

**HUMAN SUBJECTS RESEARCH PROPOSAL EXEMPT FORM**

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| Office Use Only | Date Received: | **Select the date** |
| Reviewer(s): |       |
| IRB Approval No: |       |

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| **SECTION 1: PROJECT AND RESEARCHERS’ DETAILS**  |

* 1. **Project title:**

Enter Project Title here

**1.2 Provide a 3-4 sentence summary of the project in plain language:**

 This summary should be in simple language and suitable for public consumption.

**Enter your response here**

**1.3 Project timeframe:**

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| --- | --- | --- | --- |
| **Proposed commencement date**: | Select the date. | **Estimated project completion date:**  | Select the date. |

Research must not commence without prior written approval from DYU IRB.

**1.4 Is this a request to extend an existing IRB-approved project? If so, please enter the original approval number:**

|  |  |
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| **IRB approval number:**  |       |

**1.5 Primary Faculty/Staff Applicant:**

If any other researchers, either employed by D'Youville University or from external institutions, will be involved in this project, please list their names in section 1.7.

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| --- | --- | --- | --- |
| Applicant Name: |       | Employee ID: |       |
| Applicant Position: | Choose an item. |  |  |
| School: | Choose an item. | Phone: |       |
| Department: |       |
| Email: |       |
| Research experience relevant to the project: |       |
| Role in the research: |       |

**1.6 Student Projects:**

If the project is to be undertaken by a student-researcher as part of their studies, please complete **Section 1. 7.**

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| --- | --- | --- | --- | --- |
| No: | Name: | Student ID: | Email: | Phone: |
| 1 |       |       |       |       |
| 2 |       |       |       |       |
| 3 |       |       |       |       |
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**1.7 Other researchers:**

List all other researchers or supervisors in the box below:

| **Names:** | **Department:** |
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| **SECTION 2: Exempt Review Application** |

**2.1. Choose the category (or categories) that best describes your research. Remember, your entire study must qualify under one or more of these expedited categories to be considered expedited from full IRB review. If any part of your research does not fit neatly into any of the categories, your study will be considered non-expedited and require a more detailed review process.**

1. **CRITERIA**

 Place an X next to the criterion or criteria under which you are seeking exempt review:

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| [ ]  | Research that does not utilize human subjects. |
| [ ]  | Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, from publicly available sources or of information recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects such as in content or secondary data analyses. |
| [ ]  | Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular or special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |
| [ ]  | Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), anonymous survey(s), interviews, or observations of public behavior in which the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, **and** any disclosure of the human subjects’ response outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation. |
| [ ]  | Taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or in which a food is consumed that contains a food ingredient at or below the level and for a use found to be safe or an 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. |
| [ ]  | Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey(s), interviews, or observations of public behavior where the subjects are elected or appointed public officials or candidates for public office. |
| [ ]  | Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and 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. |

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| **SECTION 3: NATURE OF THE PROJECT** |

**3.1 Aims of the project:**

State in plain English the main objective of the research/hypotheses to be investigated.

Enter your response here

**3.2 Rationale of the project:**

State the significance of this research project. How will it address existing gaps in knowledge or contribute new information to the field?

Enter your response here

**3.3 Background to the project:**

Briefly discuss any previous relevant research and cite no more than four (4) key references.

Enter your response here

**3.4 Research methodology:**

What kinds of methodology will you use in your research?

[ ]  Quantitative

[ ]  Qualitative

[ ]  Mixed Method

[ ]  Other:

**3.5 Research Design**

Briefly describe the main method you will use to gather data. Explain why this method is a good fit for your research goals (refer to Section 3.1).

Enter your response here

**3.5.1 Research Procedures**

Briefly explain how you will find participants (e.g., online ads, flyers on campus, etc.). Describe the data collection process (e.g., how you will conduct the surveys or interviews).

Enter your response here

**3.5.2 Sample Size and Justification**

Briefly explain how many participants you plan to involve in your research. Explain why you think this number is enough to obtain reliable results that answer your research questions. (Refer to Section 3.1.)

Enter your response here

**3.5.3 Expected Outcomes**

In a few sentences, describe the main results you expect from your research. These could be things you plan to discover, patterns you might identify, or new questions that may arise.

Enter your response here

**3.5.4 Potential Benefits of the Research**

Who might benefit from your research findings and how? This could be the participants themselves, future researchers, or a broader community.

Enter your response here

**3.6 Location(s) of the Research**

Briefly list all the locations where you will be conducting your research (e.g., online, specific hospitals, university buildings, etc.). If your research involves participants, mention where they will be located (e.g., at home, in a lab, etc.).

Enter your response here

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| **SECTION 4: PARTICIPANTS AND RECRUITMENT** |

**4.1 Who will be the participants in this project?**

Please describe the participants of your research. “Participants” also includes data about people or human tissue samples.

Enter your response here

**4.2 Number of Participants**

Briefly state the total number of participants you expect to be involved in your study.

Enter your response here

**4.3 Participant Age Range**

Specify the age range of the participants you will be recruiting (e.g., 18-65 years old).

Enter your response here

**4.4 Participant Selection and Exclusion Criteria**

Briefly explain who will be eligible to participate in your study (selection criteria). This could be based on age, health condition, or other relevant factors. Also, explain who will not be eligible to participate (exclusion criteria). This could be for safety reasons or because they might not provide the information you need.

Enter your response here

**4.5 Participant Recruitment**

Explain where you will find the participants for your study (recruitment source). This could be through online platforms, flyers posted in specific locations, or by contacting organizations or institutions.

Enter your response here

**4.6 How will you initially select and contact your participants?**

Outline the communication plan for participant recruitment. Provide details of all materials used, such as posters, flyers, information sheets, and consent forms. Additionally, specify the types of advertisements (emails, letters, online or physical postings) you will use and where they will be placed.

Enter your response here

**4.7** **Participant Information for Recruitment**

Will you be using any personal information like names, emails, or phone numbers to recruit participants? If so, explain how you will gain access to this information (e.g., from a school directory, online platform, etc.) and who will be responsible for accessing it.

Enter your response here

**4.8 Informed Consent**

Explain how you will obtain consent from the people involved in your research. This usually involves providing them with an informed consent form that explains the study in detail and allows them to choose whether to participate. You will also need to explain when they will be asked for consent (e.g., before the interview, when they sign up online). Consider if there will be any third parties involved (e.g., parents of child participants) who will also need to provide consent.

Enter your response here

**4.9 Language Accessibility**

If your research involves participants who may not understand English well, explain what you will do to ensure they understand the information you provide. This could involve offering translated materials, having someone translate verbally during the study, using simpler language, offering visuals and demonstrations, or other strategies.

Enter your response here

**4.10 Recordings and Photographs**

Will you be taking photos, videos, or audio recordings of participants? If so, explain how you will use these recordings (e.g., for analysis, presentations). Be sure to mention how you will inform participants about these recordings in the consent form they will sign.

Enter your response here

**4.11 Participant Travel**

Will your research require participants to travel anywhere? If so, explain where they will need to travel to and if there will be any compensation for travel costs.

Enter your response here

**4.12 If your research involves human biospecimens. (samples like blood, tissue, etc.)**

Describe the protocols you will follow to ensure compliance with federal regulations regarding handling, storage, and disposal of biospecimens (e.g., blood, tissue, etc.).

Enter your response here

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| **SECTION 5: ETHICAL CONSIDERATIONS** |

**5.1 Explain the potential burdens and risks participants may face during the study:**

Describe any inconveniences participants might experience, such as time commitment (e.g., filling out forms, attending interviews, etc.), physical discomfort (e.g., blood pressure measurement), or emotional discomfort (e.g., interview anxiety). Outline any potential emotional, social, legal, medical, or physical risks associated with participation. This could include distress, injury, or loss of confidentiality.

Enter your response here

**5.2 Explain how you will minimize risks and manage any potential negative consequences for participants.**

Describe the specific steps you will take to reduce the likelihood or severity of risks (e.g., screening procedures, monitoring for side effects, providing clear instructions). Outline the protocols in place to address potential risks should they occur.

Enter your response here

**5.3 Privacy and Confidentiality**

Explain how you will protect the privacy and confidentiality of the participants involved in your research. This could involve the following:

* + Anonymizing data (removing names and other identifiers)
	+ Storing data securely (e.g., password-protected computers)
	+ Limiting who has access to the data

Enter your response here

**5.4 Benefits vs. Risks**

Explain how the potential benefits of your research outweigh any burdens or risks participants may experience.

Enter your response here

**5.5 Outline the steps that will be taken in case of adverse events to participants in the study.**

This should include reporting procedures, participant care plans, and any necessary notifications:

Enter your response here

**5.6 Will participants receive any compensation or reimbursement for their time and /or out-of-pocket expenses incurred during the study?**

If so, please specify the amount or nature of the reimbursement /reward and explain the rationale behind it.

Enter your response here

**5.7 Does the research involve limited disclosure of the research aims? If yes, provide a justification.**

Enter your response here

**5.8 Researcher Risks**

Briefly explain any potential risks to the health or safety of yourself or the researchers involved in the study. This could be physical risks (e.g., working with hazardous materials) or emotional risks (e.g., dealing with sensitive topics). If there are no such risks, you can simply state that you do not anticipate any risks to the researchers.

Enter your response here

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| **SECTION 6: DATA – CONFIDENTIALITY, ANALYSIS, REPORTING, STORAGE AND FUTURE USE** |

**6.1 Choose the option that best describes the data you will access throughout the research:**

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| --- | --- | --- |
| **Type of data** | **Initially received /****collected** | **Stored (at completion)** |
| **Non-identifiable:** This data is collected or received without any personal identifiers or has had them permanently removed before you receive it. You cannot identify a specific person from this data. (Example: Anonymous survey responses) | [ ]  | [ ]  |
| **Re-identifiable:** This data originally had personal identifiers, but they have been replaced with codes. While you or someone else might be able to re-identify individuals by linking this data with other datasets or using the code, the data itself does not directly reveal their identities. | [ ]  | [ ]  |
| **Individually Identifiable:** This data clearly identifies participants, including names, images, dates of birth, addresses, or other unique identifiers.  | [ ]  | [ ]  |

This section highlights that the initial format of research data may differ from how it is stored for long-term use. For example, interview data with names included initially (individually identifiable) can be transformed into non-identifiable data by permanently removing names before storage. *Personal Identifiable Information* (PII) refers to any personal details that could be used to identify an individual, such as a name, birth date, address, email, phone number, or student ID.

**6.2 Describe the specific measures you will take to safeguard the privacy and confidentiality of participant data, samples, and information throughout the recruitment and data collection phases of the research. Explain how you will ensure the effectiveness of these methods.**

Enter your response here

**6.3 How will the privacy and confidentiality of participant data, samples and information be protected during the data analysis phase?**

Describe the methods you will use to de-identify participant data (if applicable). This could include removing names, addresses, or other personal identifiers. Outline where data will be stored during data analysis and who will have access.

Enter your response here

**6.4 How will participant data, samples, and information be analyzed and who will undertake this analysis?**

Enter your response here

**6.5 Will you provide participants with a summary of the research findings?**

If so, explain what format this feedback will take (e.g., study summary report, transcript excerpts etc.).

Enter your response here

**6.6 How will you share the research findings with the public at the end of the project?**

Describe the intended format(s) for dissemination, such as journal articles, books, conference papers, media coverage, or public presentations.

Enter your response here

**6.7 Describe how the records, materials, and data from the project will be stored at completion.**

Provide details of the storage location and who will have access.

Enter your response here

**6.8 Indicate the length of time that the records and materials will be retained by the University.**

Enter your response here

**6.9 Will data be used in future research or disposed of?**

 If yes, state the purpose, access, and participant notification. Otherwise, describe data disposal plans.

Enter your response here

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| **SECTION 7: CONFLICT OF INTEREST OR OTHER ETHICAL ISSUES** |

**7.1 Outline the source(s) of any project funding:**

Enter your response here

**7.2 Disclose any potential conflicts of interest:**

Enter your response here

**7.3 Outline any other ethical or relevant issues not yet discussed in this application:**

Enter your response here

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| **SECTION 8: DECLARATION BY THE RESEARCHER(S)** |

**8.1 Declaration by the Researcher(s):**

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| **I/we, the researcher(s)**:* have read the DYU Institutional Review Board (IRB) Manual for the Researchers, and I will adhere to the policies and procedures explained therein.
* have reviewed and understood the ethical principles outlined in the Belmont Report.
* have prepared this research protocol in accordance with these ethical principles and guidelines.
* will conduct this research with scientific integrity and ensure the safety and well-being of all participants.
* will obtain informed consent from all participants before their involvement in the research.
* will maintain the confidentiality of all participant data.
* will disclose any potential conflicts of interest that may arise during the project.
* will report any serious adverse events to the IRB promptly.
* will comply with all applicable regulations and guidelines governing human subject research

All persons named in **Section 1** are required to sign below:( save your signature as picture in MS word and insert below) |
| Research Director's Signature:  | **​​​** **​​​**  | Name:  |       | Date:  | **​​ Select the date** |
| Researcher’s signature:   |  **​​​**    | Name:  |       | Date:  | **​​ Select the date** |
| Researcher’s signature:   |  **​​​**   | Name:  |       | Date:  | **Select the date** |
| Researcher’s signature:   |  **​​​**  | Name:  |       | Date:  | **Select the date** |
| Researcher’s signature:   |  **​​​**  | Name:  |       | Date:  | **Select the date** |
| Researcher’s signature:   | **​​​**  | Name:  |       | Date:  | **Select the date** |
| Researcher’s signature:   | **​​​**  | Name:  |       | Date:  | **​​ Select the date** |

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| **SECTION 9: CHECKLIST** |

**The following documents are attached to this application:**

Clearly label all attached documents with relevant names (including student/staff ID).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Yes** | **No** | **N/A\*** | **Item** | **Attachment Label**  |
| [ ]  | [ ]  | [ ]  | CITI or NIH certificate of completion |       |
| [ ]  | [ ]  | [ ]  | Consent Form  |       |
| [ ]  | [ ]  | [ ]  | Site permission approval letter |       |
| [ ]  | [ ]  | [ ]  | Procedure/protocol for interviews or focus groups including topics, questions  |       |
| [ ]  | [ ]  | [ ]  | Data collection instrument (e.g. Questionnaire, Interview guide)  |       |
| [ ]  | [ ]  | [ ]  | Adverse events procedure |       |
| [ ]  | [ ]  | [ ]  | Other recruitment documentation including advertisements, flyers, recruitment letters, emails of introduction, copy of Facebook event pages and social media event sites. |       |
| [ ]  | [ ]  | [ ]  | Research with people outside the US: Evidence of permissions, approvals from overseas authorities etc. |       |
| [ ]  | [ ]  | [ ]  | Administration of Drugs Form |       |
| [ ]  | [ ]  | [ ]  | Annual Report on Project Status (if extending project) |       |
| [ ]  | [ ]  | [ ]  | Any supporting documentation |       |

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| **SECTION 10: HOW TO SUBMIT THIS APPLICATION** |

Submit your proposal and all checked documents from Section 9 to the D’Youville University Institutional Review Board via email at irbhelp@dyc.edu.