Vice Presidency for Academic Affairs

Office of Research Integrity and Compliance

***HUMAN RESEARCH PROTECTION BOARD (IRB)***

All documents submitted for IRB Review must be uploaded using web-based system provided by UAGM

Instructions: http://uagm.edu/compliance

(Applications without all required information/documents will not be accepted for IRB review)

**CHECKLIST**

**Principal Investigator** :

**Proposal Title** :

**Official Stamped Program** :  Yes  No

**Type of Application**: Include the appropriate form according with your submission (documents will be submitted using web-based System and in accordance with request.

F01**-**New Protocol  F02-Continuing Review  F03-Amendment  F04-Closure  F05-Adverse/Non Unanticipated Event

F08Exempt Study/Research Submission

**Research Materials: Select from the following and include documents** that may apply even if you will be *using internet* to obtain data (documents must have a bottom page margin of 2 inches and pages must be numbered “format 1 of 1”).

Questionnaire  Interview  Survey  Test  Focal Group  Advertisement/Recruitment tool

Recording: Audio/Video  Photos Secondary Data Other, specify

**Select type of proposal to be submitted for review:**

**Federal Proposal** - include the assessment or research activities sections and must include (refer to list below):

**Proposal (Thesis/Independent Research)-** must include the following:

|  |  |
| --- | --- |
| Table of Contents | Provisions for subject and data confidentiality |
| Introduction | Statement of potential research risks to subjects |
| Specific Aims | Statement of potential research benefits to subjects |
| Methods of Data Collection and Analysis  (Qualitative and Quantitative) | Description of the subject population, research  setting, subject recruitment procedures |
| References/Bibliography | Copyright, if applicable |
| Informed consent procedure | Other |

**Additional documents required by IRB when applicable**: (Consent Form or Written Statement, Assent Form, Research Materials, and Letter of Recruitment should be submitted with **a bottom page margin of 2 inches**,documents will not be accepted without these indications)

|  |  |
| --- | --- |
| Consent Form  Spanish  English | Assent Form  Spanish  English |
| Cooperation/Support Letter:  internal  external | Ammendment Letter |
| Advertisement/Recruitment material (Flyer) | Evidence/Receipt of questionnaire |
| Form FDA 1572 (Clinical Studies) | Package Insert (product description) |
| Investigator Brochure (Clinical Studies) | Other: |

All staff involved and responsible of the study submitted for IRB Review must complete and include with documents the following completion reports. For Clinical Trials and when necessary certificate of “Good Clinical Practice” (GCP) should be submitted.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Staff** | **Resume/ CV** | **HIPS** | **IRB** | **RCR** | **GCP\*** |
| Principal Investigator |  | /     /     /  Mo Day Yr | /     /     /  Mo Day Yr | /     /     /  Mo Day Yr | /     /     /  Mo Day Yr |
| Co-Investigator |  | /     /     /  Mo Day Yr | /     /     /  Mo Day Yr | /     /     /  Mo Day Yr | /     /     /  Mo Day Yr |
| Mentor |  | /     /     /  Mo Day Yr | /     /     /  Mo Day Yr | /     /     /  Mo Day Yr | /     /     /  Mo Day Yr |

**Important:** To obtain completion reports see instructions at the following link [http://uagm.edu/compliance](http://compliance.suagm.edu) or call your Institutional Compliance Officer at (Tel. 787 751-0178 - UAGM Cupey ext. 9-6366; UAGM Carolina- ext.9-2279; UAGM Gurabo 9-4126; UAGM Online and Office of Research Integrity and Compliance 9-7195); UAGM EEUU: Tel. (813) 932-7500 ext. 8711 email: [jimeneza1@suagm.edu](mailto:jimeneza1@suagm.edu);