

**Vice Presidency for Academic Affairs**

**Office of Research Integrity and Compliance**

***Human Research Protection Board (IRB)***

**Institutional Investigations SUBMISSION FORM**

 **(Applications without all requested information will not be accepted for IRB review)**

**Instructions:** This form should be completed in order to request IRB review for research involving human subjects. Download this form, complete and upload again in the “Web-Based Electronic System” provided by UAGM with all other documents required. Incomplete or unreadable applications will not be accepted for IRB review. It will be understood that the date on which you complete and comply with all the UAGM IRB requirements will be considered as the date you submitted your protocol for review. The 45 CFR 46 “[Revised Common Rule 2018](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)” and [21 CFR 56](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56) prohibits that any research (including recruitment of subjects or advertising) be initialized without IRB review and approval. All researchers and key personnel (i.e. Primary Investigators, Mentors, Students) involved in Research must complete the courses for Human Subjects Research (HSR), Privacy and Confidentiality (HIPS) and Responsible Conduct in Research (RCR) as required by UAGM IRB at <http://www.citiprogram.org> in order to receive approval of their protocols from the IRB . Also, Researchers must abide by the [Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) ethical principles. For some studies, researchers may be required to complete courses for Good Clinical Practice. Please refer to “Instructions for On-line Course Completion” which you can find under the Office of Research Integrity and Compliance (<http://uagm.edu/compliance>). You should also upload the obtained “completion reports” on the “Web Based Electronic System” with other required documents. For more information regarding the web-based tools provided by UAGM to facilitate the researcher's processes, or any other information you should contact a Compliance Officer of the UAGM site / location to which he belongs. If you are an external investigator who wishes to use the population of the UAGM campus / locations for your investigation, contact the Compliance Officer to which said population belongs (contact information can be found at the end of this form).

**I. BASIC INFORMATION:**

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| **Proposal Title:**       |
| **Campus/Location/Office:**       |
| **Principal Investigator: First Name:**      | **Last Name:** | **Earned Academic Degree** |
| **Telephone:** | **E-Mail:** |
| **Co-Investigator: First Name:**      | **Last Name:** | **Earned Academic Degree** |
| **Telephone:** | **E-Mail:** |
| [ ]  **Dean** [ ]  **Supervisor: First Name:**      | **Last Name:** | **Earned Academic Degree** |
| **Telephone:**  | **E-Mail:** |

\*If your study is part of a federal proposal with funds you should submit with the Form IRB-01

**II. BASIC STUDY INFORMATION:** The study/investigation start date should be fifteen (15) labor days prior to the date of submission for IRB Review. Studies will start after receiving IRB official approval.

|  |  |
| --- | --- |
| **1. Study Term (Estimated)** | (Estimated) **Start date:      -      -       (mo-day-yr)** (Estimated) **Completion Date:      -      -       (mo-day-yr)**  |
| **2. Study Type** | [ ]  Area of Need[ ] Other: [ ]  Area of Satisfaction |
| **3. Indicate if your study will be carried out online (Internet Research)** | [ ]  Yes\* [ ]  No **Explain:** |

**III. STUDY PURPOSE**

1. **Provide a Summary of the study purpose, using non-technical language.**

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1. **What do you plan to achieve with this investigation?** (Study objectives)

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**IV. FINDINGS USAGE AREA**

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| --- | --- |
| [ ]  Human Resources | [ ]  Operation & Maintenance Physical Plant |
| [ ]  Student Services | [ ]  Planning |
| [ ]  Academia  | [ ]  Others, specify:       |

**V. PARTICIPANTS INFORMATION**

|  |  |
| --- | --- |
| **1. Type of Participant: (Select where will the study take place).****If Research Subjects are not from our University’s population you must complete the F01 Form.** | [ ]  Cupey [ ]  Carolina [ ]  Gurabo [ ]  UAGM Online[ ]  UAGM Central [ ]  EEUU UAGM [ ]  Student[ ]  Associate [ ]  Volunteers/Guest [ ]  graduates[ ]  Other, specify       |
| **2.** Are the participants of your study / research considered a vulnerable population? | [ ]  Yes\* [ ]  No \* If your answer is “YES” to this premise, please indicate below the vulnerable population to which your study / investigation is directed. Complete this part, even if your study / research does not contemplate the participation of the vulnerable population by selecting “NO” under each category. |
| \*Select Vulnerable Population |
| Under age (21 years old or less) | [ ]  Yes [ ]  No |
| Prisoners | [ ]  Yes [ ]  No |
| Physically or mentally challenge subjects | [ ]  Yes [ ]  No |
| Pregnant Women | [ ]  Yes [ ]  No |
| Subjects with minimum capacity to provide consent | [ ]  Yes [ ]  No |
| Non spanish speaking subjects | [ ]  Yes [ ]  No |
| Other:  |  |
| 3. Indicate in detail how the **recruitment process** will be carried out (how, when and where). Indicate how you will carry out this process even if your study will be conducted online (Internet). Indicate if you need the assistance of an administrator to carry out the recruitment (example: emails). Explain:  |
| **4.**  Does this study include sensitive information?  | \*\*[ ]  Yes [ ]  No |

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| OHRP and DHHS Sensitive Information Categories\*\* |
| [ ]  | 1. Information related to attitudes, preferences or sexual practice.
 |
| [ ]  | 1. Information related to the use of alcohol, drugs or addictive products.
 |
| [ ]  | 1. Information related to illegal conduct.
 |
| [ ]  | 1. If the information is released, could reasonably damage an individual’s financial standing, employability, or reputation within the community?
 |
| [ ]  | 1. Information normally found in a subject’s medical record that if disclosed may lead to social stigmatization or discrimination.
 |
| [ ]  | 1. Is the information pertaining to an individual’s psychological well being or mental health?
 |
| [ ]  | 1. The research involves no more than minimal risk to the subjects.
 |
| [ ]  | 1. The research could not practicably be carried out without the waiver of consent.
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| 1. Will you share the pre-selection data from this study with any agency, entity, group, or general public?

**\*If the answer is YES justify:**       | [ ]  Yes\* [ ]  No |
| 1. Is there any relation between the investigator and the participant of the study?
 |  [ ]  Yes\* [ ]  No |
| **\*If the answer is YES** explain and describe what precautions will be taken to avoid conflict of interest and voluntariness that will guarantee: lack of coercion, freedom of choice, and undue influence.     Note: This information should also be included in the consent document. |
| 1. Will an external agency be contracted to obtain data and tabulate the final results of the study/Research ? This includes Internet Research.
 |   [ ]  Yes\* [ ]  No |
| \*If the answer is Yes, indicate what are the terms agreed with the agency on how the data collected will be handled in order to assure the privacy and confidentiality of the subjects. Online providers, the IRB UAGM will only accept those that will work with “Survey Monkey” and “Office Forms 365” (indicate below which of the two providers you will use). For other providers, contact the Compliance Officer at your Campus (you must indicate the provider's name and link where it can be verified how they will protect and ensure the privacy and confidentiality of the data and any identifiable information of the possible participant (ex: IP Address, Security Programs).\*Explain: |
| **VI. SUBJECT CONSENT INFORMATION – Indicate Consent required for your study:** |
| 1. Indicate type of consent required for your study:
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| **Option 1**[ ]  Signed Consent Required | Consent will be signed by the subject or the subjects’ legally authorized representative 45 CFR 46.117. If subject is a minor the consent document must be signed by the parent or legal authorized representative. If the minor is (7 to 13 years of age) assent should be obtained; (minors 14 to 20 years of age) will sign the consent with parent or legally authorized representative 45 CFR 46.408(a). Documents here mentioned should be submitted with your request to IRB. |
| **Option 2**[ ]  Waiver of Consent | Because the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants linking the subject with the research, and the subject’s wishes will govern. 45 CFR 46.117.c.(1). Select all that apply:[ ]  Request for waiver of consent written document.[ ]  Request for waiver of consent written document and the  consent process[ ]  Other      Justify:       |
| **Option 3**[ ]  Waiver of Consent (Minimum risk) | Because the research presents no more than minimal risk of harm to subjects, and involves Minimal Risk no procedures for which written consent is normally required outside of the research context. 45 CFR 46.117.c.(2). Select all that apply:[ ]  Request for waiver of consent written document.[ ]  Request for waiver of consent written document and the consent process[ ]  Other      Justify:       |
| 1. Please indicate the type of consent waiver you request and indicate what would be your justification for such request. (Eg: waiver of the consent document, waiver of the consent process or waiver of both processes, among others). **Waiver from the consent process will only be accepted in those cases where they are observational studies / research and / or in which information will not be obtained directly from a participant**. All other studies must include the consent process.

Explain: \* If you request the waiver of the Consent Sheet (signed) you must submit with your request and Information Sheet addressed to the participant indicating the purpose and objectives of the study / research that will be carried out. |
| 1. Complete the following to indicate what procedures will be used to obtain consent:

[ ]  **Does not apply (Select only** if consent will not be obtained as a document or as a process since it is an observational study and / or others as previously indicated. Explain:  |
| 1. Select what will be the process utilized to obtain consent (even if waiver of consent is solicited or even if the research will be done by internet) Hard copy of all documents must be included.
 |
| [ ]  In person (face to face) | [ ]  e-mail (submit templates with all other documents) |
| [ ]  Telephone | [ ]  Web link:       (submit hard copy of all documents)  |
| [ ]  Written document | [ ]  Other:       |
| [ ]  USPS mail |  |

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| 1. Explain how, where and when the consent or consent process will be obtained (describe the place where the study will be discussed with subjects).*For Internet Research investigators must explain how this process will be managed online***.**

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| 1. How will participants understanding be assessed? The answer of this question should allow you to determine if they understand the study in all it’s parts. You may ask them to explain, the purpose of the study, duration, and procedures. *For Internet Research investigators must explain how this process will be managed online.*

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**VII. INFORMATION MANAGEMENT**

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| Answer all the following questions. *For Internet Research investigators must explain how this process will be managed online.*  |
| 1. Explain how, when and where information will be obtained:

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| 1. Indicate who will be responsible (PI/CO PI) for the storage of all obtained information. Also indicate who will custody be delegated to if this person stops occupying the current position in the University?

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| 1. Where will the obtained information be stored and how will it be protected? (eg file, computer, USB, external hard drive).

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| 1. How long will all related documents be stored? If the data will be obtained using a service provider through the internet (eg survey monkey, among others), you must indicate in writing how they manage all information on their servers and / or for how long will information be stored on their servers.

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\*Institutional studies will be evaluated individually; case by case. If a Full Review is required, you will be notified.

**PRINCIPLE INVESTIGATOR / CO-INVESTIGATOR ASSURANCE:**

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| To submit and complete this form through the Web-based System it is necessary to endorse (sign electronically) your project when indicated in the process. By endorsing this form you are committing to the following: I certify that the information provided in this application is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.That the information provided in this form is complete and correct. I understand that, as Principal Investigator / Co-Investigator, I agree to comply with all the rules and procedures of the Universidad Ana G. Méndez (UAGM) and also with all federal, state and local laws related to the protection of human beings in research. In addition, that the proposed investigation is not being carried out and will not begin until IRB UAGM approval is obtained. |

**Contact your Institutional Compliance Officers if you should need further assistance:**

 **Cupey (787) 766-1717 ext. 6362/ E-mail:** **cacrespo@uagm.edu****; Fax (787) 751-3379**

 **Carolina(787) 257-7373 ext. 2279 E-mail:** **grcruz@uagm.edu**

 **Gurabo 787-743-7979 ext. 4126 E-mail:** **jomelgar@uagm.edu****; Fax: (787) 743-7115**

**EEUU UAGM (813) 932-7500 ext. 8711 - Email :** **jimeneza1@uagm.edu**

**UAGM Online y Adm. Central 787 751-0178 ext. 7195 E-mail :** **wvazquez@uagm.edu**

**To report an adverse event E-mail:** **cumplimiento@uagm.edu****; (787) 751-0178 ext 7195 and 7197**

**or non compliance in Research: E-mail** **cumplimiento@uagm.edu****; (787) 751-3120**

**Web Page - uagm.edu/compliance**