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**Application to the IRB for Approval of a Research Project**

*This form is for expedited or full review of a new proposal involving human subjects. .The NUHS Investigator of Record (the principal investigator or NUHS co-investigator if the PI is not a member of the full time NUHS faculty) is responsible for submitting and maintaining the project review to the NUHS IRB during the course of the project and to comply with all federal regulations and any additional regulations required by NUHS or state and local laws or regulations which provide additional protections for human subjects*

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| **New Project Submission Checklist**  The following items must be included with submission of a new research project if they are part of your application. Missing items will delay project review.  *Please indicate which items are included in this submission*.  Approved Research Committee application  Management plan for Financial Conflict of Interest  Recruitment flyer, poster, advertisement, etc.  Informed consent documents and tools used in consent process OR Consent script, online form, or incorporated document used for waiver of written consent OR Information sheet for waiver/alteration of consent  Questionnaires, surveys, etc. used in study  Data and procedure monitoring plan  Data and procedure monitoring forms |

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| **Project Title**: |

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| --- | --- | --- |
| Name of Project Personnel\* | Role in Project (PI, Co-investigator, NUHS, Investigator of Record, Faculty Sponsor, Key Personnel) | Date of most recent IRB approved training for Protection of Human Subjects from Research Risk |
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*For additional project personnel, provide name and training information on a separate piece of paper.*

*\*Any Project Personnel engaging in interventions that require licensure, malpractice insurance, and liability insurance, IF YOU ARE NOT AN NUHS EMPLOYEE, please attach copies of your Professional Licensure, Malpractice Insurance, and Liability Insurance.*

**I. Promoting Objectivity in Research**

Is this project seeking any funding from Public Health Services (example: NIH, NSF, HRSA, etc)?

No, PHS funding is NOT being sought.

Do any investigators, or family members thereof (spouse, dependent children) have a significant financial interest ($5000 compensation in the past 12 months, including salary, consulting, honorarium, or 5% ownership of company) with the project sponsor?

No.

Yes. Attach a description of the significant financial interest and present a plan for managing the conflict, minimizing its effect on the design, conduct, or reporting of the research, and maintaining the rights and welfare of the research participants.

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Yes, PHS funding is being sought.

Have any investigator’s disclosure been determined to be a financial conflict of interest (FCOI) under the NUHS Financial Conflict of Interest in Research policy?

No. Dean of Research has initialed section XV of this application indicating that FCOI review was completed.

Yes. Attach a copy of the FCOI management plan signed by the Dean of Research with this application.

**II. Qualification of Proposals for Expedited Review**

**Are you requesting Expedited Review of your project?**

Yes, complete this section.  No, Skip to section III.

**Does your research involve minimal risk (that is, the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)?**

Yes, complete this section.  No, Skip to section III.

Please identify all categories that apply to your research:

Clinical studies of drugs and medical devices that do not require investigational new drug or investigational exemption application.

Collection of blood samples by finger stick, heel stick, or venipuncture from (i) healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and a collection may not occur more frequently than 2 times per week; or (ii) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Prospective collection of biological specimens for research purposes by noninvasive means (e.g., hair and nail clippings, sputum specimen collected after saline mist nebulization, to name a few).

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves (e.g., body weight, electrocardiograph, ultrasound, moderate exercise or body composition assessment when appropriate).

Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as for medical treatment or diagnosis). Note: some research in this category may be exempt from HHS regulations for the protection of human subjects, 45CFR 46.101 (b) (4).

Collection of data from voice, video, digital, or image recordings made for research.

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Note some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45CFR 46.101 (b)(4).

Reapproval of an ongoing research project previously approved by the convened IRB as follows: Where (i) the research is permanently closed to the enrollment of new subjects, (ii) all subjects have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of subjects; or where no additional subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.

Reapproval of an ongoing research project, not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

###### III. Description of Human Involvement in the Research Project

1. What is the significance of this research? (Indicate in what manner this project will add to evidence already present in the literature.)

1. Describe the tasks, tests, or procedures subjects will be asked to complete: explain step by step what the subjects will be asked to do from patient recruitment through the exit interview and distinguish those procedures which are experimental from those which comprise routine clinical care.)

1. Is classroom time being used for any part of the study?

No

Yes  Describe in detail the activity planned for non-participants during the class session in order to preclude the pressures to participate.

1. What is the total period of time over which there will be human subjects’ participation?

1. Will participants receive inducements or other compensation or rewards, before, during, or after the study?

No

Yes  Indicate the type of compensation, amounts, and payment schedules.

IV. Description of the Human Subjects in the Research

1. Anticipated number (this number should be the number of subjects you will enroll in order to get the adequate data sets you will need): Male  Female  Total

If multiple sites are to be used*,* provide an estimate of the number in each category to be recruited from each site.

In addition, if you plan to study only one sex, provide scientific rationale in the inclusion/exclusion section of the application.

2. Age Range (mark all that apply):

0 - 7 yrs. (submit parental permission form)

8 – 17 yrs. (submit child's assent form, parental permission form)

18 - 65 yrs.

65 + yrs.

Others: Indicate age range:

3. Do subjects belong to any of the following special classes:

(a) children (age <18 years); Yes  No

(b) pregnant women; Yes  No

(c) fetus/fetal tissue; Yes  No

(d) questionable state of mental competence or consciousness; Yes  No

(e) prisoners or other institutionalized persons; Yes  No

(f) others who are likely to be vulnerable? Yes  No

If yes to any of the above, provide rationale for and justify their involvement:

4. Source/type of subjects:

NUHS students

NUHS patients

NUHS employees

Patients from other clinics (specify clinic(s)

Other adults

Other (specify):

5. Are there any enrollment restrictions based upon race or ethnic origin?

No

Yes . Explain the nature of the restrictions and provide justification.

Note: Within the limitations imposed by the population of the study site(s), research should include sufficient enrollment of persons of diverse racial/ethnic backgrounds in order to ensure that the benefits and burdens of research participation are distributed in an equitable manner.

6. How many research groups are involved? (e.g. control group & experimental groups) For each group of human subjects, indicate (a) anticipated number in each group; (b) age range; (c) sex; (d) ethnic background; and (e) health status (i.e. healthy subjects, patients with certain disorders).

7. What tests, procedures, exams, questionnaires will be used to determine **inclusion and exclusion** of subjects? Who will administer the tests or make the assessments?

8. What are the *specific* criteria for inclusion and exclusion of human subjects (make sure criteria matches the description you listed in items 2-4 in this section)?

(a) Inclusion Criteria:

(b) Exclusion Criteria:

9. When in the study protocol will the inclusion/exclusion be determined?How is this described in the informed consent?

V. Recruitment Procedures

1. If relevant, describe recruitment of subject, including:

1. How the subjects will be approached?
2. Who will approach the subjects?
3. How subjects will be identified?
4. Where they will be recruited. (clinics, hospitals, general public, etc)?

***Attach a copy of any material(s) that will be used to recruit subjects for this research: Advertisements, Flyers, Telephone Script, Letter, Web posting, Information Sheet, Social Media content (such as text, photos etc)***

1. Is there a "finder’s fee" or a per capita payment of any kind connected with the enrollment of subjects in this study that will be paid to persons other than the research subject?

No

Yes  Describe.

VI. Consent Process and Waivers

Describe the consent process. If you are requesting a Waiver or Alteration of Consent, complete the appropriate section(s) below.

**Standard Consent**

1. List the investigator(s) and/or key personnel who will obtain consent from participants or their legally authorized representatives.

2. Describe the consent process. Indicate when and where consent will be obtained, whether consent will be administered in writing or orally, will participants and/or their legally authorized representatives be provided sufficient opportunity to consider participation (such as a waiting period).

a. As an ongoing, interactive process, rather than a one-time information session, will consent be affirmed at multiple time points during the participant's involvement? If yes, describe the method for the consent process (e.g. clinician will document in SOAP note, research assistant will note on visit form).

3. How will participants' understanding be assessed? *This is important for studies that involve more than minimal risk***?** (Asking subjects to explain the purpose of the study to you along with the risks and benefits to themselves as participants allows you to determine if they understand the study and their part in it. If they do not understand, informed consent has not been achieved even if the subject signed the consent document.)

***Include copies of informed consent documents and tools that will be used in the consent process (videos, scripts, quizzes, handouts)***

**Request for Waiver of Written (i.e. signed) Consent.**

IRB may waive the requirement for a signed consent form for some or all participants if it finds either:

The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality

OR

The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context (e.g. phone survey)

1. Explain how the research involves no more than minimal risk.

2. Explain your justification for the waiver and describe how consent will be obtained (e.g. orally, online, incorporated into the survey).

***Include a copy of the consent script, online form or incorporated document***

**Request for Waiver or Alteration of Consent Process**

IRB may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent or waive the requirement to obtain informed consent provided the IRB finds and documents:

(1) the research involves no more than **minimal risk** to subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study. (examples for request of Waiver or Alteration of Consent would include requesting use medical records to recruit research participants or use of deceptive methods like a placebo).

In order to be considered for waiver of alteration of consent, complete the following:

1. Explain how the research involves no more than minimal risk.

2. Explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.

3. Explain why the research could not practicably be carried out without the waiver or alteration.

4. Will the participants be provided with additional pertinent information after participation?

No. Explain your answer.

Yes. Explain your answer and attached information sheet.

5. Will a debriefing occur (required if deceptive methods such as blinding, placebo, etc. are used)?

No

Yes. Describe what will be said, by whom, and when in the study protocol it will occur.

VII. Methods and Materials for the Interventions on Human Subjects

1. Are you using any existing data?

No

Yes. Indicate the years from which documents were originally created, describe how the documents were selected, and detail what information is being collected.

* If using existing data from documents, are the data publicly available?

Yes

No. Indicate who gave approval for access to the use of the records, and how the identifiers were stripped from the data.

If records are *private* medical or student records, provide the protocol for securing consent of the subjects and approval from the custodian of the records.

Written documentation for cooperation/permission from the holder or custodian of the records should be attached. (Initial contact of subjects identified through a records search must be made by the official holder of the record, e.g., primary physician, therapist, public school official.)

2. Will the human subjects complete questionnaires (demographic, health history, etc.)?

No

Yes. Specify their nature, duration and the frequency of their administration and when in the study protocol they will be administered.

***Include a copy of each questionnaire.***

3. Will the human subjects undergo any treatments or other interventions (e.g., manipulation, soft tissue treatment, ultrasound, electrical stimulation, video recording, acupuncture, imaging...) solely for the purposes of this research?

No

Yes. For *each* procedure specify:

(a) the nature (what is the treatment or intervention);

(b) duration (how long will they be exposed to the intervention);

(c) frequency (how many times will it occur through the entire protocol);

(d) whether the procedure will require a hospital stay or overnight admission.

4. Will any treatments or interventions that the human subjects will undergo be modified from standard or customary health care for the purposes of this research (e.g., de-tuned ultrasound, a sham manipulation, manipulation without force)?

No

Yes. For *each* procedure specify:

(a) the nature of the standard care

(b) the extent of the modification (e.g. de-tuned ultrasound)

(c) any resulting increase in the length or frequency of the procedure

(d) any increase in the number of clinic visits.

5. Will the investigators carry out the planned treatments or other interventions themselves?

No. Specify arrangements for qualified implementation.

Yes. For *each* treatment or intervention that requires special skills (e.g. manipulation, venipuncture, imaging...), please identify the responsible qualified investigator.

6. Will blood be removed from the human subjects for the purposes of this research?

No

Yes. Indicate: (a) route; (b) method; (c) frequency of removal; (d) total volume to be removed in milliliters or, for children, as percentage of total blood volume; and (e) total time span involved:

7. Will the human subjects be exposed to external sources of radiation?

No

Yes. Indicate: (a) type of exposure, and (b) total dosage to be delivered for the purposes of this research:

8. Will radioisotopes be administered to the human subjects?

No

Yes. For *each* radioactive compound indicate:

(a) chemical nature

(b) amount of radioactivity to be administered

(c) frequency

(d) route

(e) total duration of administration

(f) status of approval by the Illinois Department of Nuclear Safety:

9. Will noninvestigational (marketed) test articles be administered or applied to the human subjects for purposes of this research?

No

Yes. For *each* test article indicate:

(a) generic and trade names

(b) source

(c) dosage

(d) frequency

(e) route of administration or application

(f) total duration of use

(g) if it is to be used for a purpose which is not authorized by the FDA:

10. Will investigational test articles such as drugs, biologicals, substances (including placebo) or devices be administered or applied to the human subjects?

No

Yes. For *each* test article indicate:

(a) name or code number;

(b) type or chemical nature;

(c) source;

(d) presumed function or mechanism of action;

(e) dosage;

(f) frequency;

(g) route of administration or application;

(h) total duration of use; and

(i) whether the 30-day interval has elapsed or been waived and/or whether its use has been withheld or restricted by the US Food and Drug Administration (FDA);

(*please provide any investigational drug/device exemption (IDE) number and append manufacturer's information on each test article)*:

VIII. Risks and Benefits of the Research

1. Risks. Identify any potential physical, psychological, social, legal or other risks, inconveniences, or consequences to the human subjects. (e.g., injury, discomfort, extensive clinic visits, deprivation of a treatment of established efficacy, risks to confidentiality...). For each potential risk:

* Itemize and describe the risks, inconveniences, or consequences; and describe the expected frequency.
* Assess the likelihood or seriousness of the risks; degree of severity, and potential reversibility. Include any potential late effects.
* assess the risks in comparison to any alternative treatments or interventions.

3. Protection. For each risk or inconvenience indicated above:

(a) Specify the measures to be taken to protect the subjects from it, or to minimize its impact or occurrence;

(b) Assess the likely effectiveness of the protective measures;

4. Specify any provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. (Language must be in the consent form)

5. If women of childbearing age are among the subjects, specify measures to be taken to avoid harm to fertility potential, undetected fetus, or breast-fed newborn.

###### 6. Data Safety Monitoring (REQUIRED FOR CLINICAL TRIALS\*). Describe the plan to oversee and monitor the approved protocols and data collected to ensure participant safety and data integrity. Include:

* The information that will be evaluated (include the informed consent process, each intervention proposed, how information is recorded, how information is stored, etc)
* Who will perform the monitoring (should be an individual not related to the project)
* Timing of monitoring (at specific point in time or after a specific number of participants enrolled)
* Decisions to be made as a result of the monitoring process (e.g. provisions to stop the study early for unanticipated problems)

***Include copies of data safety monitoring forms that will be used.***

\*IRB may require a data safety monitoring plan based on the nature of the project (e.g. greater than minimal risk, student researchers, off campus locations). Check with the IRB Chair or Research Coordinator with questions and for resources to develop a DSM plan.

7. Benefits of participation: List any anticipated direct benefits of participation in this research project. The knowledge gained from the study could produce a benefit to society; in general this should be explained to participants. If there are no benefits to the participant, state that fact here and in the consent form. Payment is not considered to be a benefit of participation. Any benefits of treatment should be listed as potential benefits.

8. Why are the risks and/or inconveniences to the subjects reasonable in relation to the anticipated benefits to the subjects and/or the importance of the knowledge that may reasonably be expected to result from the research?

IX. Confidentiality

1. Are any subject identifiers being collected (e.g., name, social security number, etc.)?

No

Yes. What identifying information or linkages to the subjects will be recorded?

2. How is confidentiality being protected?

3. Will raw data be made available to anyone other than the Principal Investigator and immediate study personnel(e.g., school officials or medical personnel)?

No

Yes. Who will have access to raw data and why? How will it be available?

1. Describe the procedure for sharing data and how the subject will be informed that the data may be shared.

5. Will the research data and information be part of the medical chart or other permanent record?

No

Yes. Explain here and in the consent form.

6. If subjects are students, will school officials receive the data with identifiers attached?

No

Yes. Explain here and in the consent form.

1. Describe security for storage of identified and de-identified data. Include ALL locations of hardcopy data (post data collection), electronic data on desktop computer or network, and portable computing devices (laptop, flash drives, CDs).

7a. Who will be the immediate supervisor of the data ?

If not the PI, how will that person report the security of the data to the PI (indicate the method of reporting and the frequency)?

1. At any time, will data be transmitted to other individual or locations (for data analysis, data entry, etc.)?

No

Yes. Describe how you will ensure data security for transmission.

1. Research related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, or analysis of identifiable/coded data).Indicate what will happen to the identifiable data at the end this three year period.

X. Costs of the Research

1. Will patients or their health insurance carriers incur any expenses in conjunction with this research?

No

Yes. Identify each cost item, and for each item, indicate amounts, whether the written consent form discloses this potential liability, and justify the assignment of the burden.

**XI. Investigator’s Assurance:**

I certify that the information provided in this application is complete and correct.

I understand that as NUHS Primary Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, for the conduct of the study and the ethical performance of the project,

I agree to comply with all NUHS policies and procedures, as well as with all applicable federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

1. the project will be performed by qualified personnel,
2. no changes will be made in the protocol or consent form until approved by the NUHS IRB,
3. legally effective informed consent will be obtained from human subjects if applicable, and as appropriate,
4. adverse events will be reported to the IRB in a timely manner.

I further certify that the proposed research is not currently underway, and will not begin until approval has been obtained.

I have read and understand the NUHS Policy “The Protection of Human Subjects from Research Risk”.

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Signature Primary Investigator Print Name Date

XII. Faculty Sponsor’s Assurance\*

By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition,

1. I agree to meet with the investigator on a regular basis to monitor study progress.
2. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
3. I assure that the investigator will promptly report significant or unexpected adverse effects to the IRB in a timely manner.
4. If I will be unavailable, as when on sabbatical leave or vacation for example, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the Dean of Research by letter of such arrangements.

I certify that the proposed research is not currently underway, and will not begin until approval has been obtained.

I certify that the investigator and myself have read and understand the NUHS Policy “The Protection of Human Subjects from Research Risk”.

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Signature Faculty Sponsor Print Name Date

*The faculty sponsor must be a member of the NUHS faculty. The faculty member is considered the responsible party for legal and ethical performance of the project.*

**\*if PI is a student, resident, or not a full time NUHS faculty**