoners, parolees and or other convicted offenders:** |  |  |
| **Pregnant women:**  Select “Yes” if study is about pregnancy, pregnant women and/or the fetus or neonate. |  |  |
| **UNC Charlotte Students:** |  |  |

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| **8. Characteristics of the Study Population**  List required characteristics of potential subjects and those that preclude participation.  ● **Inclusion Criteria:** Describe the characteristics of the study population(s). What characteristics make someone an ideal candidate to participate in your study? (e.g., age, occupation, M/F, etc.)  ● **Exclusion Criteria:** What characteristics would make someone ineligible for participation in the study? |

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| **Inclusion Criteria:** |  |
| **Exclusion Criteria:** |  |

**9. Health Information**

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule governs disclosure of personally identifiable health information (deemed “protected health information” or PHI) by hospitals, physicians, and other HIPAA-defined Covered Entities. PHI is broadly defined to include data on a person’s physical or mental health, health care, or payment for health care. PHI includes, for example, a list of a person’s current medications or a person’s weight, smoking status or date of surgery.

As part of this research study, will you obtain any protected health information (PHI) from a hospital, health care provider, insurance agency or other HIPAA-defined Covered Entity?

No  Yes

If YES, attach the Application to Use Protected Health Information (PHI) in Research form at:

**http://research.uncc.edu/compliance-ethics/human-subjects/hipaa-info-forms**

If unsure, please review the Guidelines for Usage of Protected Health Information (PHI) in Research at:

**http://research.uncc.edu/compliance-ethics/human-subjects/hipaa-info-forms**

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| 1. **Summary Checklist – Are any of the following involved?**   The items listed below ARE NOT an all-inclusive list of methods or procedures but are intended to provide ‘triggers’ or reminders for you to provide appropriate information in subsequent questions in the application or to provide supplemental materials necessary for the review process. |

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|  | | **Yes** | **No** |
| a) Will research include use of existing data, research records, patient records, and/or human biological specimens? | |  |  |
| b) Will data collection include surveys, questionnaires or psychometric testing?  *(submit copy of survey/questionnaire with protocol application)* | |  |  |
| c) Will data collection include interviews or focus groups?  *(provide interview/focus group question with protocol application)* | |  |  |
| d) Will research include deception or less than full disclosure? | |  |  |
| e) Will research include accessing Student Educational Records? | |  |  |
| f) Will research include a data sharing agreement?  *(Provide details in Question 11 below.)* | |  |  |
| g) Will research include an equipment sharing agreement or contract?  *(Provide details in Question 11 below.)* | |  |  |
| h) Will data collection include: | \*Audio Recording? |  |  |
|  | \*Video Recording? |  |  |
|  | \*Photography? |  |  |
| \*If you answered “Yes” to any of the options in *Question H*, this information must be disclosed in the consent document AND/OR a separate release consent form. (Sample documents can be obtained from the ORS website or from the Compliance Office.) | | | |

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| **11. Full description of the study design, methods and procedures including**:   * the type of experimental design; * describe study procedures; * provide a sequential description (explained in steps, phases etc.) of what will be asked of/done to subjects; * clarify if subjects will be assigned to various groups/arms of the study (if applicable); * explain what kinds of data will be collected; * provide details on the primary outcome measurements; and * explain any follow-up procedures (if applicable).   **If you answered “YES” to any of the items in Q #10, please provide explanation/description in this section.**  **Attach 2 copies of the questionnaire(s); inventories, or scales that will be completed by participants.** |

Data will be de-identified by the Institute for Social Capital (ISC) Database Team. ISC takes all appropriate measures to protect the privacy and confidentiality of data housed in the ISC Community Database. It is ISC's policy never to disclose personally identifiable information, and all requests for data are carefully reviewed by ISC's Data and Research and Oversight Committee (DAROC) to ensure the confidentiality of sensitive information.

Consistent with those policies and practices, this study will involve the analysis of only de-identified data pursuant to a Limited Data License Agreement, which is required by DAROC as a protocol for approving the use of the data. No data containing personally identifiable information will be available to investigators. Likewise, there will be no researcher-participant interaction. Question 14 below provides a detailed summary of steps taken to protect participant confidentiality.

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| **12. Duration of entire study and duration of an individual subject's participation, including follow-up evaluation if applicable, including:**   * Provide information on the number of required visits, tests, surveys to be completed, interventions. * Provide information on the approximate duration of each intervention (i.e., how much time should the subject expect to spend). |

The data obtained from ISC involves the analysis of administrative data; participants are not actively involved at any point throughout the study.

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| **13. Where will the subjects be studied?**  If off UNC Charlotte campus, list locations.  **Attach 2 copies of letter(s) of permission to conduct the research project from school(s), organization(s) or any off-campus location.** |

The data obtained from ISC involves the analysis of administrative data; participants are not actively involved.

**14. Confidentiality**

Explain how you will protect the confidentiality of the data collected. Describe procedures for protecting against or minimizing any potential risks from breach of confidentiality or invasion of privacy. How will you protect the data with respect to privacy and confidentiality? For example:

● Where will the data be stored?

● What security measures will be applied?

● Who will have access to the data? Provide explanation of why they need access.

● If applicable, specify your plans for de-identifying or anonymizing the material if audio/video recordings or photographs will be used.

● If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator.

● If applicable, describe procedures for sharing data with entities not affiliated with UNC Charlotte.

● Provide a timetable for destroying the data and identify how they will be destroyed or provide explanation for perpetual maintenance.

***Please note:***The IRB expects researchers to access the minimal amount of data to conduct the study and to comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements.

For the data from ISC, this project involves the analysis of archived data, which have been de-identified. No personally identifiable information will be available to the investigators. The research team will obtain approval from, and follow all policies and procedures of, the Data and Research Oversight Committee (DAROC) of the Institute for Social Capital, Inc. for all aspects of this project involving the use of data from the ISC Community Database. The data provided by ISC would be classified as "UNC Charlotte Classification Level 2 – Confidential/Sensitive". Based on the UNC Charlotte Guideline for Data Handling, the data will be placed on an encrypted flash-drive that will be hand delivered to the researchers. The password for the file will be provided through a separate means of communication.

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| **15. Data security for storage and transmission.**  Check all that apply. |

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| *For electronic data:* |  |
| Secure network |  |
| Password access |  |
| Encryption |  |
| Other (describe in question #14 above) |  |
| Portable storage (e.g., laptop computer, flash drive)  Describe in question #14 above how data will be protected for any portable device |  |

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| *For hardcopy data (including human biological specimens, CDs, tapes, etc.):* |  |
| Data de-identified by research team |  |
| Locked suite or office |  |
| Locked cabinet |  |
| Data coded by research team with a master list secured and kept separately |  |
| Other (describe in question #14 above) |  |

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| **16. Full description of risks and measures to minimize risks:**  Give full descriptions and measures risk factors.  For example:   * psychosocial harm (e.g. emotional distress, embarrassment, breach of confidentiality, etc.) * economic harm (e.g. loss of insurability), and * legal jeopardy (e.g. disclosure of illegal activity) as well as * known side effects of study medication, * risk of pain and physical injury. |

The only known risks relate to a potential breach of confidentiality and the consequences of any such breach. All data files obtained from ISC will be released to the researchers only after obtaining approval from ISC's Data and Research and Oversight Committee, which reviews all data sets to ensure that there are no additional threats to confidentiality. No personally identifiable information will be attached to the interview data.

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| **17. Benefits to subjects and/or society**:  The possibility of benefits to society should be clearly distinguished from the possibility of benefit to the individual subject, if any.  If there is no direct benefit to the individual subject, say so. Do not list monetary payment as a benefit. |

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| **18. Inducements for participation:**  If monetary, specify the amount and how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completion. |

Since the data obtained from ISC are administrative data, there are no inducements for participation.

**19. Costs to be borne by subjects:**

If there are no costs to subjects, indicate this.

As this study involves the analysis of administrative data, there are no costs to participants.

**20. Data analysis:**

State how the data will be evaluated, indicate where and by whom data analysis will be performed.

**21. Methods of recruiting:**

Tell how prospective subjects are contacted. Provide recruitment script (letters, email, flyers and advertising, telephone script, verbal, website, etc.).

For data obtained from ISC there will be no active recruitment of participants.

**22. How will informed consent be obtained?**

Give full descriptions and measures for all of the following applicable risk factors:

* Describe the process.
* It is typical to obtain assent from children ages 7-17.
* When the consent of a legally authorized representative is substituted for consent of the adult subject, explain why this is necessary.
* If non-English-speaking subjects will be enrolled, a consent form should be prepared in their foreign language.
* Someone who is fluent in the subjects’ language must be available to interpret**.**

**Attach 2 copies of the informed consent document(s) printed on your department’s letterhead.**

The data provided by ISC does not involve the recruitment of individual participants since; rather, this study involves the analysis of administrative data and secondary data sources.

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| **23. Waiver of Consent Documentation and/or Procedure**  **Waiver of consent documentation:** An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if certain conditions are met and if sufficient justification is provided.  **Waiver of Consent Procedure:** An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent subjects if certain conditions are met and if sufficient justification is provided.  If waiver(s) is being requested provide brief explanation below of request for waiver(s) AND attach completed waiver form. For more details and downloadable forms, go to: http://research.uncc.edu/compliance-ethics/human-subjects/informed-consent |

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|  | **YES** | **NO** |
| **Waiver or Alteration of Consent Procedure:**  *Complete appropriate Waiver form and submit with protocol application.* |  |  |
| Requesting waiver of some elements of consent? |  |  |
| Requesting waiver of consent entirely? |  |  |
| **Waiver of Consent Documentation:**  *Complete appropriate Waiver form and submit with protocol application.* |  |  |

Explanation:

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| ***Submission Reminders*** |
| *Submit two (2) signed copies of the entire IRB Approval Application to:*  **Cat Runden or Dixie Airey, Office of Research Compliance, 3rd Flr., Cameron Hall.**  ***Have you included the following items?***  □ Informed Consent document on appropriate UNC Charlotte letterhead (parental and assent if applicable)  □ Surveys  □ Questionnaires  □ Psychometric Testing Instruments  □ Interview and focus group questions  □ Assessments  □ Pre-Test, Post-Test  □ Inventories, or scales that will be completed by participants  □ Recruitment scripts (email, telephone, verbal announcements) & Flyers  □ Request for Waiver documents  □ Letter(s) of permission/cooperation to recruit participants from and/or conduct the research project from school(s), organization(s) or any off-campus location.  □ Did you include the tutorial completion date for you and ALL of your co-investigators, responsible faculty, research assistants, etc?  □ Grant proposal methodology section, if applicable  *Involvement of co-investigators from other institutions:*  Efforts to determine the need for IRB approval from the co-investigator’s institution/organization must be documented. This documentation may be submitted along with the signed Investigator Agreement which can be found at**: http://research.uncc.edu/compliance-ethics/human-subjects**.  ***For additional assistance, call Cat Runden at (704) 687-1871 or Dixie Airey at (704) 687-1876.*** |