**Exempt Summary Template**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **\*\*\* Directions for Use for this Template \*\*\***

|  |
| --- |
| * This template should be used for studies that may be eligible for Exempt review OR Limited review.
* Instructions for each section are included in *blue italics*. As you complete each section, delete the instructions.
* For studies that qualify for Exempt review OR Limited review, your submission may also require an outline of the consent process and an information sheet or telephone/verbal script. This would be required for studies involving surveys, focus groups or interviews. Do not need to submit an informed consent document or a waiver of informed consent.
* Remove this section “Directions for Use for this template” before IRB submission
 |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| **Study Title:** | *Insert Full Title (This must match title on Research Navigator submission smart form)*  |
| **Study Number:** | *Insert Research Navigator Study Number (e.g., 17-01234)*  |
| **Principal Investigator:** | *Insert Name (List one person as PI. Person must be NYU Grossman SoM or NYU Long Island SoM Faculty)**Insert Department Name**Insert Address**Insert Email Address**Insert Phone Number* |
| **Sub-Investigators:** | *Insert names of all other NYU investigators* |
| **Study Site(s):** | *Insert a list of participating sites* |

**1. Objectives**

*Provide a complete description of the planned research. State the purpose of the study (include research questions and /or study objectives). In an experimental design study, objectives will be stated as hypotheses to be tested.*

**2. Background and Rationale**

*Summarize the available research (including published data) to provide justification for the study. Evaluate prior research for relevance to the research question under study. Discuss the anticipated results and potential pitfalls. Describe the significance of the research including potential benefit for individual subjects or society at large. Discuss how public health and social welfare might be enhanced.*

**3. Research Design**

*Provide a description of your research (type of study design, and principle variables or outcome measures that is appropriate to answer the research question(s).*

*Examples: Research about established/commonly accepted educational practices, educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior (including audio or visual recording), benign behavioral interventions with adult subjects, secondary research for which consent is not required (note: the data can be collected retrospectively and prospectively), research conducted or supported by Federal Department or Agency, food quality evaluations.*

**4. Number of Subjects**

*State total number of subjects to be enrolled or records/specimens to be included in the study. Describe the sampling approach.*

**5. Study Population**

*Describe the study population and state criteria for inclusion and exclusion if applicable.*

**6. Study Methods and Procedures**

*For this section you should:*

* *List/explain in details all procedures to be used to accomplish the aims/goals of the study*
* *List all sources of data/records (e.g., EPIC, Quadramed…)*
* *Identify procedures that will be used to recruit and screen subjects*
* *Describe methods for data collection*
* *Provide a timeline for subject evaluation and duration of subject participation*
* *Outline consent process (if applicable)*

*If your research involves the use of digital data collection tools, include the following:*

* The commercial product(s) made by Name third party companies, List name of product (mobile apps for use on smartphone and tablets, websites and web apps, and types of computer software) permit pick as applicable screen sharing, record keystrokes, gain access to device files and/or use location tracking technology will be used to collect study data. These devices will be used in accord with the Terms of Service and/or the End User License Agreements (EULA) provided by the product or device vendor. These products and devices will only be used to collect study data with IRB approval and if the subject has agreed to all applicable Terms of Service.

If applicable add

This product(s) may be owned by the subject or provided to the subject by the study team/ mobile health platform.

**7. Risk and Benefit Assessment**

**7.1 Potential Risks**

* *Describe in detail any psychological, social, legal, economic, or any other risks to subjects by virtue of participation in the study that the PI foresee*
* *Describe measures for minimizing risks to subjects and/or potential breach of confidentiality*
* *Indicate whether or not disclosure outside of research would put subjects at risk or harm*

*If your research involves the use of digital data collection tools, include the following:*

* **Risks of use of mobile health technology**

Commercial products or devices made by third party companies, including wearable fitness trackers, wearable sleep monitors, mobile apps for use on smartphone and tablets, websites and web apps, and types of computer software that permit screen sharing, record keystrokes, gain access to device files and/or use location tracking technology may be used to collect study data. These devices will be used in accord with the Terms of Service (TOS) and/or the End User License Agreements (EULA) provided by the product or device vendor. Use of such products and devices may result in loss of privacy and risk of breach of confidentiality. These products and devices will only be used to collect study data with IRB approval and if the subject has agreed to all applicable Terms of Service and EULAs. The participant will be advised to read the full EULA or TOS before agreeing to use the product. Any risks associated are outlined in the informed consent, as follows: ADD HERE IN SUMMARY IF APPLICABLE as noted in TOS or EULA

**7.2 Potential Benefits**

* *Describe in detail any potential benefits to subjects or society that the PI foresees*

**8. Data Storage and Confidentiality**

*For this section you should:*

* *Specify who will have access to study data*
* *Specify if identifiable information will be recorded. If so, how it will be coded*
* *List identifiers that will be used for this study (\*choose from the PHI table below)*
* *Indicate if identifiers will be recorded for the purpose of this research. Note: In order to access/use or record identifiers for research purposes, a waiver of authorization is necessary.*
* *Describe how study data (both paper and electronic) will be stored (e.g., in a locked cabinet, RedCap, NYULH MCIT-managed network drive…)*
* *State how long subject data will be stored, how it will be destroyed when no longer needed.*
* *If information obtained will be recorded in such a manner that the identity of the human subjects* ***can*** *readily be ascertained, directly or indirectly through identifiers, describe any provisions to protect the privacy of subjects and to maintain the confidentiality of data. Examples may be:*
* *Indicate extent to which identifiable private information is or has been de-identified and the risks that such de-identified information can be re-identified*
* *Describe use of the information*
* *Indicate extent to which the information will be shared or transferred to a third party or otherwise disclosed or released (as applicable)*
* *Indicate likely retention period of the information*
* *Describe security controls in place to protect confidentiality and integrity of information*
* *Provide potential risks of harm to subjects should the information be lost, compromised, or used in a way contrary to the research under the exemption.*

**9. Data Analysis**

*If applicable, specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.*

**10. References**

*Include a reference list of literature cited to support the proposed study*

|  |
| --- |
| **\* Protected Health Information (HIPAA Identifiers)** |
| 1 | Names |
| 2 | Street Address |
| 3 | County or Precinct |
| 4 | Any of the following: City, State, Zip Code (or equivalent geocode) |
| 5 | Any elements of dates (except year) for dates directly related to an individual (e.g., date of birth/death, dates of admission/discharge, etc.) |
| 6 | For those 90 or older: Any element of date (including year) indicative of age, or recording actual age (i.e., rather than recording age as “90 or older”) |
| 7 | Telephone numbers |
| 8 | Fax numbers |
| 9 | Electronic mail addresses |
| 10 | Social security numbers |
| 11 | Medical record numbers |
| 12 | Health plan beneficiary numbers |
| 13 | Account numbers |
| 14 | Certificate/license numbers |
| 15 | Vehicle identifiers and serial numbers, including license plate numbers |
| 16 | Implanted device identifiers and serial numbers |
| 17 | Web Universal Resource Locators (URLs) |
| 18 | Internet Protocol (IP) address numbers |
| 19 | Biometric identifiers, including finger and voice prints |
| 20 | Full face photographic images and any comparable images |
| 21 | Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data) |