**New Protocol Submission**

**Instructions:** *Please submit this completed form for all research involving human subjects to National Jewish Health. This application must be accompanied by a protocol detailing the background and rationale for the study, objectives, sample size description and justification, inclusion and exclusion criteria, research procedures, risks, data & safety monitoring plan, analytic plan, regulatory considerations, provisions for the protection of human subjects, etc.*

|  |
| --- |
| **Protocol Title/IRB NUMBER:** |
| **Date:** |
|  |

1. **PRINCIPAL INVESTIGATOR & RESEARCH TEAM**
2. Principal Investigator

|  |
| --- |
| PI Name: |
| Office Location |
| Phone: |
| Email: |
| Human Subjects Training Certificate Date: |
| Check here to confirm the following will be included: [COI & Scientific Misconduct Form](https://www.nationaljewish.org/getattachment/Research-Science/support/compliance/irb/submissions/initial-submissions/expedited-for-full-committee-review/IRB-COI-Scientific-Misconduct.doc.aspx) and CV |
| PI Status at NJH  Faculty  Fellow  NOTE: *Students and Fellows must work under the mentorship of appropriate National Jewish Health personnel and may not serve as PI but may serve as a Co-Investigator. Student or Fellow names should be entered in the Additional Personnel table below.* |

1. **Additional Personnel (insert additional rows if needed)** NA

**NOTE:** *Other study personnel include all individuals responsible for the design, conduct, or reporting of the study, including Co-Investigators. All personnel must have current human subjects training certification. All personnel must have current human subjects training certification and attach a*[*COI & Scientific Misconduct Form*](https://www.nationaljewish.org/getattachment/Research-Science/support/compliance/irb/submissions/initial-submissions/expedited-for-full-committee-review/IRB-COI-Scientific-Misconduct.doc.aspx)*. All Co-Investigators must include a CV.*

|  |  |  |
| --- | --- | --- |
| Name | Study Role | Department/Division/Unit  (if applicable) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. Fellow Advisor*(if applicable)* NA

**NOTE*:*** *A Faculty Advisor is required if the PI is a fellow.*

|  |  |
| --- | --- |
| Name: | Department/Division: |
| Address: | |
| Email: | Phone Number: |

1. Has any member of the research team ever received a FDA 483, “Warning Letter”, Notice of Disqualification, or other warning or disciplinary action from an agency or licensing authority?

Yes  No

If Yes, include a copy of the notice or report and related correspondence with your submission.

1. Has this study been disapproved or terminated by another IRB?

Yes  No

If Yes, provide the basis for the disapproval or termination:

1. Please provide information concerning the funding sources for this research.

NA (unfunded)  Industry Sponsor

Federal Government  Other Government (State, Local)

Foundation  Departmental/Academic Enrichment Funds

Other:   Industry Grant

Grantor/Sponsor Name:

Award/Contract Status:

Grant Title (if different from IRB submission title):

1. The NJH IRB charges for review of all studies. Requests for fee waivers must be based on financial need or funding source. Are you requesting an exemption from the IRB fee for this project?  Yes  No

If YES, to apply for a waiver of IRB review charges, please mark a category

The study is funded by a federal grant.

This study is not commercially-sponsored.

Explain why the Principal Investigator is unable to pay the IRB fee:

If NO, IRB personnel will invoice for IRB review. Provide contact information for the responsible party below.

Company:

Contact Person:

Address:

Telephone:

Email:

*The NJH IRB Fee Schedule is available on the IRB website.*

1. **ADDITIONAL REVIEWS/APPROVALS**
2. Has this study undergone an independent scientific review?  Yes  No

If Yes, include a copy of the independent scientific review evaluation with your submission.

1. Do any of the research staff have a Conflict of Interest?

If Yes, Is a COI management plan in place?  Yes  No - Documentation of COI review and any conflict management plans must be included with your submission.

1. Is Institutional Biosafety Committee (IBC) committee review required?  Yes  No

If Yes, include documentation of the review and any requirements or recommendations with your submission.

1. **APPLICABLE REGULATIONS**

Select the regulations or oversight agencies that you believe are applicable to this study. Although not all-inclusive, this section is intended to capture regulations or requirements relevant to the protection of human subjects that the IRB may have to consider. **Select all that apply**.

Regulatory oversight may be triggered by the following:

* Funding support
* Participation of agency employees in research activities as investigators or subjects
* By the use or study of regulated products or records
* By the subject population
* Other reasons (e.g., planned emergency research)

*If your study is NIH funded, HHS regulations apply. For more on HHS regulations and policies, visit the*[*OHRP website*](https://www.hhs.gov/ohrp/)*.*

NJH Policies

☐ HHS ([Department of Health and Human Services](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html))

FDA ([Food and Drug Administration](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm))

HIPAA ([Health Insurance Portability and Accountability Act](http://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html))

CDC ([Centers for Disease Control](http://www.cdc.gov/od/science/integrity/hrpo/))

DOD ([Department of Defense](https://www.health.mil/Reference-Center/Policies/2011/11/08/Protection-of-Human-Subjects-and-Adherence-to-Ethical-Standards-in-DoD-Supported-Research)); Branch:

DOE ([Department of Energy](https://science.energy.gov/ber/human-subjects/regulations-and-requirements/))

DOJ ([Department of Justice](https://www.gpo.gov/fdsys/pkg/CFR-2003-title28-vol2/xml/CFR-2003-title28-vol2-part46.xml))

ED ([Department of Education](http://www2.ed.gov/about/offices/list/ocfo/humansub.html))

EPA ([Environmental Protection Agency](https://www.gpo.gov/fdsys/pkg/CFR-2010-title40-vol1/xml/CFR-2010-title40-vol1-part26.xml))

FERPA ([Family Educational Rights and Privacy Act](http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html))

ICH-GCP E6 ([International Conference on Harmonization – Good Clinical Practice E6](https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf))

NSF ([National Science Foundation](http://www.nsf.gov/bfa/dias/policy/human.jsp))

PPRA ([Protection of Pupil Rights Amendment](https://studentprivacy.ed.gov/topic/protection-pupil-rights-amendment-ppra))

VA ([Department of Veterans Affairs](https://www.va.gov/oro/hrpp.asp))

Other:

None of the Above

1. **RESEARCH DESCRIPTION**
2. **Summary.** Briefly describe the proposed research **in language that can be understood by a non-scientist**. The abstract should summarize the objectives of the research and the procedures to be used, with an emphasis on what will happen to the subjects. **(Maximum 250 words)**

1. **Multicenter and Collaborative Studies.** Will the protocol be followed as written or are there components or aspects of the research that this site will not participate in or that will be modified? (e.g., local site will not recruit into one of the cohorts or into a sub-study; the age range will be narrowed; a specific procedure or test isn’t available locally so another will be performed; etc.)

NA, this is a single site study

Yes, the protocol will be followed as written

No, Explain:

1. Indicate if the research involves any of the following (check all that apply)

Biologic: *Include the Investigator's Drug Brochure or Package Insert*

Blood draw

Device: *Include the Device Instructions for Use/User Manual/Product Brochure*

Drug: *Include the Investigator's Drug Brochure or Package Insert*

Exam

Existing Biospecimens

☐ NJH BioBank Specimens

Existing Data

☐ NJH Research DataBase/dataSCOUT

Focus Group: *Include the Focus Group Questions/Guide*

Intervention to Change Behavior or Lifestyle

Observation

Radiation Exposure:

Describe the forms of radiation that subjects will be exposed to for the research

Diagnostic x-rays

Radiation therapy

Radioisotopes

Other:

Describe the amount and schedule of administration:

Record Review: *Include a list of the variables that will be collected/recorded (e.g., variable list, EMR, dataScout, data capture form)*

Survey, Questionnaire, Interview, Diary: *Include copies with the submission.*

If using REDCap, please ensure the following:

☐ If subjects will enter data directly into a REDCap survey, submit screenshots with the submission

☐ Before entering study data, move your REDCap project to Production

Therapy

This research does not involve any listed items

1. If the research includes an interventional component, such as a drug, device, therapy, or an intervention to change behavior or lifestyle; describe each intervention and its intended purpose or indicate the page(s) of the protocol where this information can be located:

NA – No interventions

1. Identify all exams, tests, or procedures that subjects will undergo for the research or indicate the page(s) of the protocol where this information can be located:

NA

1. Identify any protocol-required procedures that subjects would undergo regardless of their participation in the research and indicate whether the timing or other aspects of the procedures have been controlled or altered to facilitate the research:

NA

1. **RESEARCH SETTING/PERFORMANCE SITES**
2. Describe the settings where research activities involving human subjects will take place (e.g., home, lab, hospital, clinic).

1. Indicate all National Jewish Health sites where the research procedures will be carried out (e.g., sites where you will have direct contact with subjects or identifiable data)

Main campus

South Denver

Highlands Ranch

Aspen Valley

Vail Valley

Other NJH Site:

1. Will any of your research activities take place at non-National Jewish Health facilities?

Yes, complete question 6 below.  No - there are no non-National Jewish Health facilities

1. Will non-National Jewish Health personnel have research responsibilities?

Yes, complete question 6 below.  No - there are no non-National Jewish Health research personnel

1. Are any members of the research team or participating sites potentially under the jurisdiction of another IRB?

Yes, complete question 6 below.  No - there are no non-National Jewish Health research personnel

1. Research activities will take place at non-National Jewish Health facilities or non-National Jewish Health personnel will have research responsibilities

For each non-National Jewish Health site, indicate: (1) the site's name, (2) a description of the research activities that will be conducted by/at that site, (3) whether the site or personnel are under the jurisdiction of another IRB, (4) whether the site has granted permission for the research to be conducted, (5) whether non-National Jewish Health personnel have satisfied human subject protection training requirements; and (6) the contact information for the site point of contact

NA, there are no non-National Jewish Health facilities or personnel

1. Is this a collaborative research study being conducted at multiple sites?  Yes  No

If Yes, answer the following:

* 1. Is this investigator the LEAD INVESTIGATOR?  Yes  No
  2. Is this site the LEAD SITE or Coordinating Center?  Yes  No

If either of the above is Yes, *complete Supplement S.*

1. Are any of the research activities/data conducted by or overseen by National Jewish Health occurring outside of the United States?  Yes  No

If Yes,*please contact the IRB/HRPP Office to discuss requirements for international research*

**VI. SUBJECT POPULATION**

1. The research population includes the following (check all that apply):

Healthy Adult Volunteers

Volunteer with Disease under Study

Employees/Staff

Students of *(describe whose students)*

Fellows

Children – *complete Supplement C*

Prisoners – *complete Supplement J*

Pregnant Women, Fetuses, or Neonates – *complete Supplement P*

Adults with Impaired Decision-Making Capacity – *complete Supplement I*

Persons with [Limited English Proficiency](https://www.lep.gov/faqs/faqs.html#OneQ1), specify anticipated primary language(s):

☐ Minors who do not meet the definition of “children” and can provide their own informed consent

1. Children are defined as 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. Describe why the minors are not considered children for the purposes of the study and can legally consent to the study procedures. Include references to applicable laws. *(See NJH HRPP SOP Section 16.1, Children):*

☐ Other population vulnerable to coercion or undue influence or whose ability to give voluntary informed consent may be in question:

☐ NA (none of the above listed populations)

1. Please indicate the total **number of subjects** (or subject records) anticipated to be enrolled at this site/by this investigator. *For the purposes of this application, a subject is enrolled once they have provided consent to participate, or for studies under waivers, once data has been collected on the subject.*

* 1. If the study includes screening procedures after consent, how many subjects do you expect will meet inclusion/exclusion criteria and participate?

* 1. If the research involves multiple subject groups or cohorts, provide the anticipated number of subjects in each group or cohort (e.g., control/experimental, parents/children, etc.).

1. Provide the **age range** for the proposed subject population (e.g., 0-5 years old):
2. **Inclusion Criteria:** Specify the inclusion criteria for each of the subject groups to be included in the research or indicate the page(s) of the protocol where this information can be located.

1. **Exclusion Criteria:** Specify the exclusion criteria for each of the subject groups to be included in the research or indicate the page(s) of the protocol where this information can be located.

1. If potential subjects will be excluded based on age, gender, race, ethnicity, national origin, primary language, pregnancy or childbearing potential, or disability explain (a) the nature of the exclusion(s), and (b) the scientific basis or other justification for the exclusion(s) or indicate the page(s) of the protocol where this information can be located. *Please note that reasons of cost or convenience alone are insufficient justification for exclusion, and because such exclusions may impact equitable selection of subjects, the principle of justice (distribution of risks/benefits), and the generalizability of research findings.*

NA

Nature of the exclusion(s):

Scientific basis or other justification:

1. **Secondary Subjects -** Is information being obtained about individuals other than the “target subjects” (e.g., family members)?  Yes  No

If Yes, please explain:

**VII. IDENTIFICATION/RECRUITMENT OF SUBJECTS**

1. How do you plan to identify subjects for recruitment or records for inclusion in the study?

Check all that apply:

Study investigators and research staff will recruit patients with whom there is a current (within 5 years) clinical relationship

Describe how, when, where and by whom will potential subjects be approached: *For studies involving research-related treatment, ensure the Informed Consent form explains that subjects may ask for a second opinion about their care from another doctor who is not associated with this study.*

Study investigators will send a letter to colleagues asking for referrals of eligible patients interested in the study: *Include the Letter to Colleagues*

Study investigators or colleagues will send a letter to prospective subjects: *Include the Letter to Prospective Subject*

Use of HIP-201: *Include Form HIP-201*

National Jewish Health Research Database

Use of an NJH IRB approved recruitment database

List protocol number(s):

Describe how, when, where and by whom will potential subjects be approached:

Chart review

Clinical trial listing on the National Jewish Health website (This is a free service that increases exposure to prospective subjects): *Include the NJH Clinical Trial Listing Form*

Print/media advertisements: *Include copies of any proposed recruitment materials (e.g., brochures, posters, advertisements, social media, etc.) or scripts with your submission. All recruitment material must be approved by the IRB prior to use.*

Other methods to identify subjects for recruitment that are not listed above:

None of the above

1. Who will be responsible for determining whether potential subjects satisfy eligibility criteria and how will they do so? If the analysis of health information is necessary to determine eligibility, a medically-qualified person must be involved in the determination.

1. Will information from **records** (medical records, databases, or other data sources) be used to screen, recruit, or determine the eligibility of prospective subjects without informed consent and authorization?

No

Yes, answer the following:

1. Describe the source of records.
2. Do the records include PHI?

No

Yes. *Complete Supplement H*

1. Describe what will be obtained and how it will be used to screen, recruit, or determine the eligibility of prospective subjects to participate in this study.
2. Describe how the information will be safeguarded.
3. Will the information be retained on persons who do not ultimately participate in the study?

No

Yes. Describe what will be retained and what identifiers, if any, it will include.

1. Is this research funded by the Department of Justice?

No

Yes. *Complete Supplement W*

1. Will information be obtained through **oral or written communication** with potential subjects (or LARs) to screen, recruit, or determine eligibility by asking questions of them without informed consent?

NOTE: The revised Common Rule removes the pre-2018 Common Rule requirement for an IRB to approve a waiver of informed consent for these types of activities.

No

Yes, answer the following:

1. Describe the method of oral or written communication (e.g., phone interview, on-line questionnaire):
2. Describe how the information will be safeguarded.
3. A copy of the screening/recruitment questions and the proposed script/language that will be used to introduce the questions to the potential subject have been included*.*

No. Explain:

Yes

1. Will the information be retained on persons who do not ultimately participate in the study?

No

Yes. Describe what will be retained and what identifiers, if any, it will include.

1. Is this research funded by the Department of Justice?

No

Yes. *Either include a copy of the proposed consent (or consent script) for screening or request a partial waiver of consent (or waiver of documentation of consent if using a consent script) using Supplement W.*

1. Will **stored identifiable biospecimens** be accessed or obtained for screening, recruiting, or determining the eligibility of prospective subjects without informed consent and authorization for research that is ONLY subject to the Common Rule (e.g., not FDA-regulated, DOJ/NIJ supported)? ☐ NA

No

Yes, answer the following:

1. Describe the source of stored biospecimens.
2. Do the biospecimens (i.e., the label) include PHI?

No

Yes. *Complete Supplement H*

1. Describe what will be obtained and how it will be used to screen, recruit, or determine the eligibility of prospective subjects to participate in this study.
2. Describe how the identifiable biospecimens will be safeguarded.
3. Will information or biospecimens be retained on persons who do not ultimately participate in the study?

No

Yes. Describe what will be retained and what identifiers, if any, it will include.

1. If applicable, describe **how, where, and by whom** subjects will be recruited for participation in this study.

NA

1. If applicable, describe any steps that will be taken to protect the potential subjects’ privacy during recruitment (e.g., discussion will take place in a private room).  NA

**VIII. INFORMED CONSENT**

Unless waived by the IRB, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (LAR) or, for minors, parental permission.

Similarly, unless waived by the IRB, consent must be documented using an IRB-approved written consent form signed (including in an electronic format) by the subject or the subject's LAR. A written copy of the consent form must be given to the person signing the form.

Assent may be required when subjects are unable to personally provide consent for reasons of age, mental state, legal status or other such reason.

*For the basic and additional elements that should be included in the consent document(s) see NJH HRPP SOP Section 15.1 and 15.2*

1. Which of the following apply to this research? *(check all that apply):*

Informed consent will not be obtained. *Complete Supplement W* to request a waiver of consent.

Informed consent will be obtained and documented with a signed, written consent form.

Informed consent will be obtained, but won’t be documented by signature on a consent form. *Complete Supplement W* to request a waiver of documentation of consent. Include a copy of the oral script and/or information sheet with your submission.

Informed consent will be obtained, but the consent form (or script or information sheet) does not include all required elements of consent. (Please see the Informed Consent Checklist for the elements of consent.) *Complete Supplement W* to request an alteration of consent.

Consent will be obtained, but some information will be purposely manipulated or withheld (deception). *Complete Supplement W* to request an alteration of consent.

Surrogate consent will be obtained from Legally Authorized Representatives (LARs) for some or all adult subjects. *Complete Supplement I* for subjects with impaired decision-making capacity.

*NJH HRPP SOP Section 15.3 Legally Authorized Representative (LAR) describes persons who meet the definition of legally authorized representative for research in Colorado.*

If the research includes more than one subject group (e.g., retrospective and prospective cohorts), and the answers to the above differ based on the cohort, explain your plan for each group here:

**NOTE:** Include copies of all proposed consent documents and materials to facilitate the consent process (e.g., consent forms, scripts, information sheets, handouts, videotapes, electronic tools, etc.)

1. **Consent Process**
   1. Describe the circumstances under which consent will be obtained including where the process will take place and any steps that will be taken to ensure the potential subject’s privacy.

* 1. Who will obtain consent? Describe their qualifications and experience in obtaining research consent.

**NOTES:**

* *A person qualified to fully explain and respond to questions regarding the research interventions or procedures, risks, and alternatives must participate in the consent process.*
* *If any of the persons obtaining consent are inexperienced, a plan to train and supervise them must be included.*
* *For FDA-regulated research, all personnel obtaining consent must be delegated in writing (typically on a Delegation log) by the PI to do so.*
  1. How will you ensure that subjects or LARs have sufficient opportunity to consider whether to participate? *(Check all that apply)*

Subjects will be provided the consent form to take home for consideration prior to signing it.

Subjects will be allowed a waiting period of at least  to consider their decision.

Other (describe):

* 1. How will the subject’s or LAR’s understanding of the information presented be assessed? *(Check all that apply)*

Subjects will be asked to “[Teach-Back](http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2-tool5.html)”

Subjects will be asked open-ended questions about the research (purpose, procedures, risks, alternatives, voluntary nature)

A tool or post-test, such as ICEFT, DICCT, QuIC, or AHRQ Certification will be used. Specify:

Other, describe:

* 1. Is recruitment/inclusion of subjects with [limited English proficiency](https://www.lep.gov/faqs/faqs.html#OneQ1) (LEP) anticipated?

Yes  No

If Yes, answer the following:

* + 1. What languages do you expect the subjects will be fluent in?

* + 1. How will you ensure that subjects understand the information provided to them and will be able to ask questions and communicate with the researchers during recruitment, the consent process, and throughout participation (e.g., use of qualified interpreters):

* + 1. Will consent forms and other subject materials be translated? *(***NOTE:** *Cost alone is typically insufficient justification for not translating materials when recruitment of persons with LEP is anticipated.)*

Yes

Some but not all materials, explain:

No, explain:

**NOTE:** *Once the English version of the consent form and subject materials are approved, translated materials must be submitted to the IRB along with back translations to English or a certificate of translation prior to use.*

1. **Documentation of Consent:** *Signed, written consent forms are required unless waived by the IRB. Include copies of all proposed consent forms and materials to facilitate the consent process (handouts, videotapes, electronic tools, etc.) with your submission.*
   1. How will the subjects’ informed consent be documented? *(check all that apply)*

NA, a waiver of consent or documentation of consent is being requested

Traditional signed written consent form

Written note in medical and/or research record

By completion of a research survey or questionnaire

Consent will be administered via an electronic or web-based form

The consent process will be audio or video recorded

Use of the short form consent process *(The short form consent process should not be used when inclusion of subjects with LEP can be anticipated.)*

Other, describe:

* 1. If the enrollment of subjects who cannot read the consent form, due to visual impairment, literacy, or other issues, is anticipated, how will consent be documented? Refer to 45 CFR 46.117(b)(2) or [21 CFR 50.27(b)(2)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.27) for information regarding the use of a short form.

NA

Short form *(Include copies of any proposed short forms with your submission)*

The consent form will be read to the subject or the subject’s LAR before it is signed

Other mechanism, describe:

**IX. ONGOING CONSENT**

1. For studies with more than one interaction with subjects, informed consent should be an ongoing process that continues throughout their participation in the study. Efforts to ensure that subjects remain informed are important, particularly if changes are made to the study or new information becomes available that impacts risks, anticipated benefits, alternatives to participation or may impact their willingness to remain in the study.

How will you ensure that research subjects remain informed about the study and continue to agree to participate in the research after their initial informed consent has been obtained?

NA, this research involves a single interaction or a waiver of consent has been requested

1. If this research involves children who may reach age of majority while the research is ongoing (including use or analysis of identifiable data or specimens), explain your plans to obtain consent for ongoing participation. If you do not plan to obtain consent, please request a waiver of consent (and HIPAA authorization, if applicable) for these subjects using *Supplement W (and Supplement H for HIPAA, if applicable)*.

NA because:

this research does not include children

this research will be complete before any children reach the age of majority

data/specimens from children will be destroyed prior to age of majority

data/specimens from children will be de-identified prior to age of majority by deleting all links between any individually identifiable data and the data/specimens

1. If this research includes adults for whom consent was obtained from a legally authorized representative (LAR), and these adults may regain capacity to consent while the research is ongoing, explain your plans to obtain consent for ongoing participation. If you do not plan to obtain consent, please request a waiver of consent (and HIPAA authorization, if applicable) for these subjects using *Supplements W (and Supplement H for HIPAA, if applicable)*.

NA – this research does not include adults who did not originally provide consent themselves and may regain capacity to consent.

**X. DATA/CONFIDENTIALITY**

1. **Protected Health Information (PHI)**

The Privacy Rule defines PHI as [individually identifiable](https://privacyruleandresearch.nih.gov/pr_08.asp#8a) health information, held or maintained by a covered entity or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium (including the individually identifiable health information of non-U.S. citizens). This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse. For purposes of the Privacy Rule, genetic information is considered health information. Generally, when specimens are labeled or associated with HIPAA identifiers, the specimens are considered identifiable under HIPAA.

1. Names;

2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

4. Phone numbers;

5. Fax numbers;

6. Electronic mail addresses;

7. Social Security numbers;

8. Medical record numbers;

9. Health plan beneficiary numbers;

10. Account numbers;

11. Certificate/license numbers;

12. Vehicle identifiers and serial numbers, including license plate numbers;

13. Device identifiers and serial numbers;

14. Web Universal Resource Locators (URLs);

15. Internet Protocol (IP) address numbers;

16. Biometric identifiers, including finger and voice prints;

17. Full face photographic images and any comparable images; and

18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

* 1. Will PHI be  accessed,  used, or  disclosed for this research?  Yes  No

If Yes, answer the following:

* + 1. Briefly explain what PHI is needed and why:
    2. Is all of the PHI held by National Jewish Health?  Yes  No, explain:
    3. Indicate which of the following apply *(more than one may be selected*):

A partial waiver of the requirement for HIPAA Authorization is requested (e.g., for screening or for some subjects (e.g., retrospective cohort)) – *Complete Supplement H*

A full waiver of the requirement for HIPAA Authorization is requested – *Complete Supplement H*

The PHI accessed or used for this research is a [Limited Data Set](https://privacyruleandresearch.nih.gov/pr_08.asp#8d) (LDS) and/or a Data Use Agreement (DUA) is or will be in place prior to accessing or obtaining the data.

HIPAA Authorization will be obtained:

National Jewish Health stand-alone HIPAA Authorization template will be used

The HIPAA Authorization is embedded in the research consent document

1. **Other Protected or Sensitive Records/Information**
   1. Will information or records that subjects or others might reasonably consider to be sensitive in nature (e.g., social security numbers, genetic test results, communicable disease status, substance abuse, mental health information, illegal activity, etc.)  accessed,  used, or  disclosed for the research?  Yes  No

If Yes, explain what sensitive information is included and why it is needed:

* 1. Will a [Certificate of Confidentiality](https://grants.nih.gov/grants/policy/coc/index.htm) (CoC) be obtained for this research or is one already in place that covers this site and any recipient site or organization?  Yes  No

*PLEASE NOTE: Effective October 1, 2017 CoCs will be issued automatically for any*[*NIH-funded*](https://humansubjects.nih.gov/coc/NIH-funded)*or*[*CDC-funded*](https://www.cdc.gov/od/science/integrity/confidentiality/applinst.htm)*project using identifiable, sensitive information that was on-going on/after December 13, 2016  
o The CoC will be issued as a term and condition of award  
o There will be no physical certificate issued  
o Language must be in consent*

*For more information, see*[*NJH HRPP SOP*](https://www.nationaljewish.org/research-science/support/compliance/irb/hrpp)*Section 28.2.*

* 1. Will any additional specific safeguards beyond those described in the remainder of this section be taken to protect PHI or Other Protected or Sensitive Records/Information?

Yes  No

If Yes, explain:

1. **Data Methods/Sources/Access**
   1. Describe the methods (e.g., manual record review, dataSCOUT electronic data capture, interviews, etc.) to obtain data about or from subjects:

**NOTE***: Include copies of all questionnaires, surveys, interview questions, diaries, etc. with the submission. If the research involves interviews or focus groups that could evolve as conversation progresses, include a list of discussion topics and any “starter” questions for each topic that can reasonably be expected to be covered. If a draft of an instrument is submitted, it should be labeled as such and a final version must be submitted and approved by the IRB before use.*

* 1. Describe all data sources for the research and the general purpose of each (e.g., medical records will be reviewed to pre-screen for eligibility and obtain pertinent medical history):

* 1. Are all the data sources internal (National Jewish Health-held)?  Yes  No

If No, describe the external data sources, any needed permissions to access the data and the status of these permissions, and how the data will be securely transferred, transported, or shared:

* 1. Will personnel other than National Jewish Health employees and sponsor representatives (such as monitors) require access to National Jewish Health facilities, systems, or patients for the purposes of the research (e.g., to observe surgical procedures, to conduct focus groups)?  Yes  No

If Yes, explain (1) who (by name), (2) their home institution or organization, (3) what facilities, systems, or information they will require access to, (4) why, and (5) the plan for supervision:

**NOTE***: Investigators are responsible for ensuring that necessary leader and facility permissions are in place and that any credentialing, training, or other requirements are satisfied.*

1. **Research Records**
2. Describe the types of research records that will be created or maintained for the research (linking key, paper worksheets, electronic files, audio recordings, RedCAP video recordings, etc.):

1. Will direct identifiers (e.g., name, medical record number) be replaced with a subject code on research records other than the linking key, consent form, and HIPAA authorization?

Yes  No

If Yes, describe the structure of the code (e.g., randomly generated number, sequential number plus initials, etc.) and indicate whether a linking file (key) will be created and, if so, how it will be protected:

If No, explain which direct identifiers will be included, on what records, and why they are needed:

1. Will research records include [PHI](https://privacyruleandresearch.nih.gov/pr_08.asp#8a)?  Yes  No
2. Describe the provisions that will be taken to protect the confidentiality of subjects’ information and research data (e.g., storage of research data in a locked file cabinet, separate storage of a key to code that allows re-linking of data, encrypted files, etc.).

1. **Data Sharing**
2. Will data be transferred, transmitted, or shared transmitted outside of National Jewish Health?

If Yes, answer the following:

* + 1. What information will be transferred, transmitted, or shared?

* + 1. Who will data be sent to or shared with?

* + 1. For what purpose?

* + 1. Will the transferred, transmitted, or shared data include direct identifiers (e.g., names, medical record numbers)?

Yes  No

If Yes, explain:

* + 1. Will the transferred, transmitted, or shared data be a [Limited Data Set](https://privacyruleandresearch.nih.gov/pr_08.asp) (LDS)?

Yes  No

If Yes, a data use agreement (DUA) must be executed before the access or use of the LDS for the research. Contact Research Regulatory Affairs (RRA) for assistance with DUAs.

Will the transferred, transmitted, or shared data include PHI (other than a LDS)?

Yes  No

If Yes, explain:

* + 1. Will the transferred, transmitted, or shared data be coded?

Yes  No

If Yes, will the recipient have or be provided with access to the code or other means to re-identify subjects?

Yes, explain:

No

* + 1. Will the transferred, transmitted, or shared data include information that might reasonably be considered sensitive in nature (e.g., social security numbers, genetic test results, communicable disease status, substance abuse, mental health information, illegal activities, etc.)?

Yes  No

If Yes, explain:

* + 1. How will the data be transferred, transmitted or shared and how will it be protected?

1. Will research data or specimens be submitted to or retained in a database or repository locally or elsewhere (e.g., [BioLINCC](https://biolincc.nhlbi.nih.gov/home/), [NIDA](https://datashare.nida.nih.gov/), [NIDDK Central Repository](https://www.niddkrepository.org/home/)) for possible future research after this study is complete?  Yes  No

If Yes, please complete *Supplement F.*

1. Is the research subject to the [NIH Genomic Data Sharing (GDS) policy](https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/)?

No  Yes, answer questions i-viii below

1. Indicate whether the research will:

use data subject to the GDS policy, and/or

generate data subject to the GDS policy

1. Indicate which [NIH data repository/database](https://osp.od.nih.gov/scientific-sharing/data-repositories-and-trusted-partners/) data will be submitted to or acquired from:
2. Is NJH responsible for the NIH Institutional Certification and IRB review of the genomic data sharing plan?  Yes  No
3. Indicate whether the data is (or is proposed to be) designated as:

Unrestricted Access, or

Controlled Access

1. Are/should [Genomic Summary Results](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-023.html) (GSR) be categorized as sensitive and only available via Controlled Access? NIH’s guidance “[Points to Consider for Institutions and Institutional Review Boards in Submission and Secondary Use of Human Genomic Data under the National Institutes of Health Genomic Data Sharing Policy](https://osp.od.nih.gov/wp-content/uploads/GDS_Points_to_Consider_for_Institutions_and_IRBs.pdf)” includes discussion on this and other topics.

Yes, briefly explain:

No

1. Describe how the research will comply with NIH’s requirements for consent for broad data sharing (e.g., broad consent has been or will be obtained, opt-in procedures, management of opt-outs, etc.) (Please see the “Broad Data Sharing” section of the [NIH FAQs on the GDS Policy](https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing-faqs/) for more information).

1. Describe any [Data Use Limitations](https://osp.od.nih.gov/wp-content/uploads/standard_data_use_limitations.pdf) (DUL):

General Research Use

Health/Medical/Biomedical Only

Disease-Specific, describe:

Other, describe:

1. Describe any additional [DUL Modifiers](https://osp.od.nih.gov/wp-content/uploads/standard_data_use_limitations.pdf):

IRB approval required

Publication Required

Collaboration Required

Not- for-profit Use Only

Methods

Related Disorders

Genetic Studies Only

**NOTE:** *If submitting data per the GDS policy to a repository or database, please complete Supplement F and include a copy of the genomic data sharing plan with your submission.*

1. **Record Retention**

**NOTE***: Record retention may be dictated by regulations, grant or contract terms, policy, or journal requirements. Please consider each of these carefully before answering the below questions. At a minimum, signed research consent forms must be retained for 3 years after the completion of the research (for non-FDA studies) and HIPAA authorizations (or waivers) for 6 years after they were last relied upon.*

1. How long will research records and data be retained following completion of the study?

1. Will retained research records contain identifiable information, coded information, or fully de-identified information?

1. Where will records and data be stored, how will they be protected, and who will have access?

1. Describe any plans to eventually de-identify or destroy records:

**XI. PROVISION OF RESULTS**

1. Given the exams, tests, and procedures being done for the research, describe the likelihood and nature of [incidental or secondary findings](http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf), whether such findings will require verification (e.g., by a CLIA lab), and any plans for sharing such findings with subjects:

1. If the research includes genetic testing, indicate whether subjects will be informed of results and, if so, describe how and by whom:

1. If the research includes testing for communicable diseases, indicate whether the findings will require verification (e.g., by a CLIA lab), any plans for sharing findings with subjects, and whether findings must be reported to a state or federal agency. (NOTE: Positive HIV, Hep B and Hep C require reporting to the Colorado Health Department):

1. If the research includes blinding, indicate whether subjects will be “unblinded” to study assignment and describe when and how this will be done:

1. Indicate whether subjects will be informed of the results of the study and, if currently known, when and how this will be done:

**XII. RISKS/RISK MITIGATION**

1. List the possible risks, discomforts, or harms to subjects associated with the research. If the risks differ based on group assignment, describe for each group. Estimate the (1) probability of occurrence, (2) the seriousness, and (3) the duration of each risk. If this information is captured in the protocol or Investigators Brochure (IB) or other materials, indicate the document (such as ICF) and page numbers where the information can be located.

1. What precautions have been taken to minimize these risks and what is their likely effectiveness? Whenever possible, link the precaution(s) to the specific risk or risks. If this information is available in the study protocol indicate the page numbers where the information can be located.

1. If this is investigator generated research, identify any alternative research methods or procedures considered in designing the research that might involve less risk and describe why they will not be used (e.g., a clinical trial as opposed to a records review, IV as opposed to oral formulation, etc.) or indicate the page(s) of the protocol where this information can be located:

NA

1. If applicable, describe access to/availability of emergency medical equipment and trained personnel at each setting where research interventions or procedures involving physical risk take place:

NA – There are no physical risks to subjects anticipated in this study

1. If the research imparts social, financial, psychological or other risks to subjects, describe the availability of and access to/availability services or support to mitigate these risks:

NA

1. Does the research include screening tools, questionnaires, or procedures that may indicate the presence of serious depression and/or suicidal ideation?  Yes  No

If Yes, describe the plan to refer or intervene in the event that potential serious depression and/or suicidal ideation are identified.

1. If the research is greater than [minimal risk](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102), answer questions 7a-7i below.

NA

* 1. Describe the data safety monitoring plan or indicate the page(s) of the protocol where this information can be located:

* 1. Who will monitor and report on adherence to the protocol?

* 1. Describe how adherence to the protocol will be determined and how often the person will monitor and report on adherence to the protocol:

* 1. Who will examine and report on safety data?

* 1. By what criteria will that person assess the safety data? (examples include severity, causality, outcomes, frequency, etc.). How often will that person examine and report on safety data?

* 1. Who will ensure the accuracy, quality, and management of the data?

* 1. What steps will be taken to ensure the accuracy, quality and management of the data?

* 1. How will actual adverse events/unanticipated problems be documented, reported, and followed?
  2. List, by name, the individual (s) responsible for assessing adverse events/unanticipated problems occurring during this study. Also list the individual(s) responsible for reporting adverse events/unanticipated problems.

1. Are there any plans to do an interim analysis?  Yes  No

If Yes, describe the interim analysis plan or provide page number(s) in protocol where this information can be found:

1. Have stopping rules been established for the study?  Yes  No

If Yes, describe the stopping rules or provide the page number(s) in protocol where this information can be found:

1. Are there defined criteria for when study interventions should be discontinued?  Yes  No

If Yes, describe the criteria or provide the page number(s) in protocol where this information can be found:

1. Are there exams or procedures that the subject will be asked to have done or follow to safely withdraw from the study?  Yes  No

If Yes, describe the procedures for safe withdrawal of subjects or provide the page number(s) in protocol where this information can be found *(***NOTE:** *Withdrawal procedures should also be described in the consent)*:

1. Will subjects who withdraw from the interventional component of the study be asked for their permission to continue to gather information about them through follow up visits, phone calls, records review, or other methods?  Yes  No  NA

If Yes, describe what the subjects will be asked to permit or provide the page number(s) in protocol where this information can be found (**NOTE:** *Such plans should also be described in the consent*.):

**XIII. BENEFITS**

1. Describe the potential benefits to science and/or society which may accrue as a result of this research.

1. Are there any benefits which may accrue to the individual subjects in this research? Compensation is not considered a benefit.  Yes  No

If Yes, please explain:

**XIV. COSTS**  NA –No costs to subjects (skip to XIV)

1. Describe the costs/potential costs that subjects may incur as a result of their participation.

1. Will the subject, or the subject’s insurance, be responsible for any costs incurred as a result of participation in the research?  Yes  No

If Yes, describe each item that the subject, or the subject’s insurance, will be responsible for and the approximate cost of each:

*National Jewish Health does not allow participant’s insurance to be billed for research procedures. If this is your intention, please contact the NJH IRB/HRPP office.*

1. Will subjects be reimbursed for any expenses related to their research participation?  Yes  No

If Yes, indicate:

* 1. What subjects will or may be reimbursed for (e.g., travel, parking, public transportation, etc.) and explain any potential limitations or qualifiers:
  2. The type of reimbursement *(i.e., cash, check, cash card, etc.)*:
  3. The source(s) of funds to provide reimbursement:
  4. The timing of reimbursements

**XV. COMPENSATION**  NA –No compensation (skip to XV)

1. If subjects will receive compensation for participating in this research study, please describe*:*
   1. The amount and method of payment:
   2. The basis used to determine the amount of the payment:
   3. The distribution plan for the payment (one payment, pro-rated payment, etc.):
   4. The plan for payments in the event a subject withdraws early from the study:
2. If the research involves children or adults unable to consent to participation, explain who will receive the compensation:

*PLEASE NOTE: The IRS requires study payments of $600 or more to be reported on tax returns. Reimbursements, or payments based on receipts to cover expenses incurred by the participant because of their clinical trial participation (most often travel-related) are excluded from this requirement. These out-of-pocket expenses are not considered taxable income.*

*When cumulative payments over a calendar year equal or exceed $600 across studies, the site should obtain a W-9 tax form from each participant. The site should also generate a Form 1099-MISC once the amount paid reaches $600 and send a copy to the IRS and participant. The IRS states in the instructions to Form 1099-MISC that Box 3 should be used to report “(a) payment or series of payments to individuals participating in a medical research study or studies.”*

**XVI. NON-MONETARY GIFTS/TOKENS OF APPRECIATION**  NA–No compensation (skip to XVI)

1. If subjects will receive non-monetary gifts, incentives, or tokens of appreciation for participating in this research study, please describe*:*
   1. The item(s)\* that will be provided:
   2. The approximate retail value of the item(s):
   3. The distribution plan (i.e., when subjects will receive the items):
   4. Any conditions or requirements that must be fulfilled for subjects to receive the item(s):

\*Include a picture of the item(s) with your submission. The IRB may request a sample of the item(s) to review.

1. If the research involves children or adults unable to consent to participation, explain who will receive the item(s):

**XVII. PRIVACY**

1. If the research involves interaction with or observation of subjects, describe the provisions to protect the privacy interests of subjects. Include a description of (1) the settings where subjects will be interviewed, examined, or observed for the purposes of the research; (2) the settings where interventional components of the research and research procedures will take place, (3) any provisions being taken to maximize privacy:

NA – No interaction or observation

**XVIII. CLINICAL TRIAL**

1. Is this study a [Clinical Trial](https://osp.od.nih.gov/wp-content/uploads/2015/04/NIH%20Definition%20of%20Clinical%20Trial%2010-23-2014-UPDATED_0.pdf)?  Yes  No

Clinical Trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. [45 CFR 46.102(b)]

If Yes, answer the following:

* 1. What [phase of clinical trial](https://prsinfo.clinicaltrials.gov/definitions.html#StudyPhase) best describes this research?

Phase I  Phase I/II  Phase II  Phase II/III  Phase III  Phase IV

Feasibility  Pivotal ([Feasibility vs Pivotal device studies](http://www.fda.gov/downloads/Training/ClinicalInvestigatorTrainingCourse/UCM378265.pdf))

* 1. Is the trial “first-in-human”?  Yes  No

*If Yes, the protocol must describe the pre-clinical research and/or other relevant data that supports the performance of the study.*

* 1. Is this trial the first in a population (e.g., children)?

Yes  No

*If Yes, the protocol must describe the pre-clinical research and/or other relevant data that supports the performance of the study in the new population.*

* 1. Does the trial evaluate one or more [FDA-regulated products](http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm)?  Yes  No

If Yes, indicate the following:

Product Type(s):

Product Name(s):

*Complete Supplement D for studies of drugs and biologics. Complete Supplement M for medical device studies.*

* 1. Will the trial enroll pregnant women or women of child-bearing potential?  Yes  No

*If Yes, the protocol and consent must describe any known or anticipatable risks to pregnant women and fetuses and any measures to mitigate those risks. Birth control requirements, if applicable, must also be described.*

* 1. Will the trial collect data on “pregnant partners” (female sexual partners (of clinical trial subjects) who become pregnant while the subject is on-study)?  Yes  No

If Yes, describe the recruitment and consent process for the pregnant partner:

*A description of any measures to monitor and mitigate risks and what data will be collected regarding the pregnancy and outcome must be provided in the protocol or other documentation. A consent form and HIPAA authorization (if PHI will be used) for the pregnant partner must be included with your submission.* C*omplete Supplement P (and Supplement C if pregnant partners will include minors)*

* 1. Is the trial registered in [ClinicalTrials.gov](https://clinicaltrials.gov/)?

NA, registration is not required for this trial. Explain:

No, but trial will be registered prior to enrolling any subjects

Yes, ClinicalTrials.gov #:

**NOTE:** The following statement must be included verbatim in the consent form for FDA-regulated clinical trials that are or will be registered in ClinicalTrials.gov:

*"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."*

*\*\*If you have indicated that this study meets the definition of a clinical trial the signing of this application confirms that the requirements of the clinical trial consent form will be completed as outlined in NJH HRPP SOP Section 15.13.\*\**

**This is the end of the main application. Continue to the next page to determine if additional supplements are required.**

**XIX. SUPPLEMENTS**

The Initial Submission Form is designed to obtain the information required for IRB review of all human subjects research. Additional information is required when research involves specific populations or procedures. This information is submitted using supplements to the initial submission form.

Please complete and upload any supplements relevant to this research:

CHILDREN – *Complete Supplement C*

PRISONERS – *Complete Supplement J*

PREGNANT WOMEN, FETUSES OR NEONATES – *Complete Supplement P*

SUBJECTS WITH IMPAIRED DECISION MAKING CAPACITY – *Complete Supplement I*

REQUEST FOR WAIVER OR ALTERATION OF CONSENT OR WAIVER OF DOCUMENTATION OF CONSENT – *Complete Supplement W*

REQUEST FOR WAIVER OR ALTERATION OF HIPAA AUTHORIZATION – *Complete Supplement H*

RESEARCH INVOLVING DRUGS OR BIOLOGICS – *Complete Supplement D*

RESEARCH INVOLVING MEDICAL DEVICES – *Complete Supplement M*

STORED DATA/SPECIMENS FOR FUTURE USE – *Complete Supplement F*

COLLABORATIVE RESEARCH – *Complete Supplement S*

**NOTE**: *The IRB will not review submissions that do not include the appropriate supplements.*

**XX. SIGNATURES**

**PRINCIPAL INVESTIGATOR CERTIFICATION**

By signing below, I certify that the information contained in this application, the protocol, and any associated materials accurately reflects how the research will be conducted. Any proposed changes to the research will be submitted for IRB review and approval prior to implementation (unless necessary to eliminate an apparent immediate risk of harm, in which case the issue and action taken will be reported to the IRB promptly).

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Principal Investigator Signature Date

**IF THE INVESTIGATOR IS A FELLOW, A FACULTY ADVISOR MUST SIGN BELOW:** I have read and approve of this research plan. I believe that the fellow is competent to conduct the activity as described herein. I understand my roles and responsibilities for the oversight and conduct of this research.

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Faculty Advisor Signature Date