# Research Ethics Application for an Observational Study on Human Subjects Without Biospecimen Collection

Please use this application form if you are applying to request ethical approval by the Research Ethics Committee (REC) at INSPECT-LB for a study that involves data collected from or about human subjects without sample or biospecimen collection. If the study is a case report or if the study is a case series involving three or fewer cases, then IRB approval from the REC is not required. However, the Health Insurance Portability and Accountability Act (HIPAA) guidelines do apply, and consent must be collected from participants/patients.

It is recommended to complete and submit this application form to REC at least 45 days prior to the study start date to allow for proper review of the application.

For any assistance, please contact the REC office by email at REC@inspect-lb.org

If you are applying on behalf of the principal investigator (PI), please indicate if the PI has approved this application prior to its submission.

[ ]  No [ ]  Yes [ ]  I am the PI

No studies with ongoing or completed data collection will receive REC review or approval.

The REC will evaluate the following aspects of the application before approving research involving human subjects:

* The research design is scientifically sound.
* The choice of the prospective study population is appropriate in terms of characteristics and size.
* The recruitment of subjects is free of coercion.
* The risks to the participants are outweighed by the potential benefits.
* Any risks associated with the research are minimized to the greatest extent possible and justified by the expected benefits.
* The participant’s informed consent and/or assent is obtained from the subjects or their legally authorized representatives (LAR).
* The method to obtain consent and/or assent is ethically and legally acceptable and does not use any form of coercion.
* The privacy of all participants is respected.
* The confidentiality of the data collected is protected.
* An adequate monitoring (e.g., attendance of a LAR or legal guardian, psychological follow-up, etc.) will be performed to ensure the physical and mental safety of participants, where deemed necessary.
* Vulnerable subject populations will receive additional protection.
* The selection and recruitment procedures are equitable and correct.

|  |
| --- |
| **Applicant Information** |
| Name of the Applicant1: | Click or tap here to enter text. |
| Email of the Applicant1: | Click or tap here to enter text. |
| Title of the Application: | Click or tap here to enter text. |
| Date of Initial Submission: | Click or tap here to enter text. |
| *Please list the names of all investigators directly involved in the study, including the applicant:* |
| Name | Institution(s) | Email Address |
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1 *The applicant is the investigator who will submit this application to REC on behalf of the research team. The applicant may or may not be the PI.*

|  |
| --- |
| **Application Checklist** |
| [ ]  REC Application Form duly completed |
| [ ]  Conflict of Interest (COI) Collective Form*A* [*COI Collective Form*](https://inspect-lb.org/wp-content/uploads/2024/09/INSPECT-LB-COI-Collective-Form.docx) *must be submitted for the entire research team.* |
| [ ]  Curricula Vitae (CV)*A CV must be provided for every investigator involved in the study, excluding INSPECT-LB members* |
| [ ]  Data Collection Sheet (DCS) / Questionnaire*The DCS should be submitted in Microsoft Word or Portable Document Format (PDF), in its final format, without any tracks or visible edits, and in all the languages in which it will be used in the study. Please note that links to access the DCS or screenshots of the DCS will not be accepted.* |
| [ ]  Consent Form*The consent form should be submitted in Microsoft Word or Portable Document Format (PDF), in its final format, without any tracks or visible edits, and in all the languages in which it will be used in the study.* |
| [ ]  Assent Form (if applicable)*The assent form should be submitted in Microsoft Word or Portable Document Format (PDF), in its final format, without any tracks or visible edits, and in all the languages in which it will be used in the study.* |
| [ ]  Any other documents relevant or pertinent to the application |

|  |
| --- |
| applications that do not include all the required documents will not be considered for review. |

## Study Identification

### Study title

Click or tap here to enter text.

### Principal investigator

*[The principal investigator (PI) is the investigator in charge of the study. Please note that a student cannot serve as a PI.]*

|  |  |
| --- | --- |
| Last Name: | Click or tap here to enter text. |
| First Name: | Click or tap here to enter text. |
| Title: | Click or tap here to enter text. |
| Institution: | Click or tap here to enter text. |
| Email address: | Click or tap here to enter text. |
| Phone Number: | Click or tap here to enter text. |

### Study investigators

*[Investigators are the individuals involved in the study, other than the PI.]*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| First and Last Names | Professional Title | Institution(s)1 | Role in the Study2 | Email |
| 1. Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 2. Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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| 9. Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 10. Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

*1 Include INSPECT-LB and/or any educational or research institution the investigator is affiliated with.*

*2 The role in the study may be in the designing of it, the redaction or editing of the data collection sheet, data collection, statistical analysis, etc. An investigator may have more than one role.*

### Study timeline

[Resuming data collection after the study end date will lead to an immediate suspension or termination of the study.]

|  |  |
| --- | --- |
| Anticipated Study Start Date: | Click or tap to enter a date. |
| Anticipated Study End Date: | Click or tap to enter a date. |

### Study location

[Please list all the locations where the study, including recruitment activities will take place. If there is no physical location where the study will take place, then please explain it below using the most accurate terms (e.g., “The study will be conducted by circulating a survey online. Consequently, no location is required for this study).]

Click or tap here to enter text.

[ ]  No physical location is assigned for the study:

Click or tap here to enter text.

### Funding

[Funding refers to any form of financial support invested towards the study. It includes grants, sub-grants, contracts, internal funds, sponsors, donations, and any other source or type of funding.]

**6.1.** Is the research funded?

[ ]  No [ ]  Yes

**6.2.** For funded research, please specify the funding source/sponsor name.

Click or tap here to enter text.

### Academic program

Please indicate if this research is required for the completion of an academic program.

[ ]  No, it is not [ ]  Yes, for a master’s degree [ ]  Yes, for a doctorate degree

[ ]  Yes, for a residency [ ]  Other. Please, specify: Click or tap here to enter text.

## Study Type and Design

### Type of research

[Please check the box which best describes the research type of the study.]

[ ]  Biomedical (research on human participants that is non-interventional, non-diagnostic, and non-therapeutic)

[ ]  Clinical (research on the treatment of patients. It must be non-interventional)

[ ]  Health Services (research regarding the enhancement of the healthcare system)

[ ]  Population Health (epidemiology and public research on factors affecting human health. It must be non-interventional)

[ ]  Clinical Epidemiology (research on scale validation, screening tools, and diagnostic tools. It must be non-interventional)

*If the type of research of the proposed study does not apply to any of the above, please specify it below:*

Click or tap here to enter text.

### Study design

[Please check the box that best describes the design of the study.]

[ ]  Case series with more than three cases

[ ]  Retrospective study (descriptive)

[ ]  Cohort study

[ ]  Cross-sectional study

[ ]  Case-control Study

[ ]  Other. Please, specify: Click or tap here to enter text.

### Data collection procedure(s)

[Please check from the list below all the data collection procedures that apply to the study.]

[ ]  Surveys and questionnaires (including internet surveys)

[ ]  Interviews and/or focus groups (face-to-face or online)

[ ]  Data registries and/or medical records

[ ]  Secondary research (secondary research is the reuse of data or specimen that were originally collected for research other than the proposed research study)

[ ]  Participant observation

[ ]  Biobanking of information related to non-invasive sample collection

[ ]  Other. Please, specify: Click or tap here to enter text.

## Study Summary

**Provide a summary of the proposed research using simplified language.**

[Organize the summary into a single paragraph that delineates the following: scientific context, objective, experimental design, and expected outcomes. This summary must be a shortened version of the description provided in the scientific proposal at the end of this application and must not exceed 250 words.]

Click or tap here to enter text.

## Human Subject Selection and Data Collection

### Size of the study population

*[Please* specify *the number of human subjects who will be recruited for the study. Include the statistical calculations made to estimate the required population size.]*

Click or tap here to enter text.

### Description of the study population

*[Indicate the exact* inclusion *and exclusion criteria that apply to the study population. Both criteria must be listed.]*

* 1. Inclusion criteria:

Click or tap here to enter text.

* 1. Exclusion criteria:

Click or tap here to enter text.

### Identification and recruitment of participants

*[Briefly describe the procedure that will be used to identify and recruit the study participants. The description* must *include information about the method of selection of participants, location/setting of recruitment, and duration of recruitment. If applicable, please provide a script of the text message, WhatsApp message, email, letter, phone conversation, etc. in all the languages in which they will be used for the recruitment procedure.]*

Click or tap here to enter text.

### Vulnerable groups

**4.1.** Indicate if any vulnerable group(s) will be enrolled in the proposed research.

[ ]  No vulnerable groups will be included in this study (please go to Section IV-5)

[ ]  Pregnant women

[ ]  Children/minors

[ ]  Adults who lack capacity to consent to research

[ ]  Prisoners

[ ]  Elderly

[ ]  Subordinates/employees at institution

[ ]  Students

[ ]  Other. Please, specify: Click or tap here to enter text.

**4.2.** Describe the additional protection vulnerable subjects will receive during data collection.

Click or tap here to enter text.

### Will you advertise to solicit participants?

[ ]  No [ ]  Yes

*If yes, please select the applicable categories from the list below and provide a copy of the advertisement in all the languages in which they will be used for the study.*

[ ]  Letter [ ]  Phone [ ]  E-mail [ ]  Internet

[ ]  Poster [ ]  Publication [ ]  Other. Please, specify: Click or tap here to enter text.

## Informed Consent Process

### Are you requesting a waiver of consent for this study?

[ ]  No (please go to section V-2) [ ]  Yes

*If yes, please indicate which of the following applies to your research:*

[ ]  The research involves no more than minimal risk

[ ]  The research cannot operably be carried out without the waiver or alteration of consent

[ ]  The research requires using identifiable private information and cannot operably be carried out unless the information is used in an identifiable format

[ ]  The waiver or alteration will not negatively affect the rights and good of the participants

[ ]  Whenever appropriate, the subjects or legally authorized representatives (LAR) will be provided with additional pertinent information after participation.

### Please specify the method you will use to obtain consent

[ ]  Signed (details are to be provided in section V-5)

[ ]  Verbal (details are to be provided in section V-6)

[ ]  Electronic (details are to be provided in section V-7)

### Modality of consent collection

[ ]  Free (self-reading and signature)

[ ]  Guided (the participant is receiving support in reading and understanding the consent)

*Will the consent collection require a legally authorized representative?*

[ ]  Yes [ ]  No

### Please indicate which of the information listed below was included in the consent form (i.e., information sheet)

|  |  |  |
| --- | --- | --- |
| Item\* | Status | Justification: Provide an explanation for not including the item, unless you selected “Included.” |
| The activity is being conducted for research purposes\* | Choose an item. | Click or tap here to enter text. |
| The purpose of the study\* | Choose an item. | Click or tap here to enter text. |
| The expected duration of the subject’s participation\* | Choose an item. | Click or tap here to enter text. |
| The type of intervention for which you are seeking the participant’s involvement\* | Choose an item. | Click or tap here to enter text. |
| Any anticipated risks or benefits for the participant\* | Choose an item. | Click or tap here to enter text. |
| Statement that the participation is voluntary\* | Choose an item. | Click or tap here to enter text. |
| Alternative interventions that might protect the participant in case of any foreseeable risks\* | Choose an item. | Click or tap here to enter text. |
| If any identifiable or traceable information about the participant will be collected\* | Choose an item. | Click or tap here to enter text. |
| How confidentiality of the subject’s identifiable or traceable information will be protected\* | Choose an item. | Click or tap here to enter text. |
| If the information provided by the participant will be recorded and if yes, in what form\* | Choose an item. | Click or tap here to enter text. |
| If the information provided by the participant will be stored and if yes, in what form | Choose an item. | Click or tap here to enter text. |
| If identifiable private information will be collected, one of these statements is needed\*:[ ]  Identifiable information might be removed, and only then can the information be used for future research studies or shared with other investigators for future research studies without additional informed consent from the subject or their LAR, if this might be a possibility. OR[ ]  Subject's information collected for the research, even if identifiable information is removed, will not be used or distributed for future research studies. | Choose an item. | Click or tap here to enter text. |
| Compensation details (including when none is offered) | Choose an item. | Click or tap here to enter text. |
| Any costs that a participant may incur as a result of their participation in the study | Choose an item. | Click or tap here to enter text. |
| Name, role and contact information of one of the investigators who should be contacted for any type of inquiries about the study or for research-related injury\* | Choose an item. | Click or tap here to enter text. |
| Statement that the participant is entitled to withdraw from the study at any time and that all information collected about them until that time will be immediately destroyed once the withdrawal takes effect\* | Choose an item. | Click or tap here to enter text. |
| Circumstances under which a subject’s participation may be terminated by the investigator with a description of the termination procedure | Choose an item. | Click or tap here to enter text. |
| [ ]  Other. Please, specify: Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. |

*\* These items must be included in the consent form/statement.*

### Signed consent

*[Please* provide *a copy of the consent form, in all the languages in which it will be used for the study. The consent form must be written in a simplified language that can be easily understood by the participant.]*

### Verbal consent

*[Please copy below the verbal version of the consent form (i.e., information sheet) that will be read and explained* to *the prospective participants in order to obtain their verbal consent in place of the written consent to participate in the study. If it is not possible to provide subjects with an information sheet - for example, the only contact is virtual or by phone – please provide a consent script in all the languages in which it will be used to evaluate the consenting process.]*

Click or tap here to enter text.

### Electronic consent

*[Please copy below the consent information that will be included in the recruitment email or at the beginning of the online survey in all the languages in which it will be used. Participants will consent to the research by clicking "Agree" or "Continue" (or similar) if they wish to participate.]*

Click or tap here to enter text.

### Specify the language(s) in which the consent form(s) will be available to participants:

[ ]  Arabic [ ]  English [ ]  French

[ ]  Other. Please, specify: ­Click or tap here to enter text.

### Persons in charge of obtaining consent from participants

*[Indicate who will administer the consenting process and specify, to the best of your knowledge, if there is any form of* interest *between any of the investigators collecting the consent and any of the participants providing their consent.]*

**9.1.** If the study is conducted online exclusively, and the consent is self-reported without involvement of any other party/person, please check this box: [ ]

**9.2.** If any person is involved in obtaining consent from the participant, please fill out the table below. The individuals collecting consent and or data from participants must have received adequate training to complete these tasks. Participants are highly encouraged to complete the CITI Program (Collaborative Institutional Training Initiative Program) training or similar prior to the study inception.

|  |  |  |
| --- | --- | --- |
| Full Name and Title (Master candidate, M.D., Ph.D., etc.) | Training Completed | Direct Relationship with participant |
| 1. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 2. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 3. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 4. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 5. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 6. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 7. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 8. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 9. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 10. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |

**9.3.** If any of the investigators obtaining consent has any relationship with any of the participants, please indicate the strategy that will be used to protect the participants against any form of influence or coercion.

Click or tap here to enter text.

[ ]  None of the investigators has any relationship with any of the participants

**9.4.** If any of the participants is vulnerable or incapable of providing consent (e.g., participants with cognitive impairment or mental retardation, minors, pregnant women, prisoners, etc.), please describe the additional protection that these participants will receive during data collection.

Click or tap here to enter text.

[ ]  No participants incapable of providing consent will be enrolled in the study

[ ]  No vulnerable participants will be enrolled in the study

## Informed Assent Process

### Does the study population in your research involve children?

[ ]  No (please go to section VII) [ ]  Yes

### Will you solicit the assent of the children?

[ ]  No [ ]  Yes

### Are you requesting a waiver of assent for this study?

[ ]  No (please go to section VI-5) [ ]  Yes

### If you are requesting a waiver of assent, please select one or more of the options below, if applicable.

[ ]  The capacity of some or all of the minors is so restricted that it is unreasonable to consult them

[ ]  The intervention or procedure associated with the research has the potential to provide a direct benefit to the health or well-being of the minors and is exclusively available within the context of the research.
[ ]  The research involves no more than minimal risk

[ ]  The research cannot operably be carried out without the waiver or alteration of assent

[ ]  The research requires using identifiable private information and cannot operably be carried out unless the information is used in an identifiable format

[ ]  The waiver or alteration will not negatively affect the rights and good of the participants

[ ]  Whenever appropriate, the subjects or legally authorized representatives (LAR) will be provided with additional pertinent information after participation

[ ]  None of the above applies to the study population in this research

### Please specify the method you will use to obtain assent

[ ]  Signed (details are to be provided in section VI-8)

[ ]  Verbal (details are to be provided in section VI-9)

[ ]  Electronic (details are to be provided in section VI-10)

### Modality of assent collection

[ ]  Free (self-reading and signature)

[ ]  Guided (participant is receiving support in the reading and understanding of the assent content)

*Will the assent collection require a legally authorized representative or legal guardian?*

[ ]  Yes [ ]  No

### Please indicate which of the information listed below was included in the assent form (i.e., information sheet)

|  |  |  |
| --- | --- | --- |
| Item\* | Status | Justification: Provide an explanation for not including the item, unless you selected “Included.” |
| The activity is being conducted for research purposes\* | Choose an item. | Click or tap here to enter text. |
| The purpose of the study\* | Choose an item. | Click or tap here to enter text. |
| Th expected duration of the minor subject’s participation\* | Choose an item. | Click or tap here to enter text. |
| The type of intervention for which you are seeking the participant’s involvement\* | Choose an item. | Click or tap here to enter text. |
| Any anticipated risks or benefits for the participant\* | Choose an item. | Click or tap here to enter text. |
| Statement that the participation is voluntary\* | Choose an item. | Click or tap here to enter text. |
| Alternative interventions that might protect the participant in case of any foreseeable risks\* | Choose an item. | Click or tap here to enter text. |
| If any identifiable or traceable information about the participant will be collected\* | Choose an item. | Click or tap here to enter text. |
| How confidentiality of the subject’s identifiable or traceable information will be protected\* | Choose an item. | Click or tap here to enter text. |
| If the information provided by the participant will be recorded and if yes, in what form\* | Choose an item. | Click or tap here to enter text. |
| If the information provided by the participant will be stored and if yes, in what form\* | Choose an item. | Click or tap here to enter text. |
| If identifiable private information will be collected, one of these statements is needed\*:[ ]  Identifiable information might be removed, and only then can the information be used for future research studies or shared with other investigators for future research studies without additional informed assent from the subject or their LAR, if this might be a possibility. OR[ ]  Subject's information collected for the research, even if identifiable information is removed, will not be used or distributed for future research studies. | Choose an item. | Click or tap here to enter text. |
| Compensation details (including when none is offered) | Choose an item. | Click or tap here to enter text. |
| Any costs that a participant may incur as a result of their participation in the study | Choose an item. | Click or tap here to enter text. |
| Name, role and contact information of one of the investigators who should be contacted for any type of inquiries about the study or for research-related injury\* | Choose an item. | Click or tap here to enter text. |
| Statement that the participant is entitled to withdraw from the study at any time and that all information collected about them until that time will be immediately destroyed once the withdrawal takes effect\* | Choose an item. | Click or tap here to enter text. |
| Circumstances under which a subject’s participation may be terminated by the investigator with a description of the termination procedure | Choose an item. | Click or tap here to enter text. |
| [ ]  Other. Please, specify: Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. |

### Signed assent

*[Please provide a copy of the assent form, in all the languages in which it will be used for this study. The assent* form *must be written in a simplified language that can be easily understood by the child.]*

### Verbal assent

*[Please copy below the verbal version of the assent form (i.e., information sheet) that will be read and explained to the* prospective *participants in order to obtain their verbal assent in place of the written assent to participate in the study. If it is not possible to provide subjects with an information sheet - for example, the only contact is virtual or by phone – please provide an assent script in all the languages in which it will be used to evaluate the assenting process.]*

Click or tap here to enter text.

### Electronic assent

*[Please copy below the assent information in all the languages in which it will be used that will be included* in *the recruitment email or at the beginning of the online survey. Participants will assent to the research by clicking "Agree" or "Continue" (or similar) if they wish to participate.]*

Click or tap here to enter text.

###  Specify the language(s) in which the assent form(s) will be available to participants:

[ ]  Arabic [ ]  English [ ]  French

[ ]  Other. Please, specify: ­ Click or tap here to enter text.

### Persons in charge of obtaining assent from participants

*[Describe who will administer the assenting process and indicate, to the best of your knowledge, if there is any form of interest(s)* between *any of the investigator(s) collecting the assent and any of the participant(s) providing the assent.]*

**12.1.** If the study is conducted online exclusively, and the assent is self-reported without involvement of any other party/person, please check this box: [ ]

**12.2.** If any person is involved in obtaining assent from the participant, please fill out the table below. The individuals collecting assent and or data from participants must have received adequate training to complete these tasks. Participants are highly encouraged to complete the CITI Program (Collaborative Institutional Training Initiative Program) training or similar prior to the study inception.

|  |  |  |
| --- | --- | --- |
| Full Name and Title (Master candidate, M.D., Ph.D., etc.) | Training Completed | Direct Relationship with participant |
| 1. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 2. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 3. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 4. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 5. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 6. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 7. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 8. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 9. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |
| 10. Click or tap here to enter text. | [ ] Yes [ ] No | [ ] Yes [ ] No |

**12.3.** If any of the investigators obtaining assent from the participants has any relationship with any of them, please indicate the strategy that will be used to protect the participant against any form of influence or coercion.

Click or tap here to enter text.

[ ]  None of the investigators has any relationship with any of the participants

**12.4.** If any of the participants is incapable of providing assent (e.g., participants with cognitive impairment or mental retardation, etc.), please describe the additional protection that these participants will receive during data collection.

Click or tap here to enter text.

[ ]  No participants incapable of providing assent will be enrolled in the study

## Use of Secondary Data

[ ]  No secondary data will be used in the proposed research (please go to section IIX)

### Please indicate if any of the three conditions listed below apply to the use of secondary data in your research.

[ ]  The research involves the use of identifiable data or coded data for which the investigator has the code key. When identifiable data are used to address new aims or to conduct new research analyses (not explicitly described in the current IRB approved protocol), the PI should write and submit a new IRB application.

[ ]  When an investigator conducts secondary research with coded and linked data, and will generate results that he/she can link back to the research subjects, then IRB approval is required.

[ ]  When there are collaborations with external researchers in which the external investigator shares coded and linked data for secondary research and receives coded and linked results that link back to individual subjects, IRB review and approval is needed.

## Research Risks

### Are there any risks, of any type, associated with the study or that may possibly be associated with the study?

[Risk includes physical, psychological, social (potential stigmatization e.g. HIV), legal (research on illicit behavior) or financial (cost of study). Summarize the known or anticipated risks/harms of the study.]

[ ]  No (please go to section IX) [ ]  Yes

### Describe the potential risks associated with the study

Click or tap here to enter text.

### Will these risks be mentioned to the participants?

[ ]  No [ ]  Yes

### Will a consent form explaining those risks be used in the study?

[ ]  No [ ]  Yes

*If yes, please provide the following:*

**4.1.** A description of those risks and their details as they will be provided to the participants: Click or tap here to enter text.

**4.2.** A risk mitigation plan: Click or tap here to enter text.

### Are there other methods to conduct the proposed research that could minimize the risks described in VIII-2?

[ ]  No [ ]  Yes

*If yes, describe and justify the reasons for not using them.*

Click or tap here to enter text.

## Data Security and Protection

### Protecting participant privacy

[Privacy of personal health information must be respected during the collection, storage, and use of personal information. Describe how you will ensure that participants’ privacy will be respected during the research, as well as in scientific publications and presentations.]

Click or tap here to enter text.

### Protecting participant confidentiality

[Describe how you will ensure that participants’ confidentiality will be respected during the research, as well as in scientific publications and presentations.]

Click or tap here to enter text.

### Protecting participant anonymity

**3.1.** Please indicate which of the below describes the level of anonymization your will use for the data collected in the proposed research:

[ ]  Identified (non-anonymized)

[ ]  Linked/Reversibly anonymized without coding

[ ]  Linked/Reversibly anonymized with coding

[ ]  Unlinked/Irreversibly anonymized

**3.2.** If you are using identified data, describe and explain the strategy you will follow to protect the participants.

Click or tap here to enter text.

[ ]  The data used in the proposed study is anonymized

### Access to Data

[Identify the investigators and other individuals who will have access to the data.]

|  |  |  |
| --- | --- | --- |
| Name | Role in the Study | Is this person listed as an investigator in this proposal |
| Click or tap here to enter text. | Role | [ ]  No [ ]  Yes  |
| Click or tap here to enter text. | Role | [ ]  No [ ]  Yes  |
| Click or tap here to enter text. | Role | [ ]  No [ ]  Yes  |
| Click or tap here to enter text. | Role | [ ]  No [ ]  Yes  |
| Click or tap here to enter text. | Role | [ ]  No [ ]  Yes  |
| Click or tap here to enter text. | Role | [ ]  No [ ]  Yes  |
| Click or tap here to enter text. | Role | [ ]  No [ ]  Yes  |
| Click or tap here to enter text. | Role | [ ]  No [ ]  Yes  |
| Click or tap here to enter text. | Role | [ ]  No [ ]  Yes  |
| Click or tap here to enter text. | Role | [ ]  No [ ]  Yes  |

## Detailed Proposal

### Research Background

*[Include definitions of concepts, rationale of study, aim, research question, specific objectives, and significance of the study. Include relevant citations.]*

Click or tap here to enter text.

### Research Methods

*[Specify the target population(s), population size(s), selection strategy, inclusion and exclusion criteria, recruitment strategy, data collection methods, and the analysis plan. Include the expected limitations and biases.]*

Click or tap here to enter text.

### References

Click or tap here to enter text.

## APPENDIX: Definitions by Section

### Section IV

***Human subject***

The 2018 HHS common Rule defines a Human Subject as “a living individual about whom an investigator (whether professional or student) conducting research:

* Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
* Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”

***Vulnerable groups***

In the 2001 report Ethical and Policy Issues in Research Involving Human Participants, the National Bioethics Advisory Commission (NBAC) suggested that “vulnerability, in the context of research, should be understood to be a condition, either intrinsic or situational, of some individuals that puts them at greater risk of being used in ethically inappropriate ways in research.” The NBAC noted two general concepts defining vulnerability in research: “In general, persons are vulnerable in research either because they have difficulty providing voluntary, informed consent arising from limitations in decision-making capacity … or situational circumstances …, or because they are especially at risk for exploitation.”

### Section V

***Verbal consent***

The Human Research Protection program at the University of California San Francisco indicates that “Verbal consent means that the individual obtaining consent reads/explains a verbal version of a consent form (i.e. an information sheet), and subjects give their verbal consent in place of written consent to participate. Subjects should be given the opportunity to ask questions and be provided with a copy of the information sheet.” The content of the consenting discussions and any incidents that occurred should be documented in the research file.

### Section VI

***Assent***

The regulations of the U.S. Department of Health and Human Services on human research protection indicates that despite the fact that children (minors) are unable to provide legally effective informed consent to participate in a research study, it is possible that some may be able to provide their assent. A child's affirmative agreement to partake in research is referred to as “assent”. In the absence of affirmative agreement, the mere failure of the child to object to participate in research should not be interpreted as assent.

***Child/Children***

By the regulatory definition of the Office for Human Research Protections, children are “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted”. By the legislative texts in Lebanon, a child is defined as “every human being below the age of 18 years unless, under the law applicable to the child, majority is attained earlier”.

***Verbal assent***

Verbal assent means that the individual obtaining consent reads/explains a verbal version of an assent form (i.e., an information sheet), and subjects give their verbal assent in place of written assent to participate. Subjects should be allowed to ask questions and be provided with a copy of the information sheet. Document in the research file when the assenting discussion took place and if there were any issues.

### Section VII

***Secondary research***

Secondary research is research use of existing data for a purpose other than the original purpose(s) for which they were initially collected through interaction or intervention with living individuals, including those collected for clinical purposes.

### Section IX

***(Participant) Anonymity***

Data are deemed to be identified when the information that enables identification of the research participant - such as the name and address - is directly associated with the data collected, as is the case when the patient's nametag is affixed to a biospecimen. In contrast to “identified”, data can be “anonymized”. The European documents (CDBI, 2006; COE, 2006) employ a five-level terminology system for the anonymization of human data: anonymous, unlinked anonymized, linked anonymized, coded, and identified.

The term "anonymized" refers to data with associated information, such as the participant’s age, medical treatment, medical history, etc. However, any information that could potentially identify the research participant is removed. If the removal of the information is reversible, then the anonymization of data is described as linked anonymized. If the removal of the information is irreversible, then the anonymization of data is described as unlinked anonymized. In the case of linked/reversibly anonymized data, data are coded, and the code may allow to identify the research participant; however, investigators do not have access to the code. Coded data and linked/reversibly anonymized data have the same characteristics and the only distinction between them is that investigators have access to the codes in the case of coded data. The term anonymized in European documents may refer to either unlinked or linked anonymization. The term "anonymized" is exclusively used to describe unlinked anonymized samples in the United States.

***(Participant) Confidentiality***

Confidentiality refers to controlling access to the information that an individual has already disclosed, for example, a patient to a treating physician or to an insurance company paying for care. HIPAA defines confidentiality as “the property that data or information is not made available or disclosed to unauthorized persons or processes.”

***(Participant) Privacy***

Privacy can be understood as a person’s ability to restrict access to information about him or herself. The privacy of personal health information includes informational privacy which is the right of individuals to control access to, and the use of, information about themselves, and data privacy which entails informational privacy especially when the information in question is stored in a database. The privacy of personal health information must be respected.