# Application for Institutional Review of Research

**Involving Human Subjects**

**Note:** Please complete this form and provide brief responses to the issues raised, keeping in mind that the primary concern is the potential risk, (economic, ethical, legal, physical, political, psychological/emotional, social, breach of confidentiality, or other), to the subjects. Provide copies of all stories, questionnaires, interview questions, recruiting materials, or other documents to be used in the investigation. The Institutional Review Board (IRB) must have enough information about the transactions with the subjects to evaluate the risks of participation. Assurance from the investigator that subjects are at no risk, no matter how strong, will not substitute for a description of the transactions.

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**Name(s) and employee ID for faculty, Z-ID for students:**

|  |
| --- |
| Lynne Thomas - 00124928Drew Vandecreek - 00104718Jaime Schumacher - 01691665 |

**Status:**

[x]  Faculty [ ]  Graduate Student [ ]  Undergraduate Student

**Department:**

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| --- |
| University Libraries |

**Mailing Address (if not department):**

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**Phone:**

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| --- |
| 815.753.0576 |

**E-mail:**

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| jschumacher@niu.edu |

**Project Title:**

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| Digital POWRR - Preserving digital Objects with Restricted Resources |

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**Data Collection Start Date:**

 [x]  Upon IRB approval [ ]  Other (specify):

**Note:** Unless the authorized departmental reviewer (e.g., chair or designee) has deemed on the screening form that IRB review is not needed, all projects must receive formal written clearance from the IRB Chair (or an IRB member designated by the Chair) **prior** to the start of data collection.

**Type of Project** (Check one)

[x]  Externally Sponsored Research

A complete copy of the grant proposal or contract must accompany this application form for IRB review to take place.

Source of Funding:

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| Institute of Museum and Library Services  |

 Title of grant proposal (if different from IRB protocol):

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| --- |
| ADOPT |

* Name of principal investigator on grant proposal:

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| --- |
| Lynne Thomas, Drew Vandecreek |

* Office of Sponsored Projects file number (Note: this is not the grant number):

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| OSP# 11-333.01  |

[ ]  Departmental Research

[ ]  Graduate School Fund

[ ]  Thesis/Dissertation (IRB application should be submitted AFTER proposal defense)

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| **Advisor/Committee Chair** (& e-mail):       |

[ ]  Other

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| Specify:       |

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## **FOR ALL PROJECTS**

1. Briefly provide, in nontechnical, lay-terms (for reviewers outside your area), the following information:

1. a) Describe the purpose of your study and the reason(s) this study is needed. Include a description of your hypothesis or research question.

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| We are studying how to implement sustainable digital preservation practices on campuses with restricted resources. The first step to doing so is to discover how much data, digital objects, etc. lives on our campus that would require long-term preservation and access. |

b) Explain precisely the procedures of the study (what will your subjects be asked to do, provide, answer, etc.?).

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| Subjects will be asked a group of questions relating to their work-related data and its management. A list of questions is provided. We will also ask subjects if they are willing to volunteer copies of sample data for confidential testing of digital preservation systems and tools.. |

 c) Attach copies of all questionnaires, surveys, interview questions, listing of all information/data to be collected, etc. It is the responsibility of the researcher to obtain any relevant permission for copyrighted materials. If the research involves an oral interview or focus group discussion that could evolve as it 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 a written questionnaire or survey is attached, it should be clearly labeled as such and a final version must be submitted *before* data collection begins.

2. Risk/Benefit assessment: Explain the following:

a) The knowledge/benefit(s) to be gained from the study;

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| We will gain a good understanding of the size and type of the problem of data that needs long-term management. The findings will be integrated with the results of the project team's testing of various digital preservation technology solutions and published by the Institute of Museum and Library Services in a freely available white paper.  |

b) The benefit(s) to the subject(s) (if any) from the proposed research;

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| Subjects will eventually gain access to a sustainable system designed to maintain their data long-term based on our findings. |

c) Any potential risks (economic, ethical, legal, physical, political, psychological/emotional, social, breach of confidentiality, or other) to the subjects posed by the proposed research. (Note: Some studies may have “no reasonably foreseeable risks.” It is the content of the questions asked and answered, not the risk of completing a questionnaire, etc., that must be considered in describing risk. Investigators are required to report all unexpected and/or adverse events to the IRB. Incidents that have not been listed as anticipated risks are considered protocol deviations and NIU may be required to report them at the federal level.

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| No reasonably foreseeable risks |

d) What procedures will be used to minimize each risk and/or deal with the challenge(s) stated in “c” above.

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| Not Applicable |

e) How the potential benefits of the study *justify* the potential risks to the subjects.

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| Not Applicable |

3. Provide the following information about the study participants:

a) Participant demographics:

 Gender: M [ ]  F [ ]  Both [x]

 Are any subjects under age 18? Yes [ ]  No [x] 

 Estimated age(s):

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| Working professionals - Aged 25-65 |

 **Potentially** vulnerable populations (please indicate if any of the following groups are the **target population of the study**)

 [ ] Pregnant women & fetuses

 [ ] Prisoners

 [ ]  Decisionally impaired/mentally disabled

 [ ]  Specific ethnic group(s) (list in box):

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| Not Applicable |

 If any potentially “vulnerable populations” have been indicated above, please explain the necessity for using this particular group, or if specific groups are excluded from the study, please indicate the exclusion criteria used.

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| Not Applicable |

 Target number of participants in the **entire study** (including controls) from start to finish (keep in mind that this is just an **estimate of the total**):

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| 150 |

b) Explain in detail how and where subjects will be recruited or introduced to the study.

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| Initial contact will be made via email to those faculty and administrators who have a working relationship with the University Libraries. Contact will also be made, via email, to principal investigators of grant-funded projects that require a data management plan. A list of the PI's will be provided by the Office of Sponsored Projects. For under-represented colleges and administrative units, emails will be sent to faculty requesting volunteers for participation in the study.  |

c) Attach all subject recruitment/introductory materials (advertisements, mailings, fliers, Internet postings, etc.) to be used in the study.

d) Please explain any outside institutional (i.e., schools, hospitals) approval you will need to obtain and how approval will be sought. Provide scripts of any information that will be used to obtain needed approvals/permission. It is the responsibility of the researcher to follow all applicable policies of any outside institution(s).

4. Describe the procedures for obtaining informed consent, assent, and/or parental permission (e.g., verbal explanation of study, forms, debriefing).

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| Subjects will receive an email explaining the study, a hard copy of the informed consent to sign, and an in-person, verbal explanation of the study. |

* Append any form(s) to be used. Appropriate informed consent documents should be prepared for each group of subjects participating in the study. Consent forms should be prepared for adult participants (age 18 or over). Assent forms should be prepared for minor subjects appropriate to their ages, and permission form(s) for parents or legally authorized representatives should also be prepared. For children too young to comprehend a simple explanation of participation, parental permission is sufficient only if the research will provide direct benefit to the subject, a member of the subject's family, or other children with the same condition as the subject.
* For projects requiring Subcommittee or Full-board Review, if requesting a waiver of the requirement for obtaining the written informed consent of research participants, justification for the requested waiver is required. Complete and attach the “Request for Variation/Waiver of Consent” form.

5. Does this study involve deception? Yes [ ]  No [x]

* Describe the deception and why it is necessary and attach a copy of the debriefing statement.

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| Not Applicable |

6. Explain what, if any, support services will be provided in the event of harm to a subject (a resource list for the

 DeKalb area is available on the ORC website).

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| Not Applicable |

7. Confidentiality:

a) Describe precautions to insure the privacy of the subjects, and the confidentiality of the data, both in your possession and in reports and publications. Please keep in mind that **confidentiality** refers to ensuring that the knowledge of the identities of the participants will not be shared with others, and **anonymity** refers to no connection between the data and the identities of the participants even through a separate coded list of names.

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| All study results will be stored on a secured network in a database which disassociates all identifying information of the subjects from their answers. Any hand-written notes will be kept in university-owned locked offices. For publication purposes, results will be aggregated and reference made to individual answers at the college or admistrative unit level only with no further detail provided to maintain confidentiality. |

b) Will audio, video, or film recording be used? Yes [ ]  No [x]

If yes:

i. Specify the recording format to be used.

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| Not Applicable |

ii. **Please keep in mind that specific consent must be sought in the informed consent document(s) by including a separate signature/date line giving consent for recording.** This is in addition to the signature/date line giving consent to participate in the research project.

c) How will the records (data and recordings) be stored and/or disposed when the research is completed?

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| All research data will be stored within a database on a secure, university owned server. The data will be accessible via secure network connection only to those given credentials to view the appropriate files, in this case those members of the project team conducting the study. |

8. State the research qualifications of the individuals who will have direct contact with the subjects.

a) In addition to listing the investigators’ names, indicate their qualifications to conduct procedures to be used in this study.

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| Lynne Thomas: M.L.SDrew Vandecreek: Ph.D.Jaime Schumacher: M.L.SStacey Erdman: M.L.SKatharine White: M.L.S.Matthew Short M.L.SSarah Fraser: Graduate Research Assistant |

b) List the Human Subjects Protection training program(s) completed by the individuals listed in 8a and the date(s) of completion. Indicate any workshops, courses, tutorials, or other educational experiences attended, at NIU or elsewhere, which have covered issues relevant to human subject research. (*Note: NIU Policy requires that research investigators must complete appropriate training before conducting human subject research.*)

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| Lynne Thomas: Human Subjects Research Workshop IRB101 9/11/2012Drew Vandecreek Human Subjects Research Workshop IRB101 9/12/2012Jaime Schumacher: Human Subjects Research Workshop IRB101 9/11/2012Stacey Erdman Human Subjects Research Workshop IRB101 9/11/2012Katharine White Human Subjects Research Workshop IRB101 9/12/2012Sarah Fraser IRB101 9/11/2012; Social & Behavioral Research - Basic/Refresher 09/05/12; Matthew Short: Human Subjects Research Workshop IRB101 9/11/2012Social and Behavioral Responsible Conduct of Research - Basic 09/06/12 |

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**REQUIRED SIGNATURES: ALL PROJECTS**

CERTIFICATION

 I certify that I have read and understand the policies and procedures for research projects that involve human subjects and that I intend to comply with Northern Illinois University Policy. Any changes in the approved protocol will be submitted to the IRB for written approval prior to those changes being put into practice unless it involves an immediate safety issue for the subject during a procedure. (In such instances, the researcher is required to promptly notify the IRB after the fact.) I also understand that all non‑exempt projects require review at least annually.

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 Investigator(s) Signature(s) Date

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 Signature of Faculty Advisor Date

 (Student Project Only)

**To be completed by investigator and confirmed by advisor (if student project) and departmental reviewer. Initials indicate all required parties ratify that application is complete:**

**Checklist of items required to accompany completed application form:**

 1. \_\_\_\_\_\_ Complete grant proposal/contract (for externally funded projects)

 2. \_\_\_\_\_\_ All surveys, questionnaires, interview questions, or other instruments to be used

 3. \_\_\_\_\_\_ Subject recruitment/introductory materials

 4. ­­­­\_\_\_\_\_\_ Informed consent documents (must select at least one):

 \_\_\_\_\_\_ Consent form for adults (if participants are age 18 or over)

 \_\_\_\_\_\_ Assent form for minors (if participants are under age 18)

 \_\_\_\_\_\_ Parental permission form (if participants are under age 18)

 \_\_\_\_\_\_ Waiver of written consent requested (for Subcommittee and Full-board Review projects, must complete and attach *Request for Variation of Consent Attachment* form in order to provide justification that requested waiver meets criteria listed in 45 CFR 46.116(c) or 45 CFR 46.117(c))

**Initial indicating all listed materials are attached and application is complete; INCOMPLETE APPLICATIONS WILL NOT BE PROCESSED. The investigator will be notified of deficiencies in the application via e-mail from the Office of Research Compliance (ORC); if no response is received by the ORC within five (5) working days the application will be considered void.**

Investigator \_\_\_\_\_\_ Advisor (if student project) \_\_\_\_\_\_ Department Chair/Designee \_\_\_\_\_\_

**Departmental Determination according to 45 Code of Federal Regulations 46:** (to be completed by Authorized Departmental Reviewer)

[ ]  Project qualifies for Administrative Review.

 Cite the appropriate exempt category:

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[ ]  Project qualifies for Subcommittee Review.

 Cite the appropriate expedited category:

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[ ]  Project is referred for review by the convened IRB.

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Signature of Authorized Departmental Reviewer Date

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Please print ADR’s name

Return this form, together with necessary documentation, to the Office of Research Compliance, Lowden Hall, 301. For information or additional assistance with the approval process, please call the office at (815) 753‑8588 or access the ORC web page at [www.orc.niu.edu](http://www.orc.niu.edu).