GOSHEN COLLEGE INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

# EXEMPT RESEARCH CHECKLIST

IRB Study #:

*(IRB will assign)*

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| DIRECTIONS: This form is to be neatly typed and submitted to the IRB only when the investigator is contemplating the initiation of a research project which, in the investigator’s judgment, is exempt from full IRB review. The IRB will then determine whether the activity is covered by these regulations. Investigators can fill in the greyed areas, save the form and attach it to an email. | |
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| Research activities are exempt from regulations for the protection of human research subjects when they are considered minimal risk (the probability or magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (as defined by 45 CFR 46.102(i)) and the ONLY involvement of human subjects falls within one or more of the exempt categories listed below.  The exempt categories outlined below do not apply to research involving prisoners or research involving a test article regulated by the FDA, unless the research meets the criteria for exemption described in 45 CFR 46.101(b)(6) and 21 CFR 56.104(d).  The exempt categories outlined below are based solely on methods of research, and do not take the level of risk into consideration. Although most exempt research requires no further oversight to be conducted ethically, some exempt research raises ethical concerns or requires measures to protect participants. As such, the IRB will not consider any research exempt that does not fulfill ethical principles reflected in the Belmont Report. These basic ethical principles are:   1. Respect for Persons (Autonomy) – individuals should be treated as autonomous agents and persons with diminished autonomy are entitled to protection. 2. Beneficence – Human subjects should not be harmed and the research should maximize possible benefits and minimize possible harms. 3. Justice – the benefits and risks of research must be distributed fairly.   Research that otherwise would be exempt by federal regulations that raises ethical concerns or requires measures to protect subjects may be denied and/or moved to a higher level of review (i.e. expedited or full IRB review).  **Check the appropriate category(ies) that applies to your research project:** | |
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|  | 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [45CFR46.101(b)(1)] |
|  | 1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless all of the following are true:   (i) information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; and  (ii) any disclosure of the subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, or reputation. [45CFR46.101(b)(2)]  **NOTE: If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement) and observation of public behavior when the investigator(s) do not participate in the activities being observed. Research involving children that uses survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities being observed cannot be granted an exemption.** |
|  | 1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 above, if either:   (i) the human subjects are elected or appointed public officials or candidates for public office; or  (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. [45CFR46.101(b)(3)] |
| **If any of the above categories have been selected, answer the following:**  Will you be audio or video recording?  No  Yes. Explain how it will be assured that the identity of the subjects and/or link to the information obtained or the information recorded about the subjects does not place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation: | |
|  | 1. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [45CFR46.101(b)(4)]   **To qualify for this exemption, data, documents, records, or specimens must exist at the time the research is proposed and not prospectively collected.**  Provide a list of all data points that will be collected below or attach a data collection sheet. |
|  | 1. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:   (i) public benefit or service programs;  (ii) procedures for obtaining benefits or services under those programs;  (iii) possible changes in or alternatives to those programs or procedures; or  (iv) possible changes in methods or levels of payment for benefits or services under those programs. [45CFR46.101(b)(5)].  The program under study must deliver a public benefit (for example, financial or medical benefits as provided under the Social Security Act) or service (for example, social, supportive, or nutrition services as provided under the Older Americans Act).  The research or demonstration project must be conducted pursuant to specific federal statutory authority, must have no statutory requirement that an IRB review the project, and must not involve significant physical invasions or intrusions upon the privacy of the subjects.  This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency. |
|  | 1. Taste and food quality evaluation and consumer acceptance studies,   (i) if wholesome foods without additives are consumed; or  (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. [45CFR46.101(b)(6) and 21 CFR 56.104(d)] |

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## Section I: Investigator Information

**Principal Investigator:       Department:**

*(Last, First, Middle Initial)*

Building/Room No.:       Phone:       E-Mail:

**Faculty Sponsor:       Department:**

*(Last, First, Middle Initial)*

Building/Room No.:       Phone:       E-Mail:

**Project Duration:** Start Date:  End Date:

Project Title:

Sponsor/Funding Agency:

## Section II: Performance Site

Goshen College Campus; state location(s):

Other: state location(s):

## Section III: Research Description

1. Provide a brief description, in lay terms, of the purpose of the proposed project and the procedures to be used. Please only give as many details as necessary to explain the procedures themselves. If the IRB has questions regarding the rationale of the research, the committee will ask for those details.

1. Please state the eligibility for subjects (inclusion/exclusion criteria).

1. Will subjects be compensated for participation?

**ONLY COMPLETE 2-4 BELOW IF YOU SELECTED CATEGORY 1, 2, 3, 5, OR 6 ON THE EXEMPT RESEARCH CHECKLIST.**

1. Provide the process by which individuals will be recruited.

* 1. Explain how it will be ensured that recruitment or selection will not unfairly target a particular population or will target the population that will benefit from the project/research.

1. Explain how it will be ensured that individuals will be treated with respect during interactions/observations with them. For those individuals with diminished autonomy (e.g. children, people with limited ability to make decisions), explain how they will be protected.

* 1. Explain how individual privacy will be protected. For example, if interviewing, where will that be conducted?

* 1. Explain how individual confidentiality will be protected. For example, what kind of information will be recorded and how will that be protected?

1. How will you help to minimize potential risks that individuals may be exposed to while participating in the research? Potentials risks may include psychological, social, legal, physical, etc.

## Section IV: Co-Investigators

A. [Co-investigators](#coidef): Provide the name and department of other individual(s) assisting with the study who 1) will be responsible for the design, conduct, or reporting of the study, 2) have access to subjects (i.e. will consent subjects, conduct parts of the study), 3) will be making independent decisions about the inclusion or exclusion of participants, or 4) have access to identifying and confidential information.

1. List individuals from affiliated institutions who are directly interacting or intervening with subjects:

Name Department

**The individuals listed above are required to:**

1. **Pass the CITI human subjects protection test, with a score of at least 80% on all modules. Please refer to** [**https://www.citiprogram.org/Default.asp?**](https://www.citiprogram.org/Default.asp) **for more information.**
2. **Provide the IRB with documentation of their agreement to participate in the research. This can be accomplished by having the individual provide his/her signature next to his/her name above or including a memo (or email) from the individual documenting agreement to participate in this specific protocol.**
3. List individuals from affiliated institutions who are **not** directly interacting or intervening with subjects:

Name Department

B. **Collaborating Co-investigators**. List any co-investigators from nonaffiliated institutions for which the Goshen College IRB is providing the review and approval for their role in the study.

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| --- | --- | --- | --- |
| Name of Co-investigator | Institution | Role | Procedures performed |
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**Statement of Principal Investigator**. I have personally reviewed this application and agree with its contents and am aware of my responsibility to provide supervision and guidance during its execution (in the case of a student project).

Principal Investigator Signature: Date:

Faculty Sponsor Signature: Date:

**Note: As an alternative to providing original signatures on the form, the PI should simply e-mail the completed form to** [**rosspv@goshen.edu**](mailto:rosspv@goshen.edu)**. This e-mail serves as the PI’s signature. For the faculty sponsor’s signature, please forward an e-mail from the individual acknowledging his/her oversight responsibilities for the student research project. This will serve as the faculty sponsor’s signature.**

## Section IV: Exempt Review Determination

Accepted, Exempt Category(ies):

Denied, Reason:

Authorized Signature: Date: