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| **Research Exempt from IRB Committee Review**  Category 4: Existing Data: Records Review, Pathological Specimens  Version 2.1  Updated January 10, 2006.  This application form is based on the University of Minnesota IRB's *Research Exempt from Committee Review Application Form Category 4* 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 |

**Reminders for Exemption Category 4 Research:**

1. Records considered private based on federal and state statute, including medical records and education records, require written release by the study subject or by the custodian of the record.
2. Review of private records involving access to and/or recording of identifiable information is not exempt from IRB review and requires written subject consent.
3. Existing public records do not require prior consent to review the record.
4. Exempt Category 4 is not intended to exempt research that gathers protected health information (PHI) within a covered entity.
5. Pathological or diagnostic specimens that are considered waste and are destined to be destroyed can be used and are considered exempt from IRB review if there are no patient identifiers linked to the specimen and if the data will not be used in the diagnosis or treatment of a patient. (If either of these conditions applies, subject consent is required and IRB review is required.) Specimens retrieved as extra during a clinical procedure require IRB review and require written consent from the subject.
6. Inclusion of fetal tissue in this category of exempt research is prohibited by regulation.

1. Project Identification and Signatures

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

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* 1. Person preparing this document

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

* 1. Principal Investigator (PI)

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| **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. | | |
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| 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.***

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| **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 | |
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| 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)**:** | | |
| **Mailing Address:** | **Phone Number:** | **Fax:** |
| **Email:** | |
| **Occupational Position:** Faculty Staff Student Other: | | |
| **University Department** (if applicable): | **Highest Earned Degree:** | |
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| Original Signature of Co-Investigator | Title of Co-Investigator | Date |

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| **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:** | |
|  |  |  |
| Original Signature of Co-Investigator | Title of Co-Investigator | Date |

* 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: | | |
| **Mailing Address:** | **Phone Number:** | **Fax:** |
| **Email:** | |

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| **Name** (Last name, First name MI)**:** | **University Department** (if applicable): | |
| **Occupational Position:** Faculty Staff Student Other: | | |
| **Mailing Address:** | **Phone Number:** | **Fax:** |
| **Email:** | |

* 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: |
| Mailing Address: | Phone Number: |
| Email: |
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| 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. Include Appendix A

No. Explain how costs of research will be covered:

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3. Institutional Oversight

3.1 Is this research proposal being reviewed by any other institution or peer review committee?

Yes. *Attach copy of materials submitted for peer review.*

No.

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

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

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

1. **Collect protected health information (PHI)\* from subjects in the course of providing treatment/experimental care; or**
2. **Have access to PHI\* in the subjects’ records?**

Please read the definition of 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.

**Yes.** **If yes to a or b above, complete Appendix H to show how you will satisfy HIPAA requirements for authorization to use PHI in research.**

No.

6. Summary of Activities

*Use lay language; language understood by a person unfamiliar with the area of research. Area-specific jargon should be avoided or explicitly explained. Do not refer to the grant or abstract.*

6.1 Describe the objective(s) of the proposed research including hypothesis, purpose, research question and relevant background information, etc. (describe the original study if applicable):

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6.2 Describe the source of the records; medical, educational, employment, existing data set, or pathological specimens (waste).  
*For approval in this category you must plan to use an existing data set without access to identifiers, records review to which you have legitimate access to records when the chart is older than January 1, 1997, or where the patient has signed a consent form which is in the file after January 1, 1997, or collecting waste tissue after it has been released to pathology.*

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6.3 Number of records or specimens to be used:

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6.4 How long do you anticipate this research study will last from the time final approval is granted?

*Exempt research is generally considered short-term in nature so include a thorough description of longer lasting research.*

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7. Potential Biohazards

**7.1 Will this research include:**

**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.**

8. Potential Identification of Subjects

8.1 Is it reasonable to assume that the identity of the subjects could be determined by a review of the records or specimens?

Yes.

No.

If yes, describe and justify the need for obtaining the identifier:

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8.2 Describe how you have permissible access to records *(or include letter(s) of permission/approval documenting your permissible access)*:

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9. Confidentiality

9.1 Describe provisions taken to maintain confidentiality of data:

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9.2 Describe the security plan for data including how and where stored and duration of storage (i.e., password protection, encrypted data, etc.):

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9.3 Will data be made available to anyone other than the PI?

Yes.

No.

If yes, explain who and why they will have access to the data:

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*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”).*