Initial IRB Review of Clinical Research
Application Instructions

University policies and federal regulations require that each project involving studies with human subjects be reviewed to consider:

1. the rights and welfare of the individual(s) involved
2. the appropriateness of the methods used to secure informed consent
3. the balance of risks and potential benefits of the investigation

#### This form can be used to apply for Full Committee Review or Expedited Review. This form is not for applying for exempt research status.

* Full Committee Review
Research involving more than minimal risk to the participant requires review by the full IRB. Full review covers all research that is not specifically suited for "expedited review" or "screened as exempt from review".
* Expedited Review
Expedited review covers research that involves only minimal risk procedures. For example:
* the study of individual or group behavior in which the behavior is not manipulated and the subjects are not exposed to any stressful situation,
* the drawing of small amounts of blood,
* moderate exercise by healthy volunteers

**To request that this application be considered for expedited review**, review the categories for expedited review at <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm> and fill in Section 14 with the category for which this research should be considered. The IRB will make the final determination if this research meets the federal requirements for expedited review.

#### How to complete your application and begin the IRB review process

1. This form must not be handwritten
2. Fill out all of the questions on this form completely
3. Fill out and attach the appropriate appendices required by responses in this application
4. Attach protocol
5. Attach supporting documentation: consent form(s), assent form(s), survey instruments, interview schedules, solicitation letters, advertisements, etc
6. Complete the checklist that accompanies this form to assure all requirements for submission are completed so that review is not delayed

Contents of Application Form

1. Project Identification and Signatures
2. Funding
3. Oversight & Monitoring
4. Conflict of Interest
5. Summary of Activities
6. Subject Profile
7. Recruitment
8. Risks and Benefits
9. Potential Biohazards
10. Biological Samples
11. Care of Subjects in Case of Accident
12. Confidentiality of Data
13. Use of Protected Health Information (PHI) – HIPAA Requirement
14. Expedited Review
15. Informed Consent Process

Appendices

As you complete the application, you may be asked to include one or more of the following appendices:

*Appendices are available at*  [*http://www.nwhealth.edu/research/ORAC/irb/forms.html*](http://www.irb.umn.edu/download/medical.cfm)

A. Sponsored Projects

B. Pregnant Women/Fetuses/IVF

C. Prisoners as Subjects

E. Use of Drugs and/or Biologic Products in Research

F. Use of Devices in Research

H. Use of Protected Health Information (PHI)

I. Targeting/Inclusion of Vulnerable Populations

J. Student as Principal Investigator Worksheet

K. International Research

L. Field Work

M. Research in Schools

N. Debriefing for Research Involving the use of Deception

O. Tribal Field Work

P. Research Methods Class Protocol

R. Use of Radiation

T. Tissue/Sample Storage

W. Informed Consent Waivers

Checklist for submitting a complete application

* Provisions have been made to minimize risks and those procedures are documented in application.
* Provisions have been made and documented to care for subjects in case of accident or injury.
* Provisions have been made to obtain informed consent from all individuals related to the study. (e.g. parents, subjects, cooperating institutions, etc.)
* All questions on the application have been completed.
This includes a lay abstract stating the purposeof the study, a description of the study population, inclusion/exclusion criteria**,** process of identifying subjects, tasks the subjects will be asked to complete, anticipated risks and benefits of study participation, and procedures to maintain confidentiality*.*
* A protocol has been attached*.*
* All supporting documents have been attached. This includes survey instruments, interview schedules, solicitation letters, flyers, advertisements, etc.
* Required appendices are attached.
* If this study requires approval of another committee or cooperating agency, documentation of approval or notice of application has been attached.
* Departmental signatures, and signature of academic advisor for student research have been secured.
* A copy of this application has been made for theinvestigator's records. *If this application is approved, this copy must be maintained for 3 years after the completion of the study by the PI.*

|  |  |
| --- | --- |
| Initial IRB Review of Clinical Research Application FormVersion 2.2Updated October 2, 2006.This application form is based on the University of Minnesota IRB's *Health & Biological/Medical Application Form* and has been adapted with their permission. | IRB Use Only |
| Date received: \_\_\_\_\_\_\_\_\_\_\_Project Number: \_\_\_\_\_\_\_\_\_IRB Review Date: \_\_\_\_\_\_\_\_[ ] Approved as submitted[ ] Approved with minor suggestions for changes[ ] Approved with stipulations[ ] Deferred[ ] Not approved |

1. Project Identification and Signatures

* 1. Project Title (Project title must match grant title. If different, also provide grant title):

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| --- |
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* 1. Person preparing this document

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| --- | --- |
| Name:       | Phone number:       |
| Email:       |

* 1. Principal Investigator (PI)

|  |
| --- |
| **Name** (Last name, First name MI)**:**       |
| **Mailing Address:**      | **Phone Number:**       | **Fax:**       |
| **Email:**       |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **University Department** (if applicable):      | **Highest Earned Degree:**       |
| **As Principal Investigator of this study, I assure the IRB that the following statements are true:**The information provided in this form is correct. I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc. I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study. I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation. I will not begin my research until I have received written notification of final IRB approval. I will comply with all IRB requests to report on the status of the study. I will maintain records of this research according to IRB guidelines. The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application. If these conditions are not met, I understand that approval of this research could be suspended or terminated. |
|       |
| Typed Name of PI |
|  |       |  |
| Original Signature of PI | Title of PI | Date |

***If PI is faculty, staff or student, a Department head signature is required.***

***If PI is also the Department head, provide the signature of the Dean or Division head.***

|  |
| --- |
| **As Department head or Dean/Division head,** I acknowledge that this research is in keeping with the standards set by my department and I assure that the Principal Investigator has met all departmental requirements for review and approval of this research. |
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| Typed Name of Department head, or Dean/Division head |
|  |  |
| Original Signature of Department head or Dean/Division head | Date |

* 1. Co-Investigator(s)

Co-Investigators responsible for, or working on this project should be listed below. Include any individual who will have responsibility for the consent process, direct data collection from subjects, or follow-up.

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| --- | --- |
| **Name** (Last name, First name MI)**:**       | **University Department** (if applicable): |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **Name** (Last name, First name MI)**:**       | **University Department** (if applicable): |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **Name** (Last name, First name MI)**:**       | **University Department** (if applicable): |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **Name** (Last name, First name MI)**:**       | **University Department** (if applicable): |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **Name** (Last name, First name MI)**:**       | **University Department** (if applicable): |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |

* 1. Research Staff

Personnel you wish to be included in correspondence related to this study e.g. project managers/study coordinators

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| --- | --- |
| **Name** (Last name, First name MI)**:**       | **University Department** (if applicable): |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **Name** (Last name, First name MI)**:**       | **University Department** (if applicable): |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **Name** (Last name, First name MI)**:**       | **University Department** (if applicable): |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **Name** (Last name, First name MI)**:**       | **University Department** (if applicable): |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |

[Additional Project Personnel form](http://www.nwhealth.edu/research/ORAC/irb/forms/additionalpersonnel.doc) - If you need to add additional personnel, please use this form and attach it to the application.

* 1. Student Research

**If the PI of this research is a student**, include **Appendix J** filled out by the advisor with this application form and include the advisor’s signature below.

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| --- |
| Student Research requires the approval of an Academic Advisor. As Academic Advisor to the Student Investigator, I assume responsibility for ensuring that the student complies with University Policies and Federal Regulations regarding the use of Human Subjects in research. |
| Advisor’s Name (Last name, First name MI):      | Department:       |
|  |  |
| Original Signature of Academic Advisor | Date |

* 1. For each researcher involved with human subjects on this study, describe the training and education completed in the protection of human subjects:

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2. Funding

2.1 Is this research funded by an internal or external agency?

[ ]  Yes. IncludeAppendix A

[ ]  No. Explain how costs of research will be covered:

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3. Oversight & Monitoring

3.1 Will this research be utilizing Northwestern Health Sciences University resources or medical records?

[ ]  Yes.

[ ]  No.

3.2 Will this research data be monitored by an agency board or designee other than the investigator?

[ ]  Yes.

[ ]  No.

 If yes, describe or include the Data Safety and Monitoring Plan:

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3.3 Is this research being reviewed by any other institution or peer review committee(s)?

[ ]  Yes. Attach copy of materials submitted for peer review.

[ ]  No.

 If yes, please describe:

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4. Conflict of Interest

Federal Guidelines have been revised to require IRBs to assure that there are no conflicts of interest in research projects that could affect human subject participation. If this study involves or presents a potential conflict of interest, additional information may need to be provided to the IRB. Examples of potential conflicts of interest may include, but are not limited to:

1. A researcher or family member participating in research on a technology owned by a business in which the faculty member holds a financial interest
2. A researcher participating in research on a technology developed by that researcher
3. A researcher or family member assuming an executive position in a business engaged in commercial or research activities
4. A researcher or family member serving on the Board of Directors of a business from which that member receives University-supervised Sponsored Research Support

Northwestern Health Sciences University researchers, please refer to:

[*http://www.nwhealth.edu/research/ORAC/policies.html*](http://www.nwhealth.edu/research/ORAC/policies.html)

4.1 Do any of the Investigators or personnel listed on this research have a potential conflict of interest associated with this study?

[ ]  Yes.

[ ]  No.

If yes, has this potential conflict of interest been disclosed as per the relevant policy?

[ ]  Yes. *Include a copy of the plan for IRB review.*

[ ]  No. *The IRB cannot review a study before a potential conflict has been disclosed.*

5. Summary of Activities

The following questions must be answered in lay language or language understood by a person unfamiliar with your area of research. Area-specific jargon should be avoided or explicitly explained. Do not respond “see protocol” or “protocol attached”.

5.1 What is your research question/hypothesis?

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5.2 What research methods will you use?

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5.3 What will the subjects be asked to do?

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5.4 How many months do you anticipate this research will last from the time final approval is granted?

6. Subject Profile

6.1 Number of Subjects

How many subjects do you plan to enroll?

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| --- | --- | --- |
| Male:       | Female:       | Total:       |

How many people do you estimate you will need to take through the consent process (but not necessarily enroll) to get the data sets you need? Subjects who go through the consent process come under IRB protection and are counted toward the total number of subjects even if they have no further participation in the study (i.e., decline, screen out, etc.)

*Note that this is the number of subjects for which IRB approval will be granted.*

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| --- | --- | --- |
| Male:       | Female:       | Total:       |

If this is a multi-center study, what is the total number of subjects to be enrolled from all centers?

6.2 Age Range

Check all that apply:

[ ]  0-7 (Include parental consent form)

[ ]  8-17 (Include child’s assent form, parental consent form)

[ ]  18-65

[ ]  65 and older

Exact ages to be included:

6.3 Inclusion/Exclusion of Children in this Research

If this study proposes to *include* children, this inclusion must meet one of the following criterion for risk/benefit assessment according to the federal regulations ([45CFR46, subpart D](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd)).

Check the *one* appropriate box:

 [ ]  (404) Minimal Risk

 [ ]  (405) Greater than minimal risk, but holds prospect of direct benefit to subjects

 [ ]  (406) Greater than minimal risk, no prospect of direct benefit to subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition.

Explain how this criterion is met for this study:

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If this study would *exclude* children, [NIH guidelines](http://grants2.nih.gov/grants/funding/children/children.htm) advise that the exclusion be justified, so that potential for benefit is not unduly denied. Indicate whether there is potential for direct benefit to subjects in this study and if so, provide justification for excluding children. Note that if inclusion of children is justified, but children are not seen in the PI’s practice, the sponsor must address plans to include children in the future or at other institutions.

 [ ]  No direct benefit established (exclusion of children permissible)

 [ ]  Potential for direct benefit exists.

Provide justification for exclusion of children:

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*Refer to* [*IRB website*](http://www.research.umn.edu/irb/guidance/children/okResearch.cfm) *on research with children*

6.4 Other Protected Populations to be Targeted or Included in this Research. Check all that apply:

 *Protected by Federal Regulations*

[ ]  Pregnant Woman/Fetuses/IVF (Include Appendix B)

[ ]  Prisoners (Include Appendix C)

(Refer to [45CFR46 subpart B](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartb) and [45 CFR 46 subpart C](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartc) on the populations protected by Federal Regulations)

Protected by Federal Guidelines

[ ]  Mentally/Emotionally/Developmentally Disabled Persons (Include Appendix I)

[ ]  Minority Group(s) and Non-English Speakers (Include Appendix I)

[ ]  Elderly Subjects – 65+ (Include Appendix I)

[ ]  Gender Imbalance—all or more of one gender (Include Appendix I)

6.5 Subject Characteristics

Check all that apply:

[ ]  Inpatients

[ ]  Outpatients

[ ]  Healthy Volunteers

[ ]  Condition-matched Controls

6.6 Inclusion and Exclusion of Subjects in this Research Study

Describe criteria for inclusion and exclusion of subjects in this study

Inclusion Criteria:

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Exclusion Criteria:

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6.7 Location of subjects during research activity or location of records to be accessed for research:

Check all that apply:

[ ]  Northwestern Health Sciences University clinic system

[ ]  Non-University clinics, specify:

[ ]  Elementary/Secondary Schools, specify:       (Include Appendix M)

[ ]  Community Center, specify:

[ ]  University Campus (non-clinical), specify:

[ ]  Prisons/Halfway houses specify:       (Include **Appendix I**)

[ ]  Nursing Home(s), specify:

[ ]  Subject’s Home, specify:

[ ]  International Location:       (Include Appendix K)

**[ ]  Other special institutions, specify:**

7. Recruitment

7.1 Describe the subject recruitment strategies you will use for each group of subjects:

Attach a copy of any and all recruitment materials to be used e.g. advertisements, bulletin board notices, e-mails, letters, phone scripts, or URLs.

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7.2 Explain who will approach subjects to take part in the research and what will be done to protect subjects’ privacy in this process:

Initial contact of subjects identified through records search must be made by the official holder of the record, i.e. primary physician, therapist, public school official.

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7.3 Are subjects chosen from records?

[ ]  Yes. Who gave approval for use of the records:

 [ ]  No.

If yes, are records “private” medical or student records?

[ ]  Yes. Provide the protocol, consent forms, letters, etc. for securing consent of the subjects of the records. Written documentation for the cooperation/permission from the holder or custodian of the records should be attached.

[ ]  No.

7.4 Northwestern Health Sciences University policy prohibits researchers from accepting gifts for research activities. Is the study sponsor offering any incentive connected with subject enrollment or completion of the research study (i.e., finders fees, recruitment bonus, etc.) that will be paid directly to the research staff?

[ ]  Yes.

 [ ]  No.

 If yes above, please affirm that you have declined acceptance of gifts in the box below:

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7.5 Will subjects receive inducements before or rewards after the research study?

[ ]  Yes. Note that this information must be included in the consent form, under the heading “Compensation”, and not in the “Benefits” section. Also, payment for multiple visits should be prorated

 [ ]  No.

 If yes above, please describe:

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7.6 Will the subjects be charged for research related procedures?

[ ]  Yes.

 [ ]  No.

If yes above, please describe:

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8. Risks and Benefits

8.1 Does the Research Involve:

Check all that apply:

[ ]  Any surgical process

[ ]  Administration of approved/unapproved drugs, chemical, or biological agents

Only administration of legend drugs (i.e., a drug that is required by federal law to bear the following statement, "Caution: Federal law prohibits dispensing without prescription") dispensed by a practitioner to a patient for treatment purposes for FDA-approved indications? [ ]  Yes

 [ ]  No. (Include Appendix E)

[ ]  Administration of approved/unapproved devices (Include Appendix F)

[ ]  Radioisotopes or other sources of ionizing radiation (Include Appendix R)

[ ]  Placebos

[ ]  Controlled Substances

[ ]  Recombinant DNA (including use of vectors) (Complete Section 9)

[ ]  Human Gene Transfer (including use of vectors) (Complete Section 9)

[ ]  Biological Toxins (including truncated or mutated toxins) (Complete Section 9)

[ ]  Infectious Agents (bacteria, viruses, protozoans, fungi) (Complete Section 9)

[ ]  Embryonic stem cells

[ ]  Administration of physical stimuli

[ ]  Major changes in diet, exercise, or sleep

[ ]  Blood Draw (Complete Section 10)

[ ]  Use of private records (medical or educational records)

[ ]  Possible invasion of privacy of subject or family

[ ]  Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stresses

[ ]  Any probing for personal or sensitive information in surveys or interviews

[ ]  Presentation of materials which subjects might consider sensitive, offensive, threatening or degrading

[ ]  Use of a deceptive technique (suggestion: if deception is part of the experimental design, the protocol must include a debriefing procedure, which will be followed upon completion of the study or upon withdrawal of a subject. Attach a description of the debriefing protocol and any related materials.) (Include Appendix N)

[ ]  Other risks, specify:

8.2 Describe the nature and degree of the risk or harm checked above. The described risks/harms must be disclosed in the consent form.

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8.3 Describe the precautions that will be taken to minimize the risk to the subjects.

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8.4 Justify the risk in terms of the potential scientific yield and in relation to the anticipated benefits to the subjects.

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8.5 Benefits of Participation

List any anticipated *direct and societal* benefits to participation in this research project. If none, state that fact here and in the consent form. The benefit of receiving treatment is not necessarily a benefit to participation in the research project. That distinction is central to the informed consent process.

Note: Compensation paid to subjects is not considered a “benefit”, but should be described in question 7.5.

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9. Potential Biohazards

**If you checked any of the 3 following risks in section 8.1 above, then provide a response to the following.
Will this research include:**

**[ ]  Recombinant DNA/Human Gene Transfer**

Will this research include use of recombinant DNA or human gene transfer techniques in a Northwestern Health Sciences University facility?

[ ]  Yes

[ ]  No

If No, please explain:

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**[ ]  Biologically-Derived Toxins**

Will this research include use of biologically-derived toxins in a Northwestern Health Sciences University facility?

[ ]  Yes

[ ]  No

If No, please explain:

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**[ ]  Infectious Agents**

Will this research include identification or culturing of pathogenic organisms (in risk group 2 or above) in a Northwestern Health Sciences University facility?

[ ]  Yes

[ ]  No

If No, please explain:

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*If “yes” to any of the above, the IRB requires documentation of University Safety Committee (USC) approval.*

**Note: documentation from the USC will be required prior to IRB Final Approval.**

10. Biological Samples

10.1 Will this research include blood drawing, marrow biopsy sampling, biopsy of other tissues, etc.

 [ ]  Yes

 [ ]  No

If yes, state the amount (volume measure) and frequency in which the samples are taken. The consent form must include lay term equivalents for the amounts, e.g., teaspoons etc. Please distinguish procedures that are diagnostic from procedures that are performed solely for research.

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10.2 Are you going to store (“bank”) any samples?

[ ]  Yes. (*include* *Appendix T and submit a separate HIPAA Authorization for this portion of the research*)

[ ]  No.

11. Care of Subjects in Case of Accident

If this research involves a potential for injury, injury compensation language must be included in the consent form (see 21 CFR 50.25). Select from one of the following compensation options listed below.

If a special contract to pay for research-related injuries exists, attach documentation for IRB record.

[ ]  Non-sponsor-funded compensation

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

[ ]  Sponsor funded compensation:

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. The sponsor of the study has some funds available to pay for care for injuries resulting directly from being in this study. If you think that you have suffered a research related injury and that you may be eligible for reimbursement of some medical care costs, let the study physicians know right away.

[ ]  If the preferred injury compensation language is unacceptable to the study sponsor, the following alternative language may be used:

Under some circumstances the sponsor of the study will pay for care for injuries resulting directly from being in the study. If you want information about those circumstances or if you think you have suffered a research related injury let the study physicians know right away.

12. Confidentiality of Data

12.1 Will data identifying the subjects be made available to anyone other than the Principal Investigator, e.g., FDA, study sponsor?

[ ]  Yes.

[ ]  No.

**If yes, please explain and include in consent form:**

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12.2 Will identifiers be maintained?

[ ]  No. Continue to 12.3

[ ]  Yes. Complete questions below. (Include Appendix H)

a. What are the identifiers?

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b. Who will have access to the identifiers? (Who will keep the link?)

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c. How will you limit access to the identifiers?

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12.3 Participation in research often requires documentation in a patient’s medical record. Describe what information will be in patients’ medical records.

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13. Use of Protected Health Information (PHI): HIPAA Requirements

Please read the definition of Protected Health Information (PHI) below before answering.

PHI is defined under HIPAA as health information transmitted or maintained in any form or medium that:

1. identifies or could be used to identify an individual;
2. is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and
3. relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of healthcare to an individual.

The following records ARE EXEMPTED from the definition of PHI even though they may contain health-related information: student records maintained by an educational institution and employment records maintained by an employer related to employment status. If your study uses these kinds of records, it is not subject to HIPAA. However, existing IRB rules on informed consent and confidentiality still apply.

**Health-related information is considered PHI if (any of the following are true):**

1. the researcher obtains it directly from a provider, health plan, health clearinghouse or employer(other than records relating solely to employment status);
2. the records were created by any of the entities in "1" and the researcher obtains the records from an intermediate source which is NOT a school record or an employer record related solely to employment status; OR
3. the researcher obtains it directly from the study subject in the course of providing treatment to the subject.

**Health-related information is not considered PHI if the researcher obtains it from:**

1. student records maintained by a school;
2. employee records maintained by an employer related to employment status; OR
3. the research subject directly, if the research does NOT involve treatment.

**13.1 As part of this study, do you:**

* **Collect PHI from subjects in the course of providing treatment/experimental care;
—OR—**
* **Have access to PHI in the subjects’ records?**

**[ ]  Yes.** C*omplete Appendix H to show how you will satisfy HIPAA requirements for authorization to use PHI in research.*

[ ]  No. *Continue to section 14.*

14. Expedited Review

**If you would like this application to be considered by the IRB for expedited review, fill out this section. If not, continue to section 15.**

**To request that this application be considered for expedited review**, review the categories for expedited review (see [http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm)) and fill in Section 14 with the category for which this research should be considered. The IRB will make the final determination if this research meets the federal requirements for expedited review.(Note: Most research does not fit the categories for expedited review.)

14.1 What is the level of risk to subjects in this research study?

[ ]  Not greater than minimal risk.

**[ ]  Greater than minimal risk.** *The study does not qualify for expedited review.*

14.2 Which expedited review category 1-9 applies to this research? Category #:

15. Informed Consent Process

*Under specific conditions, when justifiable, documentation of informed consent can be waived. These limited conditions are described in* [*45 CFR 46.117*](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.117)*. If you believe that this research qualifies according to the regulations, include Appendix W.*

15.1 Recognizing that recruitment is part of the informed consent process and that consent itself is a process of communication, build upon your responses to questions 7.1 and 7.2 and describe what will be said to the subjects to introduce the research. Do not respond “see consent form”. Write the explanation in lay language. If you are using telephone surveys, telephone scripts are required.

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15.2 In relation to the actual data gathering, when will consent be discussed and documentation obtained? Be specific. Keep in mind that potential subjects need adequate time to consider participation.

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15.3 Will the investigator(s) be securing all of the informed consent?

[ ]  Yes.

[ ]  No.

If no, please name the specific individuals who will obtain informed consent and include their job title and a brief description of your plans to train these individuals to obtain informed consent and answer subjects’ questions.

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Subject Comprehension

*It is the responsibility of the investigator to assess comprehension of the consent process and only enroll subjects who can demonstrate informed understanding of the research study (*[*45 CFR 46.116*](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.116)*)*

*The federal regulations require that consent be in language understandable to the subject. If subjects do not comprehend English, translated consent forms are required or the use of short forms with an oral explanation can be accepted.*

15.4 What questions will be asked to assess the subjects’ understanding? (Questions should be open-ended and go beyond requiring only a yes/no response.)

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Documentation of Consent

15.5 Prepare and attach a consent form for IRB review.

*Please see the* [*sample consent form*](http://www.nwhealth.edu/research/ORAC/irb/forms/biomedicalconsent.doc) *and follow it carefully. Do not submit sponsor prepared forms without editing the form to include Northwestern Health Sciences University’s IRB standard language and all essential elements of informed consent.*

You have reached the end of this form. Please make sure that you have responded to every question on this application (even if your response is “not applicable”).