*Note:* ***The IRB only reviews activity that meets legal qualifications for research on human subjects*** *under the federal “Common Rule” (see* [*https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)*). If you are unsure whether your project is human subjects research, consult the IRB manual and the Office of Sponsored Programs.*

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| Title of project: |  |
| “Nutshell” description of project, e.g., “Laboratory study of exercise equipment,” “Anonymous survey of mental health professionals,” “Randomized controlled trial of cognitive-behavioral intervention for supermax prisoners,” etc. |  |
| Date submitted to IRB: |  |

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| Principal investigator: |  |
| Adelphi dept. & school affiliation: |  |
| Status at Adelphi University:a |  |
| Professional address: |  |
| Professional phone: |  |
| Professional email: |  |
| Date of most recent human subjects protection training: b |  |

a E.g., full-time faculty, part-time faculty, doctoral student, Master’s student, undergraduate, staff

b Please include an image of your certification in your proposal

*Note: A co-investigator has significant intellectual accountability for the project. Student research assistants, coders, data entry persons, and statistics consultants are not co-investigators. Copy and paste feature to make an additional section like this for each additional co-investigator. Delete this section if it does not apply.*

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| Co-investigator (if applicable): |  |
| Institutional & departmental affiliation: |  |
| Job title: |  |
| Professional address: |  |
| Professional phone: |  |
| Professional email: |  |
| Date of most recent human subjects protection training: a |  |

a Please include an image of your certification in proposal

*Note: Adelphi policy requires projects by students, part-time faculty, and administrators without full-time faculty appointments to have a full-time faculty member at Adelphi as an advisor. The advisor listed below should be the advisor as it pertains to the project, which may or may not be the student principal investigator’s thesis advisor or doctoral committee chair. Leave this section blank if it does not apply.*

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| Faculty advisor (if applicable): |  |
| Adelphi dept. & school affiliation: |  |
| Status at Adelphi University:a |  |
| Professional address: |  |
| Professional phone: |  |
| Professional email: |  |
| Date of most recent human subjects protection training: b |  |

a E.g., full-time faculty, part-time faculty, doctoral student, Master’s student, undergraduate, staff

b Please include an image of your certification in proposal.

***Determination of “exempt” status.*** Note the following:

* Many protocols that come before the Adelphi IRB are exempt.
* The Common Rule, cited above, lists categories of exempt research. Citations of sections of the Common Rule’s descriptions of specific exempt categories are given below.
* Only the IRB can determine whether a project is exempt. All human subjects research protocols must be submitted to the IRB even if they are exempt.
* The IRB will return a protocol without review unless all sections are filled out completely and correctly. It cannot make an informed determination on an incomplete proposal.
* Your protocol must fit all of the qualifications for an exempt category under the Common Rule to be classified as exempt. Otherwise, it will receive full review.

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| **Which of the following exempt categories describes your study? Put an X on the line next to one, and only one, of the exempt categories below.** | |
| **\_\_\_** | ***Evaluation of teaching methods*** conducted in normal educational settings that will not impact students’ learning of required content. *§46.104(d)(1)* |
| **\_\_\_** | ***Secondary analysis of publicly available information,*** like the General Social Survey. Restricted access data do not fit this criterion. *§46.104(d)(4)(i)* |
| **\_\_\_** | ***Secondary analysis of de-identified data.*** Panel data fit this criterion even if they involve sensitive topics; quantitative clinical data mining may fit if participants already gave broad consent for data to be used in research *§46.104(d)(4)(ii), §46.116(d)*. |
| **\_\_\_** | ***Secondary analysis of identifying data or biospecimens for which broad consent was already obtained,*** provided your research is within the scope of that broad consent. Qualitative clinical data mining often fits. *§46.104(d)(8)* |
| **\_\_\_** | ***Anonymous survey.*** Online surveys involving MTurk, Prolific, Qualtrics, etc. that collect no identifying information often fit, even if they are about sensitive topics. *§46.104(d)(2)(i)* |
| **\_\_\_** | ***Survey or interview that does not collect stigmatizing information.*** Surveys about benign topics generally fit even if they collect information that could be used to identify a participant. *§46.104(d)(2)(ii)* |
| **\_\_\_** | ***Confidential survey or interview.*** Even if data will be both stigmatizing and potentially identifying, survey and qualitative interview studies can fit into this category if they have an appropriate data security plan. *§46.104(d)(2)(iii), §46.104(a)(7)* |
| **\_\_\_** | ***Anonymous minimal risk experiment.*** Applies to, e.g., studies of performance in online games. *§46.104(d)(3)(i)(A)* |
| **\_\_\_** | ***Minimal risk experiment that does not collect stigmatizing information.*** In-person laboratory studies that do not collect stigmatizing information and only involve benign activities usually meet this qualification. *§46.104(d)(3)(i)(B).* |
| **\_\_\_** | ***Confidential experiment.*** Any experiment involving only brief, harmless, inoffensive, and physically non-invasive activities, even if it collects stigmatizing or identifying information, fits this category with an adequate data security plan. *§46.104(d)(3)(i)(C)* |
| **\_\_\_** | ***None of the above; this study should receive full review.*** This typically applies to “Deception studies” in which the subject is not informed, or misinformed, about activities required of them or the study’s true purpose *§46.104(d)(3)(iii); s*tudies that involve medications, physically invasive procedures, or strenuous physical activity; studies where the investigator does not have complete control over data security, e.g., because another institution is the data owner; dual-role studies in which human services practitioners are using data about their own clients; or studies that would fit into one of the exempt categories above except that they are about a vulnerable population to whom that exempt category does not apply. *§46.111(b)* |

***Assessment of additional review criteria.***

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| **Which of the following additional review criteria apply to your study? Put an X on the lines next to the ones that apply.** | |
| **\_\_\_** | ***Minimal risk.*** Refers to studies where the risk of harm or discomfort from the study procedures is no greater than participants encounter in their daily lives, or during routine physical or psychological examinations or tests. *§46.102(l)* |
| **\_\_\_** | ***Another institution is “IRB of Record” for this study*.** Rare, and only applies to studies that require full review. *§46.114*. |
| **\_\_\_** | ***Populations described in the Common Rule as vulnerable to coercion to participate,*** including children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons?” *§46.111(b)* |
| **\_\_\_** | ***Waiver of documentation of informed consent.*** Documentation may be waived in specific circumstances. *§46.117(c)(1)* |
| **\_\_\_** | ***Waiver of any and all informed consent (rare).*** Only applicable to, e.g., studies on incapacitated persons in emergency treatment. *Reference: §46.116(f)* |
| **\_\_\_** | ***Some of your research activities have already taken place.*** An IRB may retroactively determine your project to have been exempt, but it cannot retroactively give approval (i.e., after full review). *§46.119* |
| **\_\_\_** | ***Stigmatizing information.*** Applies if you are collecting data that could potentially be used to identify your subjects and cause them financial or legal liability or reputational harm if they fell into the wrong hands. *§46.104(d)(2)(ii), §46.104(d)(3)(i)(B)* |

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| **Adelphi policy concerns.** In addition to its role in ensuring compliance with the Federal Common Rule, the IRB also documents studies’ compliance with institutional policy. | | |
| **Which of the following Adelphi policy concerns apply to your study? Put an X on the lines next to the ones that apply.** | | |
| **\_\_\_** | **\_\_\_** | ***Large-scale survey of individuals affiliated with Adelphi.*** Such studies must be registered with the Office of Academic Research, Assessment, and Accreditation (OARAA), https://www.adelphi.edu/oaraa/survey-registration/. |
| **\_\_\_** | **\_\_\_** | ***External funding.*** These studies require completion of the Research Financial Conflict of Interest (FCOI) form, https://www.adelphi.edu/policies/research-financial-conflict-of-interest/. |

I. Provide a brief description of the project’s aims and purposes.

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II. Provide dates of initiation and completion of the project. Note that “upon approval by the IRB” and “[number of years] after approval” are acceptable entries.

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III. How many participants do you expect to recruit?

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IV. What are the characteristics of your participants in terms of demographics, special populations they belong to, etc.? If you will recruit from populations that are vulnerable to coercion, e.g., children, residential treatment clients, students recruited within their classroom settings for a project that is not exempt under §46.104(d)(1), justify that here. If you plan to exclude certain segments of the population, e.g., children of unmarried or divorced parents, people with disabilities, people with a history of psychiatric hospitalization, then justify that here as well.

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V. How will you recruit your subjects? If you will use a service like Amazon’s Mechanical Turk (MTurk) that automatically yields a data set that does not include positively identifying information, then mention that feature here.

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VI. Briefly describe your basic research methodology and study design. If you will be using deception, then justify that here.

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VII. What specific sequence of activities will be required of the subject, e.g., reading and responding to an advertisement, filling out a questionnaire, participating in a specific laboratory procedure, etc.?

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VIII. What is the estimated time commitment required of your subjects?

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IX. What potential risks, discomforts, or stresses to your subjects are expected from your study procedures, and what precautions will you take to minimize them? For instance, if you are asking questions about trauma or asking subjects to recall specific traumatizing events, it is common to include information about available mental health services for participants who are “triggered,” such as SAMHSA’s Treatment Referral and Routing Service, 1-800-662-HELP.

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X. If your study will involve in-person contact between researchers and participants, or contact between participants which would not have occurred except for your study, what policies and procedures are in place at your study setting(s) to prevent transmission of SARS-CoV-2, and what additional steps will you take toward COVID-19 safety, if any? Make sure to stipulate here that you will follow all laws and institutional policies presently in force at your study setting(s). If your study will not involve in-person contact between researchers and participants, or contact between participants that would not have occurred except for your study, enter “n/a.” Note that, for example, if you are analyzing medical chart data on COVID-19 patients and interviewing their providers via Zoom, you would still enter “n/a” here, because your study will not directly cause any in-person contact between your participants and anyone else.

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XI. What is your plan for reporting unexpected adverse events to the IRB? Adverse events are described in an Office of Human Research Protections (OHRP) guidance document: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html.

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| **Put an X on the lines next to the elements of an adverse incident reporting plan that apply to your study.** | |
| **\_\_\_** | You will report any unexpected adverse events to the IRB chair and Office of Sponsored Programs by email within 24 hours of your becoming aware of them (typical). |
| \_\_\_ | Other reporting requirements appropriate to your project (rare). Describe here: |

XII. Describe components of your data security plan. Potential concerns include:

* Data sets should be stripped of explicitly identifying information like names and IP addresses as soon as is practical in the process.
* Data should be stored where only the researchers on the project can access it.
* Secure transmission of data should be attended to as applicable, e.g., institutional e-mails, FTP software, encrypted USB drives, chain of custody for paper records, etc.
* Adelphi-supported equipment, file spaces, and e-mail addresses secured under your Adelphi password are preferred.
* Special care should be taken with stigmatizing information (as defined above), especially if someone in a position of power over your subjects like a manager, social worker, law enforcement official, or parent would have incentive to try to access your data.
* “Data owner” issues between multiple institutions involved in the same project should be clearly established.
* Any restricted-use data agreements should be included with your IRB application, especially if they require IRB review before they can be executed, and you are expected to fully comply with them.
* Paper files should be kept in locked cabinets or other storage in locked offices.
* If collection of stigmatizing and positively identifying information is unavoidable in your study, e.g., fieldwork with MS-13 members, or your study has federal funding, then a Certificate of Confidentiality may apply to your study, see https://grants.nih.gov/policy/humansubjects/coc/what-is.htm.

***For each of the following elements of your data security plan,*** provide the real or virtual location of the physical or electronic repository, how it is secured, whether it is encrypted, and who else has access to it.

Where will you store your data while you are collecting them, e.g., a locked cabinet for field notes, a digital voice recorder for interviews, a Qualtrics server?

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Where will you store your data while you are actively analyzing them? This is usually your computer’s hard drive or some medium that is “mapped” to your computer. Note that a medium where you can only upload and download files and cannot open them directly using a software package is an invalid entry here.

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Where will you store data while they are in “cold storage” and you are no longer actively analyzing them? It should be somewhere they will be safe for the seven years required under Adelphi policy.

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***Signature page.*** Provide electronic signatures, with dates, of all researchers who will be working in direct contact with study participants or handling stigmatizing or restricted-use data about them, including student coders and research assistants. Coders and assistants may be added to a project later by filling out a modification form. Faculty advisors must also sign below, even if they will not be directly involved with conducting the study.

By signing below, you indicate that you have received training in human subjects protection, and that you have read and agreed to the contents of this specific proposal.

**Principal investigator:**

Print name: Date:

Electronic signature (paste image in line with text):

Adelphi job title or student status:

**Faculty Adviser (if applicable):**

Print name: Date:

Electronic signature (paste image in line with text):

Adelphi job title:

**Other role on project:[[1]](#footnote-1)**

Print name: Date:

Electronic signature (paste image in line with text):

Institutional affiliation and job title or student status:

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| **Attachments Checklist.** Include everything in the same file if at all possible.  **Please place an X on the line for “yes” or “no” to ALL of the following.** | | |
| **Yes** | **N/A** | **Attachment** |
| **\_\_\_** | **\_\_\_** | Current human subjects protection training certificates for all researchers. |
| **\_\_\_** | **\_\_\_** | Recruitment / Solicitation Materials (letters, flyers, postings, scripts) |
| **\_\_\_** | **\_\_\_** | Informed Consent text or formatted documents, as applicable. All consent materials should include the following statement: “This research has been reviewed and approved by the Adelphi University Institutional Review Board. If you have any questions, concerns or comments, please contact the IRB chair, Dr. Carolyn Springer, 516-877-4753; springer@adelphi.edu.” |
| **\_\_\_** | **\_\_\_** | Parental permission & child assent |
| **\_\_\_** | **\_\_\_** | Survey items, including fixed-choice responses, and free-response survey questions |
| **\_\_\_** | **\_\_\_** | Schedules and scripts for focus groups and qualitative interviews |
| **\_\_\_** | **\_\_\_** | Letters of cooperation from any external organization or entity (including listservs) which are involved with the proposal, including subject recruitment. Note: evidence of registration with Adelphi’s ORAP does not need to be attached) |
| **\_\_\_** | **\_\_\_** | IRB approvals from cooperating institutions |
| **\_\_\_** | **\_\_\_** | Letters authorizing the use of existing secondary data. |
| **\_\_\_** | **\_\_\_** | Any other information that is relevant to the application. |

1. Cut and paste to make as many of these as you need, or delete this one [↑](#footnote-ref-1)