JEFFERSON—Office of Human Research

# SUMMARY OF Non-INTERVENTIONAL Human Subjects RESEARCH

**Version Date – FOR OHR USE: 11/11/21**

Use this form for social and behavioral research, research on education, questionnaire studies, and other prospective studies not involving drugs, devices or medical/surgical procedures. Please address all applicable points to create a complete and succinct synopsis of the protocol. Use language, insofar as is possible, that can be understood by a layperson, and provide meanings for all acronyms used.Attach surveys, discussion/interview guides. **Form must be typewritten.**

**For Non-Medical and Lower Risk Studies:**  Several sections in this form may not apply to your study, such as questions about standard of care, medical records, external monitors, and MCARE.  If these or other questions do not apply, please indicate ‘NA’ as your response.

**PART A- SUMMARY OF STUDY**

1. Provide a brief (2-3 sentences) lay language synopsis of the study.

2. Objectives and Significance

a. State the primary objective(s) of the study.

b. State the secondary objectives(s) of the study.

c. What benefit or knowledge will be gained?

d. State research question or hypothesis you are testing.

3. Briefly describe the background and rationale for the research/evaluative study (whichever is appropriate) in lay language. Please limit response to one paragraph. State the perceived problem and why it is being investigated. *(Do not include references and please do not cut and paste grant application or review articles.)*

4. Briefly describe the research/evaluative study design. ***(Use charts and flow diagrams if applicable****. “See protocol” is not an acceptable response.)*

a. Subjects: State inclusion and exclusion criteria.

b. Procedures: Explain study procedures/methods.

c. Data analysis: *Provide the methods by which the study objectives/aims will be assessed or measured, i.e., statistical analysis plan, qualitative research methods such as procedures for conducting theme analysis and enhancing validity, program evaluation methods and analysis plan, or mixed methods analysis plan. For a quantitative study, include what statistical tools will be applied and* ***how the study is powered****, if appropriate. Pilot studies* ***do not require*** *a statistical plan but need to outline how the results will be used to power future studies.*

5. Delineate procedures that are standard of care from those that are being performed specifically for the research.

6. How will accuracy of data be assessed?

7. Identify the sources of data obtained about human subjects in the form of specimens, records, survey instruments, interviews, focus groups, observation, or other sources.

8. The following steps must be taken to ensure that identifiable data remains confidential and secure. Please check each box to confirm your understanding. There are fields below to provide explanations and to describe deviations as well as additional measures.

1. A separate research chart must be maintained apart from the medical record/chart of the subject.
2. There are 18 identifiers described in 45 CFR 164.514 that make data identifiable. To be considered de-identified, data must not contain any of the identifiers (also see OHR-5 for list of identifiers).
3. When not in use, identifiable data should be stored in a locked cabinet or desk in a locked room.
4. Access to the data should be limited. Only the individuals who need the data should have access.
5. If hardcopies of identifiable data must be taken to another building, a locked container such as a banker bag should be used. The container should be marked with instructions for returning the container if misplaced.
6. If hardcopies of identifiable data must be mailed, there must be a contract in place which specifies the method of doing this. The data should be placed in one envelope inside of another envelope. Both envelopes should have tamper-evident seals and should be addressed to the specific recipient. Signatures should be required for receipt, or lockable mailboxes should be used.
7. If research data is stored on your work computer, encryption software must be installed on the computer. Contact IS&T if you are not sure if the encryption software is installed.
8. PHI may be emailed between Jefferson email addresses. Jefferson email must not be sent from or forwarded to a non-Jefferson email address such as your personal email.
9. Research data and PHI should not be stored on portable devices including laptops. If research data must be stored on a portable device, contact IS&T.
10. External monitors will only be given access to subjects’ medical records as specified in the signed consent form.
11. Research data and PHI must be maintained per Jefferson policies.

If you have any explanations for, or deviations to the items listed above, **please describe them:**

If applicable, **please describe any additional measures that will be taken:**

**PART B- SUBJECTS AND FACILITIES**

1. What is the expected number of subjects to be enrolled?

|  |  |  |  |
| --- | --- | --- | --- |
| **No. subjects per year** | **Total No. subjects** | **No. Subjects Nationally or Internationally (if applicable)** | **No. subjects at collaborating Institutions (if applicable)** |
| Up to: | Up to: |  |  |

2. Identify where the research will be conducted and describe the adequacy of facilities.

3. Please identify any facilities to be used for research other than those assigned to Department or division.

4. Describe provisions to protect the privacy of subjects during the course of the study. (Privacy can be defined as the subject’s desire to control the ways in which s/he is approached and/or the ways in which his/her private information is shared with others.)

5. How has the research staff been trained regarding study procedures/methods and their duties (in-service, investigator meeting, etc.)?

6. Which of the following groups are eligible to be subjects?

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| \*Women of reproductive potential |  |  |
| Pregnant women/fetuses/neonates (*if yes, and study targets pregnant women or is interventional, include OHR-27 as an addendum to the OHR-2*) |  |  |
| Men of reproductive potential |  |  |
| Vulnerable Populations (Please see list below) |  |  |
| Individuals with impaired decision-making capacity (check yes *only if research targets and could benefit this population)* Note: If yes, please also review and complete the information in this form for decisionally –impaired subjects. |  |  |
| \*Minorities |  |  |
| Prisoners (*if yes, notify the IRB in advance of the meeting*) |  |  |
| \*Economically or educationally disadvantaged persons |  |  |
| Students/employees |  |  |

7. If applicable, what additional protective mechanisms are in place to protect the rights and welfare of vulnerable populations?

8. If one of the populations with an (\*) in the table above are excluded, provide the reason.

Note: NIH policy requires that minorities and women be adequately represented as research subjects. If this is an NIH-funded study and you will be excluding either of these populations, you must provide a scientific reason for such exclusion.

**PART C - RISKS, BENEFITS, AND ALTERNATIVES**

1. What are the risks of the research? Address this at the individual and/or community level as appropriate.

2. Discuss measures taken to minimize risks and maximize benefits associated with this research.

3. What are the potential benefits of participation?

4. Explain how the risks of the research are justified by potential benefit to the subject or society.

**PART D - CHILDREN**

1. Will this study involve children (age 17 or under)?

**\_\_\_ YES -** Submit form OHR-26, “Research Involving Children.”

**\_\_\_ NO -** Delete the REST of this Children section and skip to Part E.

2. Discuss your plan for recruitment of children.

3. Describe standard of care related to this research for children (if relevant, i.e., what is the standard treatment of the condition being investigated in the age group to be studied)

4. Justify the age range of children to be enrolled.

5. Indicate the expertise of the research team with regard to children.

6. Describe the facilities to be used for children in this study.

7. Describe how the parental permission and child assent process (for 7-17 year olds) will be carried out.

**PART E – RECRUITMENT, EQUITABLE SELECTION, AND CONSENT PROCESS**

1. Discuss the recruitment plan and describe recruitment methods and materials (e.g., physician referral, newspaper ad, radio, TV spot, e-mail, membership lists, flyers, social networks, etc.) *Please attach all relevant materials for IRB review and approval.*

Use of the University logo is dictated by University Policy. Guidelines regarding the logo’s use are described on the Creative Services website. Any variation from the standards requires approval according to the policy. Misuse of the University Logo may result in disciplinary action.

2. Will all qualified subjects populations have adequate access to recruitment materials? Please explain.

3. Is the location and cultural setting of the research equally accessible to all qualified subject populations? If not, what can be done to make the location and setting more accessible?

4. Are non-English speaking participants anticipated?

(Please note that in general, non-English speaking subjects should not be excluded from studies with possible therapeutic benefit unless there is a valid scientific, ethical, or logistical reason.)

Please do one of the following:

1. Provide the rationale for excluding non-English speaking participants.

-OR-

1. The following steps will be taken if non-English speaking subjects are anticipated:

* A translated full consent form, in the subject’s language, will be IRB approved prior study initiation.
* All translated documents must be included with the IRB submission, along with proof of translation (certification from agency or name and qualifications of individual). Please note that this includes consent forms, recruitment materials, and all relevant patient-facing documents.
* At the time of the consent discussion, a translator will need to be present (in-person or via telephone interpreter service). The translator must be an adult who is fluent in both languages.
* All parties will sign the translated consent form.

-OR-

1. If the above process will not be used, please describe the process that will be used if non-English speaking subjects are anticipated:

Note: For additional information, including information about unexpected non-English speaking subjects, please see OHR Policy IC 705.

5. If you are requesting a waiver of written consent, describe the information that will be provided to subjects.

6. Who will conduct the consent interview?

7. Who will provide consent or permission (e.g., subject, legally authorized representative, parent, caregiver, etc.)?

8. Where will the consent interview take place?

9. Provide a step-by-step description of the consent process.

10. Describe your plan to assess a person’s capacity to consent.

11. Will you seek assent from decisionally-impaired individuals? If so, describe your plan for obtaining assent. Note: If decisionally-impaired subjects will be included and are not capable of consenting themselves, the OHR-8 consent template must be submitted along with a simplified consent form (e.g., OHR-8C) and/or the surrogate consent form (OHR-8B).

12. Will the potential subject be informed of the research or be provided a copy of the consent to review prior to the actual time of consent? If so, how much time in advance? How much time will be available for the consent process?

13. What provisions will be made if the potential subject does not wish to proceed with the consent interview?

14. Is surrogate consent involved? YES \_\_\_\_\_\_ NO \_\_\_\_\_\_

15. Will subjects be paid or receive any other inducements for participating? If yes, please explain. *Please note that payment of subjects must be on a pro-rated basis unless there are compelling reasons not to prorate. There cannot be a requirement to finish all study components in order for subjects to be paid, as this is considered coercive.*

16. Describe any steps taken to minimize the possibility of coercion or undue influence.

17. The following list of procedures (referred to as MCARE procedures) is used to determine which investigator signature line option should be used in the consent form.

None - The study does not involve any of these procedures -OR- Check All that Apply:

1. Administration of anesthesia (local, general, conscious sedation, etc.)
2. Performance of surgical procedures
3. Administration of chemotherapy and therapeutic radiation
4. Administration of blood and/or human source products
5. Refusal to allow transfusion of blood and/or human source products
6. Insertion of a surgical device or appliance
7. Performance of abortion
8. Performance of sterilization
9. Performance of any HIV-related testing (See Policy #113.58, HIV Testing, for specific documentation requirements)
10. Performance of ECT
11. Administration of an experimental medication, use of an experimental device, use of an approved medication or device in an experimental manner or the removal of bone, fluids or tissue for use in research or in the manufacture of a product. Experimental procedures and consent forms must be approved by the Institutional Review Board (“IRB”).
12. Invasive procedures, such as halo placement, central venous catheterization, pulmonary artery catheterization
13. Performance of vaginal delivery/cesarean section

18. Based on the answer above, select the appropriate option for the investigator signature line. The option you choose must match the option in the consent form.

Include for studies involving MCARE procedures.

By signing below, you the physician investigator, certify that you and/or a qualified practitioner who is also a co-investigator or key personnel, reviewed the purpose, procedures, risks, benefits, and alternatives to participation with the study participant. The other elements of consent may be provided by properly trained and qualified key personnel.

Include for all other studies.

By signing below, you the investigator, certify that you, a co-investigator, or other properly trained and qualified key personnel, reviewed the elements of consent with the study participant.

19. If your study involves MCARE procedures, but you do not intend to have a physician investigator or a qualified practitioner who is also a co-investigator or key personnel review the purpose, procedures, risks, benefits, and alternatives to participation with the study participant, please provide the rationale.

20. A copy of the signed and dated consent form must be given to the subject and this must be documented. How will it be documented that subjects are given a copy of the signed and dated consent form? Check All that Apply:

Checkbox on the consent form

Consent Checklist

Progress Note

EPIC

Screening and enrollment log

A log indicating that each subject received or declined the consent form

Other (Indicate Method):

**PART F - LOCATION/COLLABORATION**

1. This study involves research to be performed at/in/with *(check ALL appropriate entries)*:

Abington-Jefferson Health

East Falls (Philadelphia University)

Jefferson-Northeast

Jefferson Health-New Jersey

Jefferson-Center City

Jefferson as part of a multi-center, commercially sponsored study

Jefferson as part of an NCTN study

JKCCN sites (specify sites):

Rothman Institute (specify sites):

Methodist

Jefferson and Other Institution(s) *Please name institutions only for investigator-initiated and federally funded studies where data will be shared between institutions. Please provide copy of collaborating institution IRB approval letter if applicable. The OHR will effect IRB Authorization Agreements with collaborating institutions as required. Please name institutions:*

Collaboration with City Services *(City of Philadelphia IRB must approve study. For more information, go to* [*http://www.phila.gov/health/irb/*](http://www.phila.gov/health/irb/)*.) Please list collaborating city services:*

Unaffiliated Investigators. *Each will need to complete an unaffiliated investigator agreement available on the OHR website.* Please specify by name and role in study:

2. This question is not applicable if research is a commercially sponsored multi-center trial.

Will research be conducted in states other than Pennsylvania?  YES  NO

If YES, does research involve subjects age 17 or younger?  YES  NO

If YES to either or both, in what state(s) will research be conducted? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Below please (a) verify the age at which subjects in such state(s) have the ability to consent to participation in research, including any medical treatments or procedures, if applicable and/or (b) verify the requirements for determining who may serve as a Legally Authorized Representative, including a guardian for a child to participate in research.  You must also provide information on any state specific regulations on privacy requirements and genetic research if applicable.  Please contact the Privacy Office for information, as needed.

Age at which subjects have the ability to consent to participate in research: \_\_\_\_\_\_

State specific requirements: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. If the investigator is the lead investigator or Jefferson is the lead site in a multi-site study, please address the following:

1. Where is the repository for adverse events and unanticipated problems and how will

information be disseminated to other sites?

1. Who will tabulate and disseminate interim results?
2. Who will provide information to other sites concerning methods/procedures modifications?
3. Describe how information that is relevant to subject safety will be managed (i.e., notifying site investigators of SAEs and Unanticipated Problems Involving Risks to Subjects or Others, communicating DSMB or Interim Reports, etc.)

**Collaborative Studies:** For investigator-initiated studies that are collaborative or multi-center, or for federally funded studies where Jefferson is the lead site, please provide IRB approvals for each collaborating institution. If the institution does not have its own IRB, then the institution must first obtain a Federal-Wide Assurance (FWA) from the Office of Human Research Protection (OHRP). This registers the institution with the federal government for conducting human subjects research. The institution should then fill out an IRB Authorization Agreement (IAA) that ties the institution to the TJU IRB for this study. For more information, go to <http://www.jefferson.edu/osa/irb/forms/>.

Unaffiliated investigators involved with this study should fill out an Unaffiliated Investigator Agreement, also available at the above Website address.

**PART G - CERTIFICATION**

Federal Regulations require the following responsibilities of the Principal Investigator. Please check those items to which you have conformed, and sign.

As Principal Investigator, I certify that: *(check appropriate boxes)*

I have read the IRB Policy and Procedures Manual.

I understand the federally-mandated responsibilities of a research investigator in conducting research or evaluation involving human subjects.

I will conduct this research in accordance with these responsibilities.

I will consent all subjects with an IRB-approved consent form, if applicable to the project, and store the consent forms in a safe repository.

I will provide all subjects with a copy of their signed and dated consent form.

All personnel have been appropriately trained for their assigned roles in this research.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_**

### Signature of Principal Investigator Date