**PROPOSAL SUBMISSION APPLICATION**

**Email all application materials to** [**IRB\_submissions@phila.gov**](mailto:IRB_submissions@phila.gov)

**If the documents exceed 15MB or you experience any difficulties, contact the IRB office for instructions.**

**If all document names do not fit in the spaces provided, add additional lines as needed.**

**Please do not combine required materials into a single document.**

**Submissions are due no later than 3:00 PM on the submission deadline, which can be found on our website, www.phila.gov/health/irb.**

**PART I**

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| **1** | **TITLE OF PROPOSAL** |
| **2** | **PRINCIPAL INVESTIGATOR INFORMATION**  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Degree(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3** | **ALTERNATE CONTACT INFORMATION**  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4** | **STUDY SPONSORSHIP** (Include sponsor and grant number, if available) |

**PART II**: **CHECK AND COMPLETE ALL APPLICABLE SECTIONS**

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| # | **X** |  |
| **5** |  | **Submission of new study for full IRB review. Pages should be numbered on all documents.** |
|  | A. Executive summary – 1-2 pages – To include the following information:  Description of intent and methodology of study  Description of Philadelphia Department of Public Health, Department of Behavioral Health or other City Department involvement  Duration of study  Risks to subjects  Numbers of participants  Contact information for Principal Investigator  Notation if requesting exemption from or alteration of informed consent and/or waiver of HIPAA authorization  Document name (e.g., DoeExecSum.docx): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | B. All consent and/or assent form(s) (see PDPH IRB Consent Guidance) All submissions must be accompanied by either consent and/or assent forms or a request for a waiver of informed consent. (See section 6A,B,C)  Document name(s): ­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | C. All other materials for participant recruitment or distribution, such as flyers, advertisements, reminder cards, etc.  Document name(s): ­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | D. Full research protocol or grant proposal--If the study includes use of existing data, provide full details of the data set, data management and security plans. If you submit documents prepared for another institution, you must ensure that any form/boilerplate language not part of the description of your study is clearly marked (***e.g., in bold italics and a different size or font or with other distinctive formatting)*** so that it is not interpreted as part of your protocol.  Document name(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | E. Any data collection instruments: surveys, measurement scales, etc.  Document name(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | F. Unit manager(s)’s approval  Document name(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | G. Conflict of Interest statements for all key study staff  Document name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | H. Proof of satisfactory completion of human subjects protection training within preceding three (3) years for Principal Investigator and all study staff who will have access to participants and/or identifiable data.  Document name(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | I. Research involving Philadelphia Department of Public Health data, staff or clients must also be submitted to the Health Commissioner’s Office Review Committee. [www.Phila.Gov/Health/Commissioner/HCORevCommittee.html](http://www.Phila.Gov/Health/Commissioner/HCORevCommittee.html) |
|  |  | J. Research requiring transfer of data from the City to outside investigators will require additional approvals. http://www.phila.gov/health/pdfs/External%20Research%20Requests.pdf |

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| **6** |  | **Research involving prisoners –** Check here if the study involves prisoners. Studies involving prisoners are not eligible for exemptions or expedited review. |
| **7** |  | **Submission of request for Exempt Study Determination.** Check this section if you believe this study qualifies as exempt from IRB review. **Complete and submit the IRB Exempt Application [separate form] at any time. Do not wait for an IRB submission deadline.** If study is determined to not be exempt, or if waiver of HIPAA authorization is required, be prepared to submit materials indicated in section #1 above for full IRB review. |
| **8** |  | **Expedited review eligibility –** Check here if you believe this study qualifies for expedited review. PDPH IRB allows expedited initial review only for minimal-risk studies that are eligible for expedited review under the relevant sections of Federal Regulations, 45CFR46 and involve only materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes. |
| **9** |  | **Submission by Principal Investigator who is not affiliated with Philadelphia Department of Public Health or Department of Behavioral Health** |
|  |  | **(A) Check one of the following:** |
|  |  | (1) City co-investigator (Name and unit): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  | (2) Unit manager approval notes absence of City co-investigator |
|  |  | **(B) Check one of the following:** |
|  |  | (1) Submission includes IRB approval from investigator’s home institution or documentation of application for such approval, or |
|  | (2) Submission includes a non-affiliated investigator agreement (contact IRB office for a draft agreement), or |
|  |  | (3) Investigator is covered under the reliance agreement between Drexel University and Philadelphia Department of Public Health, or |
|  |  | (4) Submission includes documentation of request for reliance agreement of investigator’s home institution on PDPH IRB. |

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| **10** |  | **Request for alteration or waiver of written informed consent and/or waiver of HIPAA authorization.** Consult *Waiver or Alteration of Consent or HIPAA info* sheet for eligibility. Check appropriate box(es) below: |
|  |  | (A) Request for waiver of informed consent |
|  |  | (B) Request for waiver of documentation of informed consent |
|  |  | (C) Request for other alteration of informed consent--describe: |
|  |  | (D) Request for waiver of HIPAA Authorization |
| **11** |  | **PDPH IRB Data Management Security Information.** When transferring or collecting data between networks, please provide a statement including the following information: |
|  |  | (A) SSH/Secure File Transfer Protocol (SFTP) |
|  |  | (B) Advanced Encryption Standard bits (AES) 128 bit or greater |
|  |  | (C) Transport Layer Security Version (TLS) 1.2 version or greater |
|  |  | (D) Strong passwords and multi-factor authentication must be used |

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