**INSTITUTIONAL REVIEW BOARD**

 **VALLEY VIEW UNIVERSITY**

**UNIVERSITY RESEARCH CENTER**

**GHANA**

***APPLICATIONFOR ETHICAL REVIEW OF RESEARCH PROTOCOL***

Submission forms may be obtained from the VVU-IRB office or [enter email]. **Completed forms must be returned; collated and stapled/clipped, to the VVU-IRB office , Valley View University.**

The following documents should be enclosed to make a submission complete:

|  |  |
| --- | --- |
|  | **NUMBER OF COPIES** |
|  | **Academic Research** | **Other Researches** |
| **A For all research:**  |
| * Application Cover letter
 | **1** | **1** |
| * Completed Application Form
 | **2** | **6** |
| * Research Protocol/Proposal
 | **2** | **6** |
| * Informed Consent Form
 | **2** | **6** |
| * Summary of protocol (Not more than 3 pages)
 | **N/A** | **6** |
| * Data Collection Instrument(s):Case Report form, questionnaires and/or interview guide
 | **2** | **6** |
| * Proof of notification or written approval or permission from study site/facility (where study is to be conducted**)**
 | **2** | **6** |
| * Proof of payment of IRB Fees
 | **1** | **1** |
| * Soft Copies of all submitted documents
 | **1** | **1** |
| **B. Specifics:**  |
| Curriculum Vitae of Principal Investigator showing research experience (for Clinical and Field trials) | **N/A**  | **1** |
| * Written approval or permission on official letterhead from Supervisor (for Academic Purposes)
 | **1** | **N/A**  |
| * Other Relevant Documents (Please specify)
 | **2** | **6** |

***Please note that ethics review is conditional upon submission of all the required documents above***

***1.0 GENERAL INFORMATION***

* 1. **Title of Research**

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| --- |
|  |

* 1. **Principal Investigator’s Status**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| (VVU Staff | **[ ]** ) |  |  | (Student | **[ ]** ) | (Other | **[ ]** Please specify……………………………………) |

* 1. **Purpose of Research**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| (Non-Degree Purposes  | **[ ]** ) | (Diploma  | **[ ]** ) | (1st Degree  | **[ ]**  | (2nd Degree  | **[ ]** ) | (PhD  | **[ ]** ) |

* 1. **Nationality of Principal Investigator**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| (Ghanaian | **[ ]** ) | (Non- Ghanaian (Resident) | **[ ]** ) | (Non-Ghanaian (Non-Resident) | **[ ]** ) |

**1.5 Principal Investigator**

|  |  |
| --- | --- |
| Name |       |
| Degree(s)  |       |
| Title: Prof/Dr/Mr/Miss/Ms |       |
| Institution & Department |       |
| Telephone:      | Postal Address: |
| Email:      |

**1.6 Co-Investigator (I)**

|  |  |
| --- | --- |
| Name and Signature |       |
| Degree(s) |       |
| Title: Prof/Dr/Mr/Miss/Ms |       |
| Institution & Department |       |
| Telephone: Email:  | Postal Address:      |

**1.7 List all other co-investigators below (names, degrees, departments and institutions).**

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* 1. **Student project:**
		1. **For which degree/diploma is the study being conducted?** *(Please state specific degree and Institution)*

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* + 1. **Who will be the supervisor?** *(Check where Applicable)*

 [ ]  Principal Investigator (named above) [ ]  Other (*fill in details below*)

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|  |  |
| --- | --- |
| Name and Signature of Supervisor (If different from PI) |  |
| Department |  |
| Telephone:      Email:      | Postal Address:      |

* 1. **Where will the Research be carried out (site)?** *(Provide name of Hospital/Institution and specific Department or*

*Town/District/Village etc.*)

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**\***Please submit proof of notification or written approval/permission on official letterhead from proposed research site/facility

* 1. **Have you had Good Clinical Practice (GCP) or Good Laboratory Practice (GLP) training in the past three years? (for Clinical Research)**

Yes[ ]  No[ ]  N/A [ ]

Please state the name of place and dates of training. (Attach evidence e.g. certificate)

**\***GCP training for PIs is mandatory for all proposals to conduct clinical trials

**1.11 Does your research involve administration of a new drug?** Yes[ ]  No[ ]  N/A [ ]

**1.12 If yes to 1.11, do you have Food and Drugs Authority (FDA) Approval?** Yes[ ]  No[ ]

**1.12.1 Have you applied to the FDA?** Yes[ ]  No[ ]

**1.13 Can your work be classified as research?** (*Read the following statements and check where applicable*): The activity I wish to undertake is a systematic investigation[[1]](#footnote-1), including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge[[2]](#footnote-2).

Yes (my work is research) [ ] No (my work is not research) [ ]  (*The board only review research*)

**1.14 Does your work involve human participants?** Yes[ ]  (*Check below, where applicable*): No[ ]  but my work involves identifiable human tissue/records No[ ]  *(please consult us, your proposal may not require ethics review)*

[ ]  My work will involve a living individual about whom an investigator conducting research obtains data through intervention[[3]](#footnote-3) with the individual

[ ]  My work will involve a living individual about whom an investigator conducting research obtains data through interaction[[4]](#footnote-4) with the individual.

[ ]  My work will involve a living individual about whom an investigator conducting research obtains identifiable[[5]](#footnote-5) private information[[6]](#footnote-6).

[ ]  My work will involve using records already gathered on people.

[ ]  My work has earlier been approved by VVU-IRB *(please submit letter of approval or quote previous approval Number)*

[ ]  My work will involve using human samples. If so, where will the samples be kept? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Note:** *Ethical issues surrounding the storage of blood and/or tissue samples internationally stipulate that if blood specimens are to be stored for future analysis and it is planned that such analysis will be done outside the facility/country where research is to be conducted, then the blood must be stored in the facility with release of sub-samples only conditional on approval of such a project by authorities of the facility as well as VVU-IRB.*

**1.15** **Work Plan**

|  |  |  |
| --- | --- | --- |
| Project Start date: |  | (dd/mm/yr) |
| Recruitment Start Date: |  | (dd/mm/yr) |
| Recruitment End Date: |  | (dd/mm/yr) |
| Project End date: |  | (dd/mm/yr) |

**1.16 How do you intend to fund the study?**

Donor/Grant [ ]  (*please name sponsor*)

VVU [ ]  (*please specify fund*)

Ghana Government[ ]  (*please name agency*)

Other[ ]  (*please name agency)*

Self *(please explain how you can guarantee this, if for clinical or interventional research)*

What is your total budget? (Please state how much) …………………………………………….

**Enter Summary of Budget**

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**1.17 Has the requisite administrative payments for this application?** Yes[ ]  No[ ]

***2.0 INFORMATION ABOUT YOUR PROPOSED RESEARCH***

* 1. **Study Background** *(include relevant African and/or Ghanaian Literature, with references)*

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**2.2** **Study Aim and Objectives**

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**2.3** **Study Hypothesis or Conceptual framework**

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**2.4** **Study Design** *(please elaborate)*

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**2.5 Procedures to be undertaken**

**Please mark** **[x]  all research procedure(s) that will be employed:**

Record review [ ]  Interview schedule or guide (must be attached)[ ]

Questionnaire (must be attached)[ ]  Physical Examination [ ]

 Drug or other substance administration[ ]  X-rays [ ]  Biopsy [ ]

Isotope administration [ ]  Blood sampling: venous[ ]  ; arterial [ ]

Please summarise all procedures/processes to be involved in the study *(maximum of 1 page):*

|  |
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**2.6 Inclusion and Exclusion criteria for the Study Population** *(Please list and explain where necessary)*

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**2.7 Please describe how and where you will contact or approach participants to enrol in your study**

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**2.8 Please describe how you will undertake the consent process and its documentation**

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**2.9 Will participants be completely anonymous?** Yes[ ]  No[ ]

Explain how participants’ identities will be protected

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**2.10 How long, and in what way will records be retained?**

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**2.11 Who will have access to the stored Data?**

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**2.12** **What risks are there to participants** *(include possible loss of confidentiality, discomfort, inconvenience, delays in service delivery etc.***)**

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*Risk should, as much as possible, be minimal i.e., the probability and magnitude of harm or discomfort anticipated in the research should not be greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exam or test.*

**2.13 Methods of minimising risks of participation in the study** *(address all risks named in 2.12 above)*

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**2.14 Potential direct benefits to participants** (*benefits that research participants hope to gain, in the course of the study, solely as a result of participation)*

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**2.15 Compensation to participants** (*for inconvenience, time, re-imbursement for transport, reciprocation for commitment, good will or participation)*

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**2.16 Potential benefits to study population, science and/or society** *(relevance of proposed study to society)*

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**2.17 Sample size** (please justify the selected number statistically in your proposal)

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| --- | --- |
| Number of participants to be enrolled per year |       |
| Total number of study participants |       |

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| --- | --- | --- | --- | --- |
| **Principal Investigator's Signature** |  |  |  | **(dd/mm/yr)** |

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**Name of Principal Investigator**

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| --- | --- | --- | --- | --- |
| **Student’s Signature *(if applicable)*** |  |  |  | **(dd/mm/yr)** |

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| --- | --- | --- | --- | --- |
| **Supervisor's Signature *(if applicable)*** |  |  |  | **(dd/mm/yr)** |

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**Name of Supervisor**

1. *Typically, a predetermined method for studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory. Examples: observational studies, interview or survey studies, group comparison studies, program evaluation, test development, interventional research.* [↑](#footnote-ref-1)
2. *Typically requires that results (or conclusions) of the activity are intended to be extended beyond a single individual or an internal program. Examples: activities where there is an intent to publish the results in a peer-reviewed journal or to present at a regional or national meeting, as well as, theses or dissertation projects conducted to meet the requirements of a graduate degree.*  [↑](#footnote-ref-2)
3. *Both physical procedures (e.g., venipuncture) and manipulations of living individuals or the living individuals’ environments.* [↑](#footnote-ref-3)
4. *Communication or interpersonal contact between the investigator (or research team) and the living individual. Examples: interviews, questionnaires, surveys, observations, manipulations of subject behaviour, diet, or environment, physical measurements, specimen collection (e.g., blood tissue), administration of experimental drugs or devices.* [↑](#footnote-ref-4)
5. *If 1) the identity of the individual from whom the information was obtained is ascertained or may be readily ascertained by the investigator; or 2) the identity of the individual from whom the information was obtained is associated or may be readily associated with the information.* [↑](#footnote-ref-5)
6. *Private Information: information about behaviour that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place or information that has been provided for specific purposes that the individual can reasonably expect will not be made public (e.g., medical record, employee or student records).*  [↑](#footnote-ref-6)