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**INSTITUTIONAL REVIEW BOARD | COMITÉ DE REVISION INSTITUCIONAL**

**New request to approve Research / Study Form: HUI-IRB-02**

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| **Assigned IRB reviewer(s)** | | **To be completed by the IRB** |
|  | | **Protocol number:**  **HIU-IRB-F02-** |
| **IMPORTANT**  PLEASE, READ THE WHOLE DOCUMENT CAREFULLY  Law 45 CFR 46, “Common Rule”, forbids starting any research/study (including recruiting participants or placing ads) without an IRB’s revision and approval.  In order to comply with federal regulations and guidelines of the Humboldt International University Institutional Review Committee - HIU-IRB, the main researcher (IP), must complete all items below. In addition, he/she must submit all of the required annexes (consent forms, instruments of research - questionnaires, interviews, etc.). In the case of applications from doctoral students, the signature of the dissertation’s Chair (Mentor) should appear as evidence of review and agreement. Only complete applications are accepted.  Send a signed copy (PDF) to the Coordinator of HIU-IRB, and upload a copy of the same in the space provided in the Portfolio for the Dissertation area in the HIU online platform.  This request can be handled through two different procedures:  Complete Revision  Exempt Revision  If the study/research complies with the requirements for the application of Exempt Revision, the HIU-IRB Coordinator, will propose the review to an IRB member, who will endorse it or not.  If the Coordinator detects non-compliance with ALL the conditions for an Exempt Revision, he will turn the application to a Complete Revision.  If a Complete Revision is required, the Coordinator will include the case analysis in the next HIU-IRB regular meeting, and will entrust two of the members with its review and the preparation of a reasoned proposal of decisions.  In the case of a favorable resolution of the request, the HIU - IRB President will sign the Declaration of Approval in the space provided. This will be valid for two years. In the case of unfavorable cases, the application will be returned with an attachment on the non-compliance aspects.  Use a word processor to complete this form. All shaded sections must be completed. Make sure that all pages are numbered sequentially. Once completed, save in PDF format, and get the pertinent signatures.  All researchers (Main Researchers, Faculty, Students and all key personnel) should receive training and obtain the Certificate on Research with Humans with the CITI system to receive exemption or approval of their applications to the IRB. As applicable, one of the following training modules must be completed: Protection of Humans (IRB), Confidentiality and Privacy, and RCR. For this step, the Main Research (requester) is responsible to complete all pertinent details at ([www.citiprogram.org](http://www.citiprogram.org)), to obtain and submit such certificate. | | |
|  | **REQUEST TYPE** | |

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| **Through this document, I submit to the HIU-IRB this authorization request as per the indicated procedure:** |
|
| ☐ Complete Revision ☐ Exempt Revision |

1. **MAIN RESEARCHER INFORMATION**

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| --- | --- | --- | --- | --- |
| **1. Name** | Last Name | First Name | | Acad. Degree |
| **2. Address** |  | | | |
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| **3. Phone / e-Mail** | E-Mail | | Phone | |
| **4. Category** | ☐ Postgraduate student ☐ Undergraduate student ☐ Faculty ☐ Other | | | |

1. **PERSONAL INFORMATION FOR:** ☐ Chair/Mentor☐ Main co-Researcher (if applicable)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1. Name** | Last Name | First Name | | Acad. Degree |
| **2. Address** |  | | | |
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|
| **3. Phone / e-Mail** | E-Mail | | Phone | |
| **4. Category** | ☐ Faculty ☐ Other (explain): | | | |

**NOTE: If the study has more than one Main Co-Researcher, please add this information at the end of the document following this same format.**

1. **PERSONNEL ASSISTING THE STUDY/RESEARCH.** If applicable **–** Enter the names of the key personnel (¹) that collect or handle data (example: Research Assistant, among others.). In columns, provide the dates of obtaining the corresponding certificates obtained through the CITI Program on Confidentiality and Privacy (HIPS), Protection of Humans (IRB) and RCR for all key personnel with this request.

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| --- | --- | --- | --- | --- |
| **Full Name** | **e-Mail** | ***HSR***  **month/day/year** | **HIPS/HIPAA**  **month/day/year** | **RCR**  **month/day/year** |
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**¹** Key personnel is defined in the glossary of NIH's Funding, Terms of Standards and Acronyms as participants in a notice of approval "award", which contributes considerably to the scientific development or execution of a project, including the main researcher. If necessary, add additional rows.

1. **BASIC INFORMATION ABOUT THE STUDY / RESEARCH**

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| --- | --- | --- | --- |
| **1. Study/Research Títle** |  | | |
|
| **2. Project duration after IRB approval** | Estimated beginning date: Estimated end date:       /      /      /      /      /      /  Month Day Year Month Day Year | | |
|
| **3. Research purpose** | ☐ Undergraduate ☐ Final Master’s Project ☐ Doctoral Dissertation  ☐ Other, explain | | |
|
| **4. Funds granted by:** | ☐ HIU Internal Funds (includes scholarships) ☐ Unfunded  ☐ External Funds, explain | | |
| **5. Study type** | ☐ Social Behavior ☐ Survey to users or experts ☐ New Product  ☐ Other, explain | | |
| **6. Information about other IRB’s** | Has this study/research been submitted for the approval of another IRB?  ☐ No ☐ Yes In this case Where?  ☐ Approved ☐ Not Approved When? | | |
| **7. Study/Research Place** |  | | |
| **8. Internet Use Yes** ☐ No ☐  If using the internet as a means to carry out or support the study / research, researchers must comply with Laws and Federal Regulations so IP should report how it will carry out the processes requested in this form in the network environment. (Add an annex explaining the ways and the means to be used) | | | |
| **9. Additional Revision**  **The IRB must analyze and approve (if applicable), proposed research / study subject to other special requirements by present laws and regulations.**    **Indicate if these special topics apply to this Investigation/Research**  **If you answer “Yes” to any of these questions, you must include an explanatory annex for each one.** | **Revision type** | **Required Revision** | **Comments** |
| **BIOSECURITY.** Use of Recombining ADN and its derivatives (bio-dangerous agents). | ☐ **Yes ☐ No** |  |
| **RADIOLOGICAL.** Use of radioactive drugs or radioisotopes in humans. | ☐ **Yes ☐ No** |  |
| **CLINICAL TRIALS** | ☐ **Yes ☐ No** |  |
| **ANIMALS USE AND CARE**. | ☐ **Yes ☐ No** |  |
| **EXPLOSIVES / CARCINOGENS / DRUGS** | ☐ **Yes ☐ No** |  |
| **CREATION OF DANGEROUS RESIDUES** | ☐ **Yes ☐ No** |  |
| **OTHER SUBSTANCES POTENTIALLY DANGEROUS** | ☐ **Yes ☐ No** |  |

1. **PURPOSE AND OBJECTIVES OF THE STUDY / RESEARCH**

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| 1. **Summary of the study/research problem. (Extract it from the Dissertation Project) (No more than 250 words)** |
| 1. **What do you expect to get from doing this study/research? Objectives. (Extract it from the Dissertation Project) (No more than 250 words)** |

1. **POPULATION DESCRIPTION**

According to Law 45 CFR 46, human being means a living individual from which a researcher (professional or student) does research and obtains: (1) data through intervention or interaction with the individual or; (2) identifiable private information (e.g.: pathological samples, academic, or medical records among others.)

|  |  |  |  |
| --- | --- | --- | --- |
| **1. Number of participants** | ☐ Both genders: up to a maximum of       people  ☐ Only Women (if applicable): up to a maximum of       people  ☐ Only Men (if applicable): up to a maximum of       people | | |
|  | ☐ Students | | ☐ Public Staff |
| **2. Type of participants** | ☐ Teachers-Professors | | ☐ Patients in a Health System |
|  | ☐ Experts | | ☐ Managers or Company workers |
|  | ☐ Others | | Explain: |
| **3. Vulnerable population**    **Explain why you will use vulnerable populations in the research/investigation proposal** | **Select all that apply:** | | |
| ☐ Minors | ☐ Pregnant women | |
| ☐ Illiterate | ☐ Aborted fetus or the result of delivery | |
| ☐ Seriously ill | ☐ Handicapped | |
| ☐ Ethnic minorities | ☐ Physical or mental limitations | |
| ☐ Confined | ☐ None of the above | |
| ☐ Others | Explain | |
| **4. Criteria for population inclusion and exclusion.**  **(Extract from Dissertation Project)** | Inclusion (who are the study participants)  Explain  Exclusion (who will NOT participate in the study):  If applicable, explain: | | |

1. **PARTICIPANTS’ RECRUITMENT PROCEDURES**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Will participants receive some incentive, economical compensation, or award before or after the study? (Answer even if the study will be internet based. Explain how it will get to participants)** | | | ☐ Yes **☐ No** |
| **If answer is YES, explain** | | | |
| 1. **Identify tools that will be used for participants’ recruitment (check all that apply).**   **Include all document related to this process, even if it is through the internet (if so, provide link)** | | | |
| ☐ Brochures | ☐ Advertisement (Newspapers/Magazines/TV/Radio/Internet) | | |
| ☐ Phone or email | ☐ Letter or Direct Contact request | | |
| ☐ Others | Explain: | | |
| **C. Will participants be recruited through information from a private registry?** | | **☐Yes ☐No** | |
| **If the answer is YES, specify source and mention NOTE below.** | | | |
| **NOTE: You must include a letter from the person responsible for registration, where he allows and authorizes that you can access the personally identifiable information for the purpose of this study. The letter should explain how access to identifiable information is ethically possible (in case there is confirmation that the participant has given permission to contact and authorize the distribution of his name, address and other identifying information).** | | | |

1. **DATA COLLECTION**

If you check “YES” in any of the following procedures, make sure you include that in your proposal and justify the need of the process in your investigation proposal. Describe precautions that will be taken to minimize risks. All items must be answered.

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** | **Answer “YES” or “NO” for each of the following premises and explain if you agree with what is requested from you.** |
| ☐ | ☐ | 1 State uses existing data or it is archived?  If the answer is “YES”, you should attach the institutional questionnaire that authorized the research to access this information.  If it did not exist, you should make a certified declaration on behalf of the person interested in this information, to authorize access to data If it did not exist, you should submit a certified declaration on behalf of the person in charge of the information to authorize Access to data or samples kept. |
| ☐ | ☐ | 2. ¿Will anonymous data be obtained? (nobody will be able to identify the participants) |
| ☐ | ☐ | 1. Will partially anonymous data be obtained? (Only the research will be able to identify the participant) Explain: |
| ☐ | ☐ | 1. Does Study/Investigation include using Surveys / Questionnaires?   If the answer is “YES”, attach a sample of Survey/Questionnaire to apply. |
| ☐ | ☐ | 1. If data is obtained anonymously, does it contain sensitive or concerning topics?   If answer is “YES”, explain reasons: |

1. **SENSITIVE OF INCRIMINATORY INFORMATION:** It is important to answer “YES” or “NO” in all the questions, even if the researcher understands that his study / investigation does not contain sensitive or incriminatory information.

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| --- | --- | --- |
| **YES** | **NO** | **A. Does the proposal contain sensitive or incriminatory information?** |
| ☐ | ☐ |
| ☐ | ☐ | 1. Does it contain questions about attitudes and sexual preferences or abortion? |
| ☐ | ☐ | 1. Does it contain questions about using alcohol, drugs or other addictive substances? |
| ☐ | ☐ | 1. Is the information collected related to illegal conducts? |
| ☐ | ☐ | 1. Is the information collected related to learning problems? |
| ☐ | ☐ | 1. If the information collected get publicized, could it hurt the participant’s finances, employment, or reputation in his community? |
| ☐ | ☐ | 1. If the information is collected from a medical record, and gets revealed, could it cause social stigmatization or discrimination? |
| ☐ | ☐ | 1. Is the information collected about the participant’s psychological well-being or mental health? |
| ☐ | ☐ | 1. Is the information collected related to depression or suicide? |
| ☐ | ☐ | 1. Is the information collected related to genetic or hereditary information? |
| ☐ | ☐ | **B. Does investigation include the use of information about third persons like family history or sexual contacts?**  If the answer is YES, describe how the consent and privacy of third persons will be protected. |
| **If you answered any affirmatively** | | 1. **Explain in detail how the participants’ sensitive information will be stored and protected.** |
| **If you answered any affirmatively** | | 1. **D. Describe specific procedures you will use to secure the confidentiality of the participants’ data.** |
| **If you answered any affirmatively** | | 1. **How long will documents related to this study/investigation be stored? (Example: consent, questionnaire, among others). Explain how they will be saved and how they will be destroyed after the mentioned study period ends.** |

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| **RISKS / BENEFITS** |

1. **RISKS**

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| Include a summary of the participants’ risk nature and magnitude (including secondary effects), stress or discomfort that could be expected when participating in this study. Consider the following questions when doing so:   1. What are the potential risks/discomfort associated with each intervention, or experimental procedure? *If there is data available, estimate: a) the likelihood that damage may occur, b) its severity, c) its reversibility. What procedures will be used to prevent / minimize any potential risk or discomfort? Examples of risks include physical, psychological (such as stress, discomfort, or invasion of privacy) and social risks (such as loss of employment or insurance). Research on the internet, (example: the possibility that third parties may see the information shared (hackers) resulting in an invasion of privacy that might result in loss of employment, insurance, among others).* |
| 1. In accordance with the above, choose the following risk of research   ☐ **Minimal risk** *(example: Tiredness or any discomfort that could happen within a normal activity in daily life).*  ☐ **More than minimal risk** *(example: physical, psychological, social risk).* |

1. **CONFIDENTIALITY**

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| 1. Will participants be asked to fill out any kind of document that will provide identifiers that will be shared with other entities? (example: volunteers from health organizations, support groups) | ☐ **Yes ☐ No** |
| If answer is YES, explain: | |
| 2. Will participants’ data be coded? | ☐ **Yes ☐ No** |
| If answer is YES, explain: | |
| 3. Will data be used for other purposes in addition to this investigation project? | ☐ **Yes ☐ No** |
| If answer is YES, explain: | |
| 4. Will participants’ information or coded data be available for any of the following?  Select all that apply. NOTE: Data must always be available for IRB revision.  ☐ Main Researcher ☐ Mentor ☐ NIH ☐ FDA  ☐ Study sponsor ☐ Other, explain: | |
| 5. Will any photographic, video or sound recording instrument be used to collect data?  If answer is YES, explain: | \*☐ **Yes ☐ No** |
| *NOTE: Consent must describe the security measures that will be taken to protect the confidentiality of the data in the Consent (example: who will have access to it, how and for how long it will be stored, among others). Investigations on the internet where data collection will be done using a provider of service (Survey Monkey, Google Forms, among others), with an online tool (internet), shall submit documentation that describe how the security of collected data will be handled.* | |
| 6. Will any tool, questionnaire, or other instrument to collect data be used? | ☐ **Yes ☐ No** |
| If answer is YES, explain: | |
| 7. You must inform what method you will use for the final disposition or destruction of any identifiable data. Include electronic means such as audio, photo, video film, electronic data, questionnaire, or any other data collection document. | |
| 8. Explain how you will dispose of data obtained using scheduled surveys, online surveys online (internet), among others. You must indicate the program that will be used to eliminate this information ("delete and/or erase" will not be acceptable). In the case of surveys, online quizzes, where, in most cases, data is obtained using service providers via the internet (survey monkey, among others) you must obtain in writing how they will use the data on their servers, this information should be placed as part of the documents accompanying the IRBNet Protocol. (You may be asked to submit other related documents). Explain how this process will happen: | |

1. **FINANCIAL INFORMATION**

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| 1. Will there be any payment or compensation to participants for their contribution to the investigation? | ☐ **Yes ☐ No** |
| 1. Describe the participants’ compensation method. *Include cash, gifts, gift cards, discount coupons, travel reimbursement, among others.* | |
| b) Specify quantity, if applicable, and indicate if it is cash or check. ☐ Cash ☐ Check $ | |
| c) Explain when and how compensation will occur. | |
| d) Based upon participation extension, will it be divided in equal parts?  If you answered YES, describe disbursement and quantity: $ | ☐ **Yes ☐ No** |
| 2. Is there any cost related to the investigation that goes above those incurred in standard treatments?  (Example: additional testing, hospitalization, prescriptions, gadgets, among others).  **Indicate who will be responsible for payment**: | |
| 3. ¿Is there any financial responsibility for the participant or third persons with insurance companies?  If you answered YES, indicate quantity: $ | ☐ **Yes**  **☐ No** |
| 4. What is the maximum amount for which the participant can be responsible, without considering the insurance of third persons? $ | |
| 5. Are there additional expenses for the participant related to this protocol?  If you answered YES, please describe and include details in the consent document. | ☐ **Yes ☐ No** |

1. **CONSENT**

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| Federal laws require a consent document, ***written and signed***, unless an alteration or resignation is justified. See details below in this page. Provide an annex with a copy of the consent document. Avoid using jargon or technical terms.  **Note: After the participant signs the consent document, he must be provided with a copy of the document.**  According to Law 45 CFR 46.116 (d) to grant an alteration or release, it must contain the following elements  (1) . The research involves no more than minimal risk to the subjects  (2) Release or alteration will not adversely affect participants’ rights or well-being.  (3) Investigation could not occur without the release or alteration.  (4) When appropriate, participants will receive additional information after their participation.  In addition, one of the alternatives should be applied in accordance with Law 45 CFR 46.117 (c):   1. The only record that connects participants with research is the consent document and the main risk is the potential damage as a result of a breach of confidentiality. Each participant will be informed if he wants to see documents that link him to the investigation and his wish will be granted, or   (2) That investigation only has minimal risk to hurt participants and does not have procedures through which the written consent would be necessary beyond the context of the investigation. | | |
| 1. **PARTICIPANT’S INFORMATION IN THE CONSENT DOCUMENT.** | | |
| 1. Define which will be the consent type that will be used in the investigation: | | |
| **Option 1**  ☐ Written Consent is required | Consent document will be signed by the participant(s). If there are minors, it will be signed by the parent or person in charge 45(CFR) 46.117 (**minor 7-13**) **must include assent; (minor 14-20) will sign consent in agreement with the parent**. This document must be included with all other required documents. | |
| **Option 2**  ☐ Consent Release | Because the only connection between the participant and the research would be the consent document and the main risk would be the possible damage resulting from a breach of confidentiality. The participant will be asked if he wants information to link him to research and his wishes will be respected. In accordance with Law 45 CFR 46.117.c (1). Select all that apply:  ☐ Request release of consent document  ☐ Request release of the process to get consent  ☐ Release of some element in consent, explain  Justify: | |
| **Option 3**  ☐ Consent reléase Minimal Risk | Because research has no more than minimal risk. Procedures that will be used are that normally a document of consent is not required when they are conducted outside research.45 CFR 46.117.c.(2). Select all that apply:  ☐ Request release of consent document  ☐ Request release of the process to get consent  ☐ Release of some element in consent, explain  Justify: | |
| **NOTE: If you request a consent document release, you must deliver an "Informative Sheet" to the participant. This Informative Sheet must be submitted with the other documents to be delivered to the participant and which will be submitted for IRB review.** | | |
| 1. Indicate what will be the procedures to be used to obtain consent (even if you request a consent release or use the internet as a medium): | | |
| 1. Indicate how you will get the consent (Selecta all that apply): | | |
| ☐ in person (face to face) | | ☐ electronic mail |
| ☐ phone | | ☐ web page/link (include document even if you include link): |
| ☐ written document | | ☐ other: |
| ☐ regular mail (Postal) | | ☐ N/A release of the process to get consent |
| 1. Explain **how, when and where** the consent will be obtained as a (signed) document or the consent as a process (informative sheet) (describe the place where you will discuss the study with participants). \* Remember that you must complete this part even when requesting consent release as a document because you must explain how you will get the consent as a process. If the study is through the internet, you must indicate how you will handle the information requested through the cyber environment. | | |
| 1. How will you assess if participants understand the purpose of the study? Participants’ response must include purpose, duration and study procedures, among others. If the study is through the internet you must indicate how you will handle the information requested through the cyber environment. | | |

1. **RESEARCHER’S CERTIFICATION ABOUT CONFLICT OF INTEREST**

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| It is expected that all researchers have signed an appropriate declaration of Conflicts of Interest in their workplaces. If you have not done so, please be sure to sign the appropriate documents before you submit your protocol to HIU-IRB   * Have you (your spouse, a child, a family member or anyone else working with you in this place, example: investigator or co-investigator, responsible for the award or administration of sponsored programs) requested or accepted bonuses, favors or anything of monetary value from contractors in the amount of one hundred dollars ($100.00) or more? ☐ **Yes ☐ No**   (If you answered YES, you must submit a letter explaining any conflict of interest).   * Have you (your spouse, a child, a family member or anyone else working with you in this place, example: investigator or co-investigator, responsible for the award or administration of sponsored programs) used your position with the purpose of giving the idea of being motivated by an economical benefit for them or others such as those who have family, businesses or other deals? ☐ **Yes ☐ No**   (If you answered YES, you must submit a letter explaining any conflict of interest).   * Have you (your spouse, a child, a family member or anyone else working with you in this place, example: investigator or co-investigator, responsible for the award or administration of sponsored programs) received profits working as an HIU officer (employee, associate, agent, and spouses of the officer, employee, associate or HIU staff and dependent children) in excess of $10,000 and representing more than 5% interest as the owner of an entity? ☐ **Yes ☐ No**   (If you answered YES, you must submit a letter explaining any conflict of interest).   * Have you (your spouse, a child, a family member or anyone else working with you in this place, example: investigator or co-investigator or sub-investigator, responsible for the award and/or administration of externally funded programs) received salaries, gratuities, or other contract payments or from subordinate parts when they worked with the officer (employee, associate, agent, and spouses of the officer, employee, associate or HIU staff and dependent children) in excess of $10,000 for a period of twelve months? ☐ **Yes ☐ No**   (If you answered YES, you must submit a letter explaining any conflict of interest). |

1. **RESEARCHERS’ WARRANTIES AND OBLIGATIONS**: To complete the process of submitting your application for IRB review, submit all the documents listed in the annexes to this document's application. In addition, by signing, you agree to the following

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| --- | --- |
| **XV – MAIN RESEARCHER’S WARRANTY AND OBLIGATIONS (IP)** | |
| I certify that all the information provided in this presentation (including all supporting documents) is a complete and accurate description of the proposed study. I agree to the following: | |
| |  |  | | --- | --- | | Main Researcher’s Initials |  |   This study will be conducted in the manner described in this presentation and will not be implemented (including the recruitment of subjects or consent) until all the Institutional Review Boards have granted permission to conduct the research. Changes to this study will not be implemented until a form of modification was filed and the same has been approved by the Institutional Review Committee (HIU-IRB)   |  |  | | --- | --- | | Main Researcher’s  Initials |  |   If HIU’s Institutional Review Committee approves this study via a full or accelerated procedure, I will refer it to an ongoing review as set forth in the approval letter. If the analysis of the study or data exceeds the approval period, I will send a submission form for continuous review of studies approved by the Institutional Review Committee in a timely manner (well in advance to the date of renewal). I understand that the study activities could not continue beyond the approval period.   |  |  | | --- | --- | | Main Researcher’s  Initials |  |   I will submit a copy of the consent form signed by the subject or patient if applicable. | |  |  | | --- | --- | | Main Researcher’s Initials |  |   I will keep all signed informed consent documents and records related to study for a minimum of three (3) years (or more, according to the funding agencies stipulations) from the date of completion of the study.   |  |  | | --- | --- | | Main Researcher’s Initials |  |   I will inform in writing any serious adverse event to the Institutional Review Committee within 24 hours, and all other not anticipated adverse events and problems within 5 business days.   |  |  | | --- | --- | | Main Researcher’s Initials |  |   I will give participants all new significant information obtained during this study and will submit reports on the new information to the Review Committee as an amendment to the study.   |  |  | | --- | --- | | Iniciales del IP |  |   If my study has been approved on the levels of accelerated or complete review, I will inform the Institutional Review Committee when the study has ended (no more data will be received or new analysis will be done). This report will be submitted no more than 30 days from the end of the study through a closing report form from the Institutional Review Committee. |
| **Signature of the Main Researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Full Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |

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| **VII – ADVISOR’S (CHAIR) WARRANTIES AND OBLIGATIONS (FOR STUDENTS MAIN RESEARCHERS)** |
| If this study is to complete a degree diploma requisite, the thesis advisor or director must sign the following testimony.   * All departmental approvals by the students’ committee of students have been completed (if applicable) and by the thesis director or counselor. * I agree that the University and the Institutional Review Committee consider that the responsibility of the Faculty Advisor is equal to that of the student with regard to:   + The quality of the research design and the protocol correctness   + The appropriateness of the methods of recruitment, of the design of the process to inform subjects about the nature of the study and the process for obtaining informed consent.   + The legibility, correctness and format of assent and informed consent documents and the explanation of all informed consent procedures.   My signature below attests that I have read this presentation in its entirety, and think that it is correct, complete, appropriate, and complies with the principles of the Belmont report, having completed all departmental approvals by the students’ committee. |
| **Advisor’s signature (Chair) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Full Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

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| **(HIU-IRB exclusive use) HIU-IRB CONCLUSION. SIGNATURE.** |

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| **HIU-IRB CONCLUSION ABOUT THIS REQUEST** |
| The Institutional Review Board at Humboldt International University, after the corresponding analysis of the request and the documents presented by the Main Researcher:  (Full name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Considering grounds to justify the fulfillment of Law 45 CFR 46, "Common Rule", which prohibits beginning any research/study without review and approval from an IRB, and other laws and regulations. I do note that HIU-IRB considers the request as:  ☐ **Approved ☐ Not Approved** |
| **HIU-IRB President \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **HIU-IRB Secretary \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

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