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| Cornell IRB - New Protocol Application Form |
| Instructions |
| For all studies |
| Read this section before you begin completing the application formUse this form for **all new research projects involving human participants**, regardless of the anticipated level of IRB review (i.e., exempt, expedited, or full board).About the application form:* **Form Organization**: Different sections apply to different types of studies; follow the instructions in the section headings.
* **Expand/Collapse Headings**: This form uses the “Expand/Collapse” feature; some sections are hidden under headings. Click on the small arrow on the left side of a heading to reveal the text beneath. Click it again to hide the text.
* **More Information**: “[(?)](#_1_-_Instructions)” means there is more information about a word or topic. Hover your mouse over the symbol to read the note/definition. Do not click on the symbol; it will not take you anywhere useful.
* **Hyperlinks**: Within Word on PC computers, in order to follow a hyperlink you need to press the Control (Ctrl) key, and then left-click on the link.
* **PC vs. Mac:** There are different versions of this form for PC and Mac computers. This version is for PCs.

About the submission process:* Submit the completed form to the IRB office via email (irbhp@cornell.edu).
* Include any participant recruitment materials [(?)](#_1_-_Instructions), informed consent documents, data collection instruments [(?)](#_1_-_Instructions), study procedures [(?)](#_1_-_Instructions), letters of support, or any other study-related documents.
* To help you, you can find IRB [policies](https://www.irb.cornell.edu/policy/), [guidance documents](https://www.irb.cornell.edu/regulations/guidance.htm), [consent form templates](https://www.irb.cornell.edu/forms/), and other resources on the [Cornell IRB website](https://www.irb.cornell.edu/).
* To avoid delays in protocol processing time, ensure everyone on your research team has completed [online human participant research ethics training](https://www.oria.cornell.edu/training_landing.cfm). Training is required every five years.
* If you have any questions about the process, contact the IRB office (irbhp@cornell.edu, 607-255-5138).
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| General Information |
| For all studies |
| Project Title: |       |
| Principal Investigator (PI) Full Name: |       |
| Cornell NetID:      College/Division and Department/Unit:       |
|  | Status: | [ ]  | Undergraduate Student | [ ]  | Graduate Student | [ ]  | Post-Doctoral Fellow |
|  |  | [ ]  | Faculty | [ ]  | Staff | [ ]  | Other: |       |
| Faculty Advisor Full Name: (Required for student PIs; skip if not applicable):       |
|  Cornell NetID:       College/Division and Department/Unit:       |
| Cornell research team members [(?)](#_Cornell_research_team) (Note: add non-Cornell team members in question [1.5.3](#_Non-Cornell_Ithaca_research) below): |
|  |
| Name (First Last) | Cornell NetID | College andDepartment |
|       |       |       |
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| Collaborations:Will researchers from other (non-Cornell Ithaca) institutions—including Weill Cornell Medicine—be involved [(?)](#_Will_researchers_from) in this project?[ ]  Yes [ ]  NoHas another IRB or ethics board reviewed the study, or will they in the future?[ ]  Yes [ ]  No |
| If “Yes”, provide details (name of IRB, approval date or estimated timing of future review, etc.). If already obtained, provide the approval letter when you submit this protocol application. |
|       |
| Non-Cornell Ithaca research team members\* [(?)](#_Non-Cornell_Ithaca_research): |
| Name | Email Address | Affiliated Institution | City and Country |
|       |       |       |       |
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| \*Submit human participant research ethics training documentation for non-Cornell research team members along with this protocol application. |
| **Funding Information:**Indicate if any part of your project is funded by a sponsor [(?)](#_Indicate_if_any). Funding could be from a gift or a sponsored project. |
|  |
|  | [ ]  | Funded | [ ]  | Not funded | [ ]  | Pending proposal |
| If the project has been funded, or there is a pending proposal:Name of funding source:      OSP Number\*:      \*OSP number is a Cornell number used to track sponsored projects. If you are unsure of the OSP number for this project, access [the PI Dashboard](https://pidash.cornell.edu/) to search, or contact OSP.Financial Conflict of Interest Disclosure:Please read [Cornell Policy 1.7 Financial Conflicts of Interest Related to Research.](https://www.dfa.cornell.edu/sites/default/files/policy/vol1_7.pdf) Have all Cornell faculty listed on this protocol (including faculty advisor) disclosed their external commitments and financial interests as required by Cornell Policy 1.7, including any that are reasonably related to this research project?[ ]  Yes [ ]  No |
| For all personnel listed on this protocol: Do any of the personnel, their spouses/partners, or dependent children have any significant financial interests that are reasonably related to this research?[ ]  Yes [ ]  NoFor all personnel listed on this protocol: Do any of the personnel, their spouses/partners, or dependent children have any personal financial interest or commitment with any company or entity that sponsors, supports or provides materials or data for this research?[ ]  Yes [ ]  No |

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| The IRB will not approve this project until it has been determined that any conflict of interest related to this research has been adequately managed by the Cornell COI office. |
| **Brief lay summary of purpose, research questions and hypothesis:** |
|       |
| How will this study contribute to existing knowledge? |
|       |
| Type of Study:Does your study involve active collection [(?)](#_Does_your_study) of data, human biospecimens, or physiological data?[ ]  Yes [ ]  No |
| If “Yes”, answer the questions in [Section 2](#_Active_collection_of_1) below. |
| Does your study involve secondary use [(?)](#_Does_your_study_1) of data or human biospecimens?[ ]  Yes [ ]  No |
| If “Yes”, answer the questions in [Section 3](#_Secondary_use_of_2) below. |

- skip if not applicable (click arrow on left to open)

# Active collection of data, human biospecimens, or physiological data

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| Type of Active Collection: Review the types of studies listed below. Check all that apply. |
|  | Type of research |  |  |
|  | 1. Surveys, interviews, focus groups (online, in person, by phone)
 | [ ]  |  |
|  | 1. Observing or recording public behavior [(?)](#_Active_collection_of) without intervening or interacting with the participants in any way
 | [ ]  |  |
|  | 1. Observing or recording public behavior [(?)](#_Active_collection_of) influenced by manipulators or stimuli that you or your research team has provided
 | [ ]  |  |
|  | 1. Observing or recording behavior in a private setting [(?)](#_Active_collection_of)
 | [ ]  |  |
|  | 1. Studying normal educational practices in educational settings [(?)](#_Active_collection_of)
 | [ ]  |  |
|  | 1. Experiments; games; studying responses to behavioral interventions, stimuli [(?)](#_Active_collection_of), or changes to the environment; or interactions with mobile devices or apps [(?)](#_Active_collection_of)
 | [ ]  |  |
|  | 1. Taste test or food acceptance study
 | [ ]  |  |
|  | 1. Collection of anthropometric measurements [(?)](#_Active_collection_of)
 | [ ]  |  |
|  | 1. Collection of physiological or biometric data using noninvasive devices [(?)](#_Active_collection_of)
 | [ ]  |  |
|  | 1. Restricted or manipulated diet/intake
 | [ ]  |  |
|  | 1. Minimally invasive collection of human biomaterials [(?)](#_Active_collection_of)
 | [ ]  |  |
|  | 1. Functional magnetic resonance imaging (fMRI) scans
 | [ ]  |  |
|  | 1. Invasive biomedical procedures [(?)](#_Active_collection_of)
 | [ ]  |  |
|  | 1. Studies involving administering drugs, biologics, supplements, or chemical agents
 | [ ]  |  |
|  | 1. Other:
 | [ ]  |  |
| Select the method(s) of data collection you plan to use. Check all that apply. |
| (skip if not applicable) |
|  | [ ]  | Interviews (in person, phone, Skype) | [ ]  | Observation |
|  | [ ]  | Paper surveys | [ ]  | Psychological testing |
|  | [ ]  | Phone surveys | [ ]  | Cognitive or behavioral measures, including daily diaries |
|  | [ ]  | Internet surveys [(?)](#_Select_the_method(s)) | [ ]  | Focus groups |
|  | [ ]  | Social media/online networking sites | [ ]  | Photos, audio/video recording |
|  | [ ]  | Self-health monitoring [(?)](#_Select_the_method(s)) | [ ]  | Anthropometric measurements [(?)](#_Select_the_method(s)) |
|  | [ ]  | Using electronic devices [(?)](#_Select_the_method(s)) | [ ]  | Taste test |
|  | [ ]  | Student records\* [(?)](#_Select_the_method(s)) | [ ]  | Other methods:       |

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| \*If you plan to collect student records (i.e., assignments, exams, student grades), please describe. Note: These types of data may be regulated under [FERPA](https://registrar.cornell.edu/service-resources/ferpa). You may need approval from the [Cornell Registrar](https://registrar.cornell.edu/) to use student grades for research purposes. |
|  |
|       |
| Questions for only those studies involving biospecimen or physiological data collection: |
| (skip to [2.4](#_Questions_for_all), if not applicable) |
| Provide additional details about biospecimen or physiological data collection. Refer to [Cornell IRB biomedical templates and guidance](http://www.irb.cornell.edu/biomedicalresources/index.htm). Select all that apply:  |
|  | Collection of: |
|  | [ ]  | Blood | [ ]  | Nasal swab |
|  | [ ]  | Urine | [ ]  | Skin |
|  | [ ]  | Feces | [ ]  | Hair |
|  | [ ]  | Saliva | [ ]  | Nails |
|  | [ ]  | Other (describe):       |
|  | Use of: |
|  | [ ]  | Non-invasive medical or physiological procedures [(?)](#_Provide_additional_details) |
|  | [ ]  | Diet or intake restrictions or manipulations |
|  | [ ]  | Administration of drugs, biologics, supplements, or chemical agents |
|  | [ ]  | Other medical procedures [(?)](#_Provide_additional_details) (describe):       |
| Describe the storage, handling, transportation and disposal procedures for any biospecimens.Consult [Cornell IRB guidance](https://www.irb.cornell.edu/biomedicalresources/index.htm) on safe handling of such materials, and contact the [Cornell IBC](https://www.ibc.cornell.edu/) for additional guidance on biosafety practices. |
|       |
| Do you plan to use any biospecimens for commercial profit?  |
| [ ]  Yes [ ]  No [ ]  N/A |
| If so, will the participants share in that profit? Either way, you will need to communicate your plans to participants via the [consent form](https://www.irb.cornell.edu/forms/). |
|       |
| Do you expect to generate any clinically relevant results [(?)](#_Do_you_expect) from your research? |
| [ ]  Yes [ ]  No |
| If so, will you disclose individual results to participants, and under what conditions? Either way, you will need to communicate your plans to participants via the [consent form](https://www.irb.cornell.edu/forms/). |
|       |
| Do you have any plans to include whole genome sequencing in your research?  |
| [ ]  Yes [ ]  No |
| If so, you will need to communicate your plans to participants via the [consent form](https://www.irb.cornell.edu/forms/). |
|       |
| Questions for all studies involving active data or biospecimen collection: |
| Provide details of all active data and/or biospecimen collection procedures involved in your study, including which study personnel will be responsible for which procedures. Consult [Cornell IRB guidance](https://www.irb.cornell.edu/biomedicalresources/index.htm) on qualifications needed for personnel conducting specific biomedical procedures:  |
|       |
| Provide a sequential list of all study components, including any follow-up sessions. List the estimated time needed for each component, as well as the total time commitment (e.g., 10 minutes for consent briefing, 30 minutes to read the new online course content, 20 minutes for the quiz, 20 minutes for debriefing. Total 80 minutes):  |
|       |
| Where will data or biospecimens be collected? Include types of facilities (e.g., specific lab, classroom, online) as well as the geographic location (e.g., Cornell University, San Francisco, Mumbai):  |
|       |
| If the research will be conducted at multiple locations, will the same protocol be followed at each site (i.e., will the same data collection procedures be used), or will different elements of the study take place at different sites? |
|       |
| Participant Population: Describe the participant population:      How many participants do you plan to enroll?      What is the age range of the participants?       |

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| Select all the categories of participants that will be included in your study:       |
|  | [ ]  | Healthy adults | [ ]  | Pregnant or nursing women |
|  | [ ]  | Children under 18 | [ ]  | Prisoners or individuals under detention or on probation |
|  | [ ]  | Cornell students\* | [ ]  | People in foreign countries |
|  | [ ]  | Cornell employees | [ ]  | People unable to read, speak or understand English |
|  | [ ]  | Employees or members of aspecific company or organization | [ ]  | People with limited literacy |
|  |  | [ ]  | People with specific health conditions’ |
|  | [ ]  | Cognitively impaired persons | [ ]  | Other (describe):       |
| \*If Cornell students are the study participants, are you seeking to enroll them from one or more specific classes? |
| [ ]  Yes [ ]  No |
| If yes, describe which classes, and explain whether the instructors are involved in the research (as PI, study personnel, or Faculty Advisor), or are simply giving permission to recruit from their classes: |
|       |
| Participant Recruitment [**(?)**](#_Participant_Recruitment_(?)) Procedures: |
| Select all methods that you plan to use to solicit potential study participants:  |
|  | [ ]  | Flyers/Posters | [ ]  | Cornell participant pool (SONA, etc.) |
|  | [ ]  | Mailers (U.S. Post) | [ ]  | Presentations in meetings or classes |
|  | [ ]  | Online ads | [ ]  | Phone or in-person conversation |
|  | [ ]  | Email | [ ]  | MTurk |
|  | [ ]  | Social media/online networking sites | [ ]  | Other (describe):       |
|  | [ ]  | TV, radio, print ads |  |  |
| Describe each recruitment method that you selected above. If contacting specific, individual people [(?)](#_Describe_each_recruitment), describe how you will obtain their contact information. If you will need special permissions to conduct your recruitment, please describe, and include the approval letter(s) with this application submission.  |
|       |
| List and provide the rationale for any inclusion and exclusion criteria [**(?)**](#_List_and_provide) for participation:  |
|       |
| Describe any compensation or incentives—including course credits, gift cards, or cash—that you plan to provide to participants, including the amount and the point at which it will be provided: |
|       |
| Potential risks to participants: |
| Select all potential risks associated with participation in your study: |
|  | [ ]  | Use of deception ([refer to IRB guidance template](https://www.irb.cornell.edu/documents/IRB_debriefing_template_4-30-13.pdf)) | [ ]  | Use of content that may be considered offensive, threatening or degrading |
|  | [ ]  | Manipulation of psychological or social state [(?)](#_Select_all_potential) | [ ]  | Social or economic risk [(?)](#_Select_all_potential) |
|  | [ ]  | Probing for personal or sensitive information insurveys or interviews [(?)](#_Select_all_potential) | [ ]  | Identification of child, intimate partner, orelder abuse |
|  |  | [ ]  | Risk of injury or bodily harm |
|  | [ ]  | Use of private records [(?)](#_Select_all_potential) |  |
|  | [ ]  | Identification of illegal activity | [ ]  | Risk of physical pain |
|  | [ ]  | Possible invasion of privacy | [ ]  | Other risks (describe)       |
|  | [ ]  | There are no risks of any kind to any participants enrolled in this study. *(Select this option only if none of the risks above are selected.)* |
|  |  |
| Describe the nature and degree of the potential risks selected above—if any—and how you will minimize these risks. Skip to next question, if not applicable. (Note: any risks must be disclosed in the consent form) |
|       |
| Describe potential benefits to participants, if any. If there are none, state “none.” (Note: compensation is not considered a benefit):  |
|       |
| Answer the following to help the IRB determine if your study is a clinical trial: |
| Are participants prospectively assigned [(?)](#_Are_participants_prospectively) to an intervention [(?)](#_Are_participants_prospectively) in this study? |
| [ ]  Yes [ ]  No |
| Is the study designed to evaluate the effect of the intervention(s) on participants? |
| [ ]  Yes [ ]  No |
| Is the effect being evaluated a health-related biomedical or behavioral outcome [(?)](#_Is_the_effect)? |
| [ ]  Yes [ ]  No |
| If you answered “Yes” to all three of the above questions, then your study may meet the U.S. government’s definition of a clinical trial. Please review [NIH guidance](https://grants.nih.gov/policy/clinical-trials/definition.htm) on clinical trials; the IRB staff will also communicate with you about relevant requirements as part of your protocol review process.If you have previously determined that your study is a clinical trial, and you have already registered it on [ClinicalTrials.gov,](https://www.clinicaltrials.gov/) provide the ClinicalTrials.gov ID Number:       |
| If you have any other information you would like to share pertaining to clinical trials, please do so here:  |
|       |
| Informed consent process:  |
| Describe how you plan to inform participants about the purpose and procedures for this study. Describe the consent process and materials you plan to use. If relevant, include information about:  |
| * Informed consent for adult participants
* Child assent
* Parental/guardian permission
* Consent from a legally authorized representative, for cognitively impaired participants
* Debriefing for studies involving deception or incomplete disclosure
* Written, oral, and/or online consent materials and procedures
* Consent procedures conducted in a language other than English. Note: you will need to provide translated versions of consent materials (and back-translations, if the original was not made by a professional translator).
 |
| Find consent and debriefing templates [here](https://www.irb.cornell.edu/forms/). Remember to submit these materials with your application form. |
|       |
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| If you are conducting secondary analysis [(?)](#_Describe_how_you) of data or human biospecimens, also answer the questions in [Section 3](#_Secondary_use_of_2) below. Otherwise, skip down to [Section 4: Privacy and Confidentiality](#_Privacy_and_Confidentiality_1). |

- skip if not applicable (click arrow on left to open)

# Secondary use of data or human biospecimens

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| Type of Secondary Data/Specimen Use: Review the types of studies listed below. Check “Yes” or “No” for each row. |
|  | Are you conducting this type of research? |  |
|  | 1. Secondary use of identifiable data [(?)](#_Type_of_Secondary) about living individuals | [ ]  Yes [ ]  No |
|  | 2. Secondary use of identifiable biospecimens [(?)](#_Secondary_use_of) from living individuals | [ ]  Yes [ ]  No |
|  | 3. Secondary use of de-identified data or human biospecimens\* [(?)](#_Secondary_use_of) | [ ]  Yes [ ]  No |
|  | 4. Other:       | [ ]  Yes [ ]  No |
|  |  |  |  |  |
| \*Note: Use of de-identified data or biospecimens—if the researcher was not involved in the collection of the data or biomaterials nor has access to any identifying information—is not considered human subjects research under [Federal regulations](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html). If you have selected this option only, before continuing, contact the IRB office for assistance. Your research may not require approval by the IRB.  |
| Select all the types of secondary data/materials from living individuals you are using in this study:  |
|  | Data: |
|  | [ ]  | Restricted use data [(?)](#_Select_all_the) |
|  |  | Note: Use of these data should be covered by a [Data Use Agreement](https://www.osp.cornell.edu/Policies/mta.html) executed by the Office of Sponsored Programs |
|  | [ ]  | Publically available data [(?)](#_Select_all_the) |
|  | [ ]  | Other type of data (describe):       |
|  | Human biospecimens:  |
|  | [ ]  | Blood | [ ]  | Feces | [ ]  | Skin | [ ]  | Saliva |
|  | [ ]  | Urine | [ ]  | Nasal swab | [ ]  | Hair | [ ]  | Nails |
|  | [ ]  | Other (describe)       |
| Provide a brief description of the secondary dataset(s) or biomaterials, as well as their source:  |
|       |
| Briefly describe the restrictions—if any—on the use of these secondary data/samples for research. |
|       |
| Provide a list of data fields (e.g., weight, birthdate, home zip code, etc.) for each secondary data set [**(?)**](#_Provide_a_list)**:** |
|       |
| Do the secondary data/samples contain sensitive information about the research participants?  |
| [ ]  Yes [ ]  No |
| If yes, explain: |
|       |
| Do the secondary data contain Protected Health Information (PHI) [(?)](#_Do_the_secondary) covered under HIPAA? |
| [ ]  Yes [ ]  No |
| If yes, describe how you obtained permission to use this data, and what entity is providing it. See Cornell’s [guidance on HIPAA covered data for research](https://www.irb.cornell.edu/documents/HIPAA_Guidance_for_Researchers.pdf). |
|       |
| If using human biospecimens for secondary research, describe how the specimens will be stored, handled, used, transported, and disposed of. Consult the [Cornell IRB guidance](https://www.irb.cornell.edu/biomedicalresources/index.htm) on safe handling of such materials, and contact the [Cornell IBC](https://www.ibc.cornell.edu/) for additional guidance on biosafety practices.  |
|       |
| Was anyone on your research team involved in the original collection of these data or biospecimens?  |
| [ ]  Yes [ ]  No |
| If yes, describe:  |
|       |
| **Was any part of the original data/biospecimen collection effort funded by Cornell, or supported by Cornell faculty, staff or students?** |
| [ ]  Yes [ ]  No |
| If yes, describe:  |
|       |

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| Privacy and Confidentiality Information and Procedures for All Types of Studies |
| For all studies |
| Select the identifiers that researchers will collect or record (Note: we recommend collecting/recording the minimum identifiable data that is needed for your research): |
|  | [ ]  | Name | [ ]  | IP address |
|  |  |  |  |  |
|  | [ ]  | Full date of birth [(?)](#_Select_the_identifiers) | [ ]  | Biometric identifiers [(?)](#_Privacy_and_Confidentiality) |
|  |  |  |  |  |
|  | [ ]  | Mailing or email address | [ ]  | Photos/images/audio recording |
|  |  |  |  |  |
|  | [ ]  | Phone or fax numbers | [ ]  | Signatures [(?)](#_Privacy_and_Confidentiality), handwriting samples |
|  |  |  |  |  |
|  | [ ]  | Social Security number | [ ]  | Cornell NetID |
|  |  |  |  |  |
|  | [ ]  | Medical records | [ ]  | MTurk Worker ID |
|  |  |  |  |  |
|  | [ ]  | License, certificate or Vehicle ID | [ ]  | Other identifier:       |
|  |  |  |  |  |
|  | [ ]  | No member of the research team will have access to any personal identifiers. *(Select this option**only if you have not selected any of the others above.)* **If no identifiers are being collected or recorded, skip to Section 5: Documentation Checklist.** |
|  |  |
|  |  |
| Describe why each identifier is required: |
|       |
| Data Security Practices: Select all that you will follow, if relevant and appropriate for your study [**(?)**](#_Data_Security_Practices:): |
|  | [ ]  | Datasets will be de-identified. Data elements will be separated into a coded data set to be usedfor research purposes and a “key” [(?)](#_Data_Security_Practices:) to be kept under researcher’s control.  |
|  |  |
|  | [ ]  | PI will maintain a list of individuals who have access to the data. |
|  |  |  |
|  | [ ]  | Access to identifiable information will be controlled: all electronic devices used by the researchteam will be password protected, and data will not be saved on researchers’ mobile devices. |
|  |  |
|  | [ ]  | Any physical data/materials [(?)](#_Data_Security_Practices:) will be kept under lock and key (in locked cabinets or access-controlled offices). |
|  |  |
|  | [ ]  | Identifiable data will only be saved in approved, encrypted Cloud file share locations (e.g., |
|  |  | [Cornell Box](https://it.cornell.edu/box)). See the IT@Cornell [Regulated Data Chart](https://it.cornell.edu/regulated-data-chart) for options. |
|  | [ ]  | Data with identifiers will not be transmitted by email. (Use [Cornell Dropbox](https://it.cornell.edu/dropbox) instead.) |
|  |  |  |
|  | [ ]  | If data containing personal identifiers will be stored on a laptop or tablet, either the data or thewhole device will be encrypted. |
|  |  |
|  | [ ]  | Identifiable data will be encrypted if it is stored on a networked computer or device, or storedon or transmitted via the web. |
|  |  |
|  | [ ]  | Each authorized person will access research data using an account assigned for their own use,rather than shared or group accounts. |
|  |  |
| Please provide any additional information you would like to share about your data security plans: |
|       |
|  |
| Note: Computers (including tablets) that leave the Cornell campus should be encrypted. The university has licensed the PGP encryption software and made it available to all Cornell employees for no-fee. For more information about Cornell IT security options, visit this website: <https://it.cornell.edu/security-and-policy> |
| Describe how and where research data [**(?)**](#_Describe_how_and) will be stored and accessed by the research team [**(?)**](#_Describe_how_and): |
|       |
| What do you plan to do with the research data? Select all that apply: |
|  | [ ]  | No plans to share the data with anyone outside the research team. Will securely keep the data under my control and destroy the data after any publications from this project are done. |
|  |  |
|  |  |
|  | [ ]  | Store the data with identifiers for future research. (This will require additional consent fromparticipants). |
|  |  |
|  | [ ]  | De-identify the data and store it for future research using security methods described here. |
|  |  |  |
|  | [ ]  | Share data with identifiers with other Cornell or non-Cornell researchers or in a common datarepository. (This will require additional consent from participants) |
|  |  |
|  | [ ]  | De-identify the data and share it with Cornell or non-Cornell researchers or in a common datarepository. |
|  |  |
|  | [ ]  | De-identify the data and make it publically available to meet sponsor and publicationrequirements. |
|  |  |
|  | [ ]  | Other (describe)       |
| Will names or other identifiers [**(?)**](#_Will_names_or) be used in publications or presentations?  |
| [ ]  Yes [ ]  No |
| If yes, please explain the reason why, and be sure to describe this intention in the consent form. |
|       |
| If there is any other information to share about your study that you haven’t already provided, provide it here: |
|       |

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| Documentation Checklist |
| For all studies |
| This is a list of the additional documentation that you may need to submit alongside the completed protocol application form:For active data/biospecimen collection:* Informed Consent materials [(?)](#_Documentation_Checklist)

See [Cornell IRB SOP 10: Informed Consent Options, Processes, and Documentation](https://www.irb.cornell.edu/documents/SOP%2010%20-%20Informed%20Consent.pdf)See [Cornell IRB consent templates](https://www.irb.cornell.edu/forms/)* Participant Recruitment materials [(?)](#_Documentation_Checklist)
* Data collection instruments [(?)](#_Documentation_Checklist)
* Study Procedures [(?)](#_Documentation_Checklist) (See [Cornell IRB biomedical SOP templates](http://www.irb.cornell.edu/biomedicalresources/index.htm))
* Other IRB/ethics board approval letters
* Any other special permissions/approvals needed to conduct your research

Examples include letters of support from:* + The principal of a primary school, or the professor of a course from which you will recruit participants
	+ Director/Manager of the [Cornell MRI Facility](https://mri.cornell.edu/) or the [Human Metabolic Research Unit](https://www.human.cornell.edu/dns/research/facilities/hmru)
	+ Head of an organization that you are studying and from which you are recruiting participants

For secondary use of data/biospecimens:* Confirmation that a data use agreement has or will be signed through [OSP](https://www.osp.cornell.edu/Policies/mta.html)
* Any special permissions needed for access to or storage of data/biospecimens (e.g., letter of support for use of the [Cornell Restricted Access Data Center](https://ciser.cornell.edu/data/secure-data-services/cradc/) - CRADC)

For all types of research:* Documentation of human participants research ethics training for any non-Cornell research team members (Cornell personnel training will be checked directly through [CITI](https://about.citiprogram.org))
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| Investigator Attestation |
| For all studies. To be signed by the principal investigator (PI). If the PI is a student, the faculty supervisor must also sign\*. |
|  |
| Principal Investigator: I certify that the information I provide in this application is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Institutional Review Board for Human Participants. |
|  |  |
|  | Click or tap to enter a date. |
| Signature of Principal Investigator |  | Date |
|       |  |  |
| Print Name of Principal Investigator |  |

|  |
| --- |
| \*Faculty Supervisor (required if the PI is a student):The faculty supervisor must either sign this document, or send the attestation below by email. For the latter, copy and paste the attestation statement, include the student investigator’s name and project title in the email, and send it to irbhp@cornell.edu. The email submission must come from the faculty supervisor’s Cornell email account. |
|  |
| I have examined this completed form and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of the research participants. I will take responsibility for providing supervision of the student; for informing her/him of the need for the safekeeping of all raw data (e.g., surveys, questionnaires, interview notes, video/audio recordings, test protocols, etc.), as well as the signed consent forms, in a University office or computer file; and for overseeing all compliance with the IRB’s policies and procedures. |
|  |  |
|  |  | Click or tap to enter a date. |
| Signature of Faculty Supervisor |  | Date |
|       |  |  |
| Print Name and Title of Faculty Supervisor |  |  |
|  |  |  |

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| --- |
| Submitting Your Application |
| You have now completed this form. Please review it to ensure that it is filled out completely and accurately. Save, then submit the form as an attachment via email to irbhp@cornell.edu, along with any additional study materials (as outlined in the Documentation Checklist - Section 5, above).If you have any questions or need assistance, please contact the IRB staff:Phone: 607-255-5138Email: irbhp@cornell.edu |