Form B-3

Exempt Research Request

General Information Sheet

Using this form – To check the checkboxes, double click on the box. To enter text in the text boxes, click once on the gray box and then type your response*.*

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| --- | --- |
| **UT Health San Antonio IRB Tracking Number** |  |

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| **Section 1 –** For **Exempt Research**, the research must fall within at least one Exemption Category found in items 1-6 below AND all of the following must be true. The research:   * The research is [minimal risk](https://www.uthscsa.edu/vpr/services/glossary#Minimal-Risk). * If the research involves children as participants it does NOT include: * Interacting with children; OR * If the research involves prisoners as participants, it must only include them as part of a broader subject population that only incidentally includes prisoners * The research is not FDA regulated human research.   Note: If the above items are not true or the research does not meet one or more of the 6 categories below then the submission needs to be submitted under Expedited Review.  *Contact the OIRB for assistance at (210) 567-8250 or* [*IRB@uthscsa.edu*](mailto:IRB@uthscsa.edu)*.* | | | | | | | |
| * 1. Does your research evaluate different instructional strategies or compare the effectiveness of instructional techniques, curricula, or classroom management methods in an established or commonly accepted educational setting?   [*45CFR46.104(d)(1)*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101) | | | | | | | |
|  | No – *Go to 1.2* | | | | | |
|  | Yes – answer the following question*:* | | | | | |
| 1.1.1 Will the study interfere with normal education practices? | | | | | |
|  |  | Yes – **C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\NVSY3N9F\6503264653_40dc082989_z[1].jpg** - **Not Eligible** for Exemption. | | | | |
|  |  | No – C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg- Your study qualifies for Exemption | | | | |
| * 1. Does your research involve interactions involving educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observations of public behavior (including visual or auditory recording) influenced by the investigator?   [*45CFR46.104(d)(2)*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101) | | | | | | | |
|  | No – *Go to 1.3* | | | | | |
|  | Yes – answer the following question: | | | | | |
| 1.2.1 Does your study include **an intervention**? | | | | | |
|  | Yes - **C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\NVSY3N9F\6503264653_40dc082989_z[1].jpg** - **Not Eligible** for Exemption. *You cannot use this form.* | | | | |
|  | No – Select the category(ies) which apply to this study: | | | | |
|  | | The information obtained is not identifiable. C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg - Eligible for Exemption | | |
|  | | Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability; or be damaging to the subjects' financial standing, employability, insurability or reputation. C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg- Eligible for Exemption | | |
|  | | Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg- Eligible for Exemption (A [Limited Review](https://www.uthscsa.edu/vpr/services/glossary#Limited-IRB-Review) is required) | | |
| 1.3 Does your research involve [benign behavioral interventions](https://www.uthscsa.edu/vpr/services/glossary#Benign-Behavioral-Intervention) in conjunction with the collection of information?  [*45CFR46.104(d)(3)*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101) | | | | | | | |
|  | No – *Go to 1.4* | | | | | |
|  | Yes - Select the category(ies) which apply to this study: | | | | | |
|  | The information obtained is not identifiable. C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg- Eligible for Exemption | | | | |
|  | Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability; or be damaging to the subjects' financial standing, employability, insurability or reputation. C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg- Eligible for Exemption | | | | |
|  | Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg- Eligible for Exemption (A [Limited Review](https://www.uthscsa.edu/vpr/services/glossary#Limited-IRB-Review) is required) | | | | |
| 1.4 Does your research involve the collection of data and/or specimens that are originally collected for other purposes (i.e., educational records, medical records, specimens in pathology, etc.)?  [*45CFR46.104(d)(4)*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101) | | | | | | | |
|  | No – *Go to Item 1.5* | | | | | |
|  | Yes – Select the category(ies) which apply to this study: | | | | | |
|  | The identifiable private information or identifiable biospecimens are publicly available. C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg – Eligible for Exemption #4 | | | | |
|  | The information is recorded by the investigator in such a way that the identity of subjects cannot readily be ascertained, and the investigator does not contact subjects or try to re-identify subjects. C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg – Eligible for Exemption #4 | | | | |
|  | | | **Confirm the following:**  Access to record will occur only **once**.  **NO study codes** will be assigned to the subjects on the subject list  *Note: No Institutional follow-up required. Refer to* [*Institutional Review Policy*](https://www.uthscsa.edu/sites/default/files/Services/forms/ocr-institutional_review.pdf)*.* | |
|  | The secondary research activity is regulated under HIPAA (HIPAA waiver is required). C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg – Eligible for Exemption #4 | | | | |
|  | | | Access to record may occur **more than once**  A **link may be created**  *Note: Institutional follow-up is required if the study is still active in 3 years. Refer to* [*Institutional Review Policy*](https://www.uthscsa.edu/sites/default/files/Services/forms/ocr-institutional_review.pdf) | |
|  | The secondary research activity is conducted by or on behalf of a federal entity and involves the use of federally generated non-research information provided that the original collection was subject to specific federal privacy protections and continues to be protected. C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg – Eligible for Exemption #4 | | | | |
|  | None of the above, **C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\NVSY3N9F\6503264653_40dc082989_z[1].jpg** - **Not Eligible** for Exemption. *You cannot use this form.* | | | | |
| 1.5 Is this project a Research or Demonstration Projects Approved by Federal Department/Agency Head? *(This is not common)*  [*45CFR46.104(d)(5)*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101) | | | | | | | |
|  | No – *Go to Item 1.6* | | | | | |
|  | Yes – Check the box for each true statement below (all must be true to be eligible for exemption): | | | | | |
|  | 1.5.1 The research is conducted by or subject to the approval of federal Department or Agency heads | | | | |
|  | 1.5.2 The research is designed to study, evaluate, or otherwise examine at least one of the following:  (select as applicable):  public benefit or service programs  procedures for obtaining benefits or services under public benefit or service programs  possible changes in or alternatives to public benefit or service programs  possible changes in methods or levels of payment for benefits or services under public benefit or service programs | | | | |
|  | 1.5.3 The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act). | | | | |
|  | 1.5.4 The research is conducted pursuant to specific federal statutory requirement | | | | |
|  | 1.5.5 There is no statutory requirement that an IRB review the research. | | | | |
|  | 1.5.6 The research does not involve significant physical invasions or intrusions upon the privacy of participants. | | | | |
|  | All are **checked** (1.5.1 to 1.5.6) - C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg - Eligible for Exemption | | | | | |
|  | Any are **unchecked** (1.5.1 to 1.5.6) - **C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\NVSY3N9F\6503264653_40dc082989_z[1].jpg** - **Not Eligible** for Exemption. *You cannot use this form.* | | | | | |
| 1.6 Does your research involve taste and food quality evaluation or consumer acceptance studies? *(This is not common)*  [*45CFR46.101(b)(6)*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101) | | | | | | | |
|  | No – *Go to Item 1.7* | | | | | |
|  | Yes - C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg- Eligible for Exemption - Select the appropriate statement below: | | | | | |
|  | Wholesome foods without additives are consumed | | | | |
|  | If a food is consumed that contains a food ingredient or an agricultural chemical or environmental contaminant, the food ingredient or agricultural chemical or environmental contaminant is at or below the level and for a use found to be safe by one of the following: (delete those not applicable) the Food and Drug Administration; the Environmental Protection Agency; the Food Safety and Inspection Service of the U.S. Department of Agriculture. | | | | |
| 1.7 Did you answer YES to at least one of items 1.1-1.6 above? | | | | | | | |
|  | No – **C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\NVSY3N9F\6503264653_40dc082989_z[1].jpg** (if **No** to **all items** 1.1-1.6, your study is **not eligible** for Exemption, submit as Expedited or contact OIRB for assistance) | | | | | |
|  | Yes - C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\45N76HQH\check-mark[1].jpg- Eligible for Exemption – *Go to Section 2* | | | | | |
|  | | | | | | | |
| **Section 2 – Will you obtain specimens or private information without needing to interact with individuals?** | | | | | | | |
|  | No *continue to Section 3* | | | | | |
|  | Yes | | Approximately how many separate records or specimens do you plan to obtain? | | | |
|  | | | | | | | |
| **Section 3 – Will you be interacting or intervening with living individuals?** | | | | | | | |
|  | No | | | | | |
|  | Yes | | | | | |
| What is the age range? | | | | |  |

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| **Section 4 – Identification of Subjects/Records/Specimens** | | | |
| 4.1 How will you identify subject or data/specimens for inclusion criteria? | | |
|  | During regularly scheduled event: [describe event: i.e., clinic visit, class, staff meeting, etc.] |
|  | Records Search: [describe event: i.e., medical records, academic records, employee records, etc.] |
|  | Other: |
| 4.2 Does the information reviewed contain both health information and identifiers? | | |
|  | No- *Skip to Section 5* |
|  | Yes - submit Form J – HIPAA Waiver – *Go to Section 5* |

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| **Section 5 – Initial contact** | | | |
| 5.1Provide a brief summary of how subjects will be asked to volunteer. | | |
|  | Personal Contact |
|  | PI clinic |
|  | Other: |
|  | N/A. (i.e., Charts, EMR) |

|  |  |
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| **Section 6**  Purpose and rationale  *Insert purpose, objectives and research questions/hypotheses here.* | [insert Purpose and Rationale here] |
| **Section 7**  Background  *Describe past experimental and/or clinical findings leading to the formulation of your study.* | [insert Background here] |

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| **Section 8 – Subject Population**  *e.g., a population can be individuals with type 2 diabetes controlled with diet and/or a population of healthy controls. Or a population can be individuals attending an education program, etc.* | | |
| **8.1 Study Population(s) Being Recruited**  In your recruitment plan, how many different **populations** (groups, cohorts, etc.) of subjects do you plan to target? | | |
| **Provide number of populations here**: |  | |
| **8.2 Inclusion & Exclusion Criteria**  List each different population on a separate row and provide a short descriptive **label** for each:  *(e.g., normal-healthy, diabetics, parents, children, etc.)*  *To add rows use copy & paste* | Identify the criteria for **inclusion** below: | Identify the criteria for **exclusion** below: |
| [insert here] | [insert here] | [insert here] |
| [insert here] | [insert here] | [insert here] |

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| **Section 9 – Research Plan / Description of the Research Methods** |
| 9.1 Step-by-Step Methods*Provide a* ***comprehensive narrative*** *describing the* ***research methods****.*  [insert here] |
| 9.2 Data Analysis Plan*Provide the* ***plan for data analysis*** *(include as applicable the* ***sample size calculation).***  [insert here] |