Head of Department
Research Grants and Contracts Manager
University of Leicester
University Road
Leicester United Kingdom
LE1 7RH

Grant Ref: MR/M01987X/1

Date: 31 March 2015

Dear Head of Department

GRANT OFFER: Research Grant, Research Grants
GRANT TITLE: Genetic Admixture and Host-Pathogen Interactions in Helicobacter pylori Infection

The MRC is offering a grant towards the cost of the above project, subject to the terms and conditions set out below.

Return of the 'Offer Acceptance' will be taken as acceptance of the grant on the terms stated. If you are unable to accept the grant you should return a 'Decline' confirmation as soon as possible. Upon receipt of the 'Offer Acceptance' a 'Start Confirmation' request will be issued.

Grants are cash limited and expenditure against the grant must not exceed the value awarded apart for reasons stated in the standard terms and conditions.

Please note copies of this letter have not been sent to the grant holder and co-investigators (as appropriate); it is your responsibility to distribute copies as is necessary.

Yours faithfully

Grants Pre Award Team
UK SBS
A service provided on behalf of MRC

Organisation: University of Leicester

Grant Holder: Dr Sandra de Sousa Beleza

Grant Title: Genetic Admixture and Host-Pathogen Interactions in Helicobacter pylori Infection

Starts: 1 May 2015 **Ends:** 30 April 2018 **Duration:** 36

GRANT VALUE

Funds Awarded

	Authorised FEC (£)			RC Contribution (£)			
	net	Indexation	Total	net	Indexation	Total	% FEC
DI - Staff	129,465	2,109	131,574	103,572	1,687	105,259	80
DI - T&S	9,000	147	9,147	7,200	117	7,317	80
DI - Other Costs	216,895	3,533	220,428	173,516	2,826	176,342	80
DA - Investigators	36,726	598	37,325	29,381	479	29,860	80
DA - Estate Costs	61,444	1,001	62,445	49,155	801	49,956	80
DA - Other Directly Allocated	7,915	129	8,044	6,332	103	6,435	80
Indirect - Indirect Costs	142,954	2,328	145,282	114,363	1,863	116,226	80
Total Value of Award	604,399	9,844	614,244	483,520	7,875	491,395	

Cost of Access to Facilities 0
(Funds not awarded to Grant Holding Organisation)

STAFF

Staff Summary

	Authorised FEC net	RC Contribution net	Number Of Staff Months
Investigator	36,726	29,381	10
Researcher	129,465	103,572	37

Staff and DI Investigator Details

Start Date	End Date	Duration	FTE Percent	Name or Post Identifier	Summary Fund Heading	Authorised Cost (Excluding Indexation)
1 May 2016	30 April 2017	12	5	Dr M J Blades	Directly Incurred	2318.28
1 May 2015	30 April 2018	36	100	PDRA	Directly Incurred	127146.84

DA Investigator Details

Average Hours/week	Name or Post Identifier
0	Professor M Oggioni
10	Dr S de Sousa Beleza

EQUIPMENT DETAILS

Description	Delivery Date	Country Of Origin	Total Value

FACILITY AND SERVICE DETAILS

Facility	Cost of Access	Number of Units

PROJECT PARTNERS

Organisation	Department	Last Name	First Name	In Kind Value(£)	Monetary Value (£)

GRANT ADDITIONAL INFORMATION

In line with the implementation of the Wakeham review, the indirect costs on this grant have been adjusted by the efficiency factor associated with the efficiency group in which your organisation has been placed, which in most cases results in a reduction compounded over the duration of the grant. Further information is available at:
http://www.rcuk.ac.uk/research/Efficiency/Efficiency2011/

GRANT CONDITIONS

CALL CONDITIONS

RESEARCH COUNCIL CONDITIONS

SCHEME CONDITIONS

Terms and Conditions of Grants

Terms and Conditions of Research Council fEC Grants

These terms and conditions relate to grants, comprising Research Grants and Fellowships, costed and funded on the basis of full economic costs (fEC), calculated in accordance with the TRAC methodology (universities and other higher education bodies) or by an equivalent methodology by other Research Organisations.

Grants awarded by the Research Councils are made to Research Organisations on the basis of this single set of core terms and conditions. The Research Councils are:

* Arts and Humanities Research Council (AHRC)
* Biotechnology and Biological Sciences Research Council (BBSRC)
* Economic and Social Research Council (ESRC)
* Engineering and Physical Sciences Research Council (EPSRC)
* Medical Research Council (MRC)
* Natural Environment Research Council (NERC)
* Science and Technology Facilities Council (STFC)

Individual Councils may add additional conditions to the grant to reflect the particular circumstances and requirements of their organisation, or the nature of a particular grant. Acceptance of a grant constitutes acceptance of both the core conditions and any additional conditions. Any request by the grant holder to the council to vary these terms and conditions must be submitted through the Je-S grants maintenance facility and approved in writing by someone authorised to do so on behalf of the Council.

The Research Councils reserve the right to vary these terms and conditions

Definitions Research Council: any of the bodies listed above

* Grant: support for a proportion of the full economic costs of a project. A Grant may be either a Research Grant or a Fellowship.

* Research Grant: a contribution to the costs of a stated research project which has been assessed as suitable for funding through the procedures established by the relevant Research Council.
* Fellowship Grant: an award made through a fellowship competition providing a contribution to the support of a named individual. It covers the cost of the time dedicated by the fellow to their personal research programme, and may or may not include research support costs.

Grant Holder: the person to whom the grant is assigned and who has responsibility for the intellectual leadership of the project and for the overall management of the research. The Grant Holder is either the Principal Investigator (in the case of a Research Grant) or a Research Fellow (in the case of a Fellowship Grant)

Co-Investigator: a person who assists the Grant Holder in the management and leadership of a project.

Research Organisation: the organisation to which the grant is awarded and which takes responsibility for the management of the research project and the accountability of funds provided.

Full Economic Costs (fEC): a cost which, if recovered across an organisation's full programme, would recover the total cost (direct, indirect and total overhead) including an adequate recurring investment in the organisation's infrastructure.

Directly Incurred Costs: costs that are explicitly identifiable as arising from the conduct of a project, are charged as the cash value actually spent and are supported by an audit record.

Directly Allocated Costs: the costs of resources used by a project that are shared by other activities. They are charged to projects on the basis of estimates rather than actual costs and do not represent actual costs on a project-by-project basis.

Indirect Costs: non-specific costs charged across all projects based on estimates that are not otherwise included as Directly Allocated Costs. They include the costs of the Research Organisation's administration such as personnel, finance, library and some departmental services.

Exceptions: Directly Incurred Costs that Research Councils fund at 100% of FEC. subject to actual expenditure incurred, or items that are outside FEC.

Transparent Approach to Costing (TRAC): an agreed methodology used by universities and other higher education bodies for calculating full economic costs.

Funding Assurance Programme: a programme of visits and office-based tests to seek assurance that grant funds are used for the purpose for which they are given and that grants are managed in accordance with the terms and conditions under which they are awarded.

Data Protection Regulations
The Research Councils will use information provided on the grant proposal for processing the proposal, the award of any consequential grant, and for the payment, maintenance and review of the grant. This may include:

* Registration of proposals.
* Operation of grants processing and management information systems.
* Preparation of material for use by referees and peer review panels.
* Administration, investigation and review of grant proposals.
* Sharing proposal information on a strictly confidential basis with other funding organisations to seek contributions to the funding of proposals.
* Statistical analysis in relation to the evaluation of research and the study of trends.
* Policy and strategy studies.

To meet the Research Councils' obligations for public accountability and the dissemination of information, contents of research proposals may also be made available on the Research Councils' web sites and other publicly available databases, including Gateway to Research, and in reports, documents and mailing lists.

After completion of the grant, the Research Council may contact the Grant Holder concerning funding opportunities or events, or for the purposes of evaluation. In some instances, the Research Council may wish to authorise an affiliate organisation to contact the Grant Holder on its behalf. It is assumed that, by agreeing to these terms and conditions, the Research Organisation consents to this on behalf of the Grant Holder, but if the Grant Holder prefers not to be contacted in this way, he or she should state this to the Research Council. Grant Holders may choose to opt out at any point, provided they comply with all other terms and conditions associated with the grant.

Freedom of Information Act and Environmental Information Regulations

Attention is drawn to the provisions of the Freedom of Information Act 2000 (FOIA) and the Environmental Information Regulations (EIRs). Research Councils have issued Publication Schemes which set out the types of information publicly available on their websites or published as documents. In addition, Research Councils have an obligation to respond to specific requests and may be required to disclose information about or provided by Research Organisations. In some cases the Research Council may consult the Research Organisation before disclosure, but it is under no obligation to do so. If a Research Organisation considers that any information it provides to a Research Council would be subject to an exemption under FOIA or the EIRs it should clearly mark the information as such and provide an explanation of why it considers the exemption applies and for how long. The Research Council will consider this explanation before disclosure, but it is not obliged to accept it as binding.

Where a Research Council determines that a Research Organisation is holding information on its behalf that it requires in order to comply with its obligations under FOIA or EIRs, the Research Organisation undertakes to provide access to such information as soon as reasonably practicable on request of the Research Council and in any event within 5 working days.

In some cases Research Organisations may be directly responsible for complying with FOIA and the EIRs; in such cases the Research Councils accept no responsibility for any failure to comply by the Research Organisations.

Grant Conditions GC1 - GC25 GC 1 Responsibilities of the Research Organisation

* The Research Organisation must ensure that any part of the Full Economic Cost of the project not funded by the Research Council grant is committed to the project before it starts.
* The Research Organisation must ensure that the Grant Holder and Co-Investigators are made aware of their responsibilities and that they observe the terms and conditions of grants.
* The Research Organisation must ensure that the research supported by the grant complies with all relevant legislation and Government regulation, including that introduced while work is in progress. This requirement includes approval or licence from any regulatory body that may be required before the research can commence.
* The Research Organisation is expected to adopt the principles, standards and good practice for the management of research staff set out in the 2008 Concordat to Support the Career Development of Researchers, and subsequent amendments. The Research Organisation must create an environment in which research staff are selected and treated on the basis of their merits, abilities and potential. It must ensure that reliable systems and processes are in place so that the principles of the Concordat are embedded into practice within the Research Organisation. It must ensure compliance with all relevant legislation and Government regulation, including any subsequent amendments introduced while work is in progress.
* The Research Organisation is responsible for compliance with the terms of the Equality Act 2010 including any subsequent amendments introduced while work is in progress; and for ensuring that the expectations set out in the RCUK statement of expectations for equality and diversity are met.
* The Research Organisation is expected to adopt the principles, standards and good practice for public engagement with research set out in the 2010 Concordat for Engaging the Public with Research: http://www.rcuk.ac.uk/per/Pages/Concordat.aspx. The Research Organisation must create an environment in which public engagement is valued, recognised and supported. It must ensure that reliable systems and processes are in place so that the principles of the Concordat are embedded into practice within the Research Organisation.
* The Research Organisation must appoint a Research Fellow as an employee for the full duration of the award.
* The Research Organisation must integrate the Research Fellow within the research activities of the host department, whilst ensuring that he or she is able to maintain independence and focus on their personal research programme.
* The Research Organisation must notify the Research Council of any change in its status, or that of the Grant Holder, that might affect the eligibility to hold a grant.
* The Research Organisation must ensure that the requirements of the Employing Organisation under the Department of Health's Research Governance Framework for Health and Social Care (or equivalent) are met for research involving NHS patients, their organs, tissues or data, and that the necessary arrangements are in place with partner organisations. Where it also accepts the responsibilities of a Sponsor (as defined in the Governance Framework), it must also ensure that the requirements for Sponsors are met.
* The Research Organisation must ensure proper financial management of grants and accountability for the use of public funds.
* The Research Organisation must ensure that adequate business continuity plans are in place to ensure that operational interruptions to the research are minimised.

GC 2 Research Governance

It is the responsibility of the Research Organisation to ensure that the research is organised and undertaken within a framework of best practice that recognises the various factors that may influence or impact on a research project. Particular requirements are to ensure that all necessary permissions are obtained before the research begins, and that there is clarity of role and responsibility among the research team and with any collaborators. The Research Councils expect research to be conducted in accordance with the highest standards of research integrity and research methodology.

Research Ethics

The Research Organisation is responsible for ensuring that ethical issues relating to the research project are identified and brought to the attention of the relevant approval or regulatory body. Approval to undertake the research must be granted before any work requiring approval begins. Ethical issues should be interpreted broadly and may encompass, among other things, relevant codes of practice, the involvement of human participants, tissue or data in research, the use of animals, research that may result in damage to the environment and the use of sensitive economic, social or personal data.

Use of Animals in Research

Wherever possible, researchers must adopt procedures and techniques that avoid the use of animals. Where this is not possible, the research should be designed so that:
* The least sentient species with the appropriate physiology is used.
* The number of animals used is the minimum sufficient to provide adequate statistical power to answer the questions posed.
* The severity of procedures performed on animals is kept to a minimum. Experiments should be kept as short as possible. Appropriate anaesthesia, analgesia and humane end points should be used to minimise any pain and suffering.

The provisions of the Animals (Scientific Procedures) Act 1986, and any amendments, must be observed and all necessary licences must have been received before any work requiring approval takes place.

N.B. Please see GC5 "Changes in Research Project" in the event of any proposal to change the arrangements for use of animals in a Research project.

Medical and Health Research

The Research Organisation is responsible for managing and monitoring the conduct of medical and health research in a manner consistent with the Department of Health's Research Governance Framework for Health and Social Care (or equivalent). There must be effective and verifiable systems in place for managing research quality, progress and the safety and well-being of patients and other research participants. These systems must promote and maintain the relevant codes of practice and all relevant statutory

review, authorisation and reporting requirements.
Research involving human participants or data within the social sciences that falls outside the Department of Health's Research Governance Framework must meet the provisions and guidelines of the ESRC's Research Ethics Framework. While this research may involve patients, NHS staff or organisations, it is defined as research that poses no clinical risk or harm to those who are the subjects of research. Research Organisations must ensure that appropriate arrangements are in place for independent ethics review of social science research that meets local research ethics committee standards.
Significant developments must be assessed as the research proceeds, especially those that affect safety and well-being, which should be reported to the appropriate authorities and to the Research Council. The Research Organisation must take appropriate and timely action when significant problems are identified. This may include temporarily suspending or terminating the research.
The Research Organisation is responsible for managing and monitoring statutory requirements for which it accepts responsibility, for example, in relation to legislation on clinical trials, use of human organs, tissues and data.
Guidance by the MRC on the conduct of medical research, and by ESRC on the conduct of social science research, provided on behalf of all Research Councils, must be observed.

Health and Safety

The Research Organisation is responsible for ensuring that a safe working environment is provided for all individuals associated with a research project. Its approach and policy on health and safety matters must meet all regulatory and legislative requirements and be consistent with best practice recommended by the Health & Safety Executive.
Appropriate care must be taken where researchers are working off-site. The Research Organisation must satisfy itself that all reasonable health and safety factors are addressed. The Research Councils reserve the right to require the Research Organisation to undertake a safety risk assessment in individual cases where health and safety is an issue, and to monitor and audit the actual arrangements made.

Misconduct and Conflicts of Interest

The Research Organisation is required to have in place procedures for governing good research practice, and for investigating and reporting unacceptable research conduct, that meet the requirements set out in the Concordat to Support Research Integrity (2012) http://www.universitiesuk.ac.uk/highereducation/Pages/TheconcordattosupportresearchintegrityAspx and the Research Councils' Code of Conduct and Policy on the Governance of Good Research Conduct (2009) and any subsequent amendments. The Research Organisation must on request provide information on its management of research integrity and ethics in response to the Research Councils' assurance questions, as described at: http://www.rcuk.ac.uk/funding/researchintegrity/
The Research Organisation must ensure that potential conflicts of interest in research are declared and subsequently managed.

GC 3 Use of Funds

Subject to the following conditions, grant funds may be used, without reference to the Research Council, in such a manner as to best carry out the research. Grant funds include a provision for inflation based on the GDP Deflators published by HM Government. The value of the grant may be varied by the Research Council during the lifetime of the grant in accordance with the deflators or to take into account any other Government decisions affecting the funding available to the Research Councils. Grant funds are provided for a specific research project. Under no circumstances may Directly Incurred and Exceptions funds be used to meet costs on any other grant or activity.
Directly Incurred and Exceptions funds cannot be used to meet the costs of an activity that will fall beyond the actual end date of the grant, e.g. when travel falls after the end of the grant, the costs cannot be charged to the grant even if the tickets, etc. can be purchased in advance. Any proposal to purchase an item of equipment in the last 6 months of the grant is subject to prior written approval by the Research Council. The Research Council will wish to be assured that the item of equipment is essential to the research.

GC 4 Starting Procedures

The process for activating a grant consists of two separate stages. The Research Organisation must formally accept the grant by completing and returning the Offer Acceptance within 10 working days of the offer letter being issued. Returning the Offer Acceptance will result in the Start Confirmation and the Payment Schedule being issued. The Start Confirmation must be submitted within 42 (calendar) days of the research/training starting and the start date shown on the start confirmation will be regarded as the start date of the grant. The start of the grant may be delayed by up to 3 months from the start date shown in the offer letter, the duration of the grant remaining unchanged. The grant may lapse if it is not started within this period. The start of the grant may precede the start date shown in the offer letter, but must not be earlier than the date of the offer letter itself.
The start of the grant should be defined as follows:

For research grants with DI staff: the date on which the first DI staff supported by the grant start work;

For research grants with DI staff, but where it is intended that staff should not be in post at the start of the grant: the date on which expenditure on any other DI or DA (excluding estates) heading first occurs;

For research grants without DI staff: the date on which any DI or DA (excluding estates) expenditure first occurs.

Grants may not be started in any other way without prior approval from the Research Council.

Expenditure may be incurred prior to the start of the grant and be subsequently charged to the grant, provided that it does not precede the date of the offer letter.

GC 5 Changes in Research Project

The Research Council must be consulted in the event of any major change in the proposed research, including failure to gain

access to research facilities and services, or to gain ethical committee approval for the research, particularly those which make it unlikely that the objectives of the research can be achieved. In addition, for research involving the use of animals or human participation, any substantive changes from the experimental design endorsed by the awarding Board or Panel that might impact on the ethical characteristics of the award must be authorised by the Research Council. Such changes would include, but may not be limited to, the use of different animal species and/or the experimental design or clinical protocol. If appropriate, revised proposals may be required. The Research Council reserves the right to make a new grant in place of the existing grant, or to revise, retain or terminate the existing grant. It is the responsibility of the Research Organisation to manage the resources on the grant, including the staff, and the Research Council need not be consulted if staffing levels on the grant are changed. However, a proportionate reduction should be made in the value of Estates, Indirect Costs and Infrastructure Technicians claimed by the Research Organisation in the following circumstances:

1. a post that attracts these costs is not filled.
2. a staff member who attracts these costs leaves more than six months before the end of the period for which the post was funded and is either not replaced, or is replaced by a category of staff that does not attract the costs e.g. project student or technician.

GC 6 Transfers of Funds between Fund Headings

Transfers of funds between fund headings are permitted only within and between Directly Incurred costs and Exceptions, excluding equipment. Equipment funding is ring-fenced and transfers into or out of the equipment headings, whether under Directly Incurred or Exceptions, is not permitted. Transfers will be at the rate applicable for the heading, as set out in the award letter. Funds can only be transferred and used to meet the cost of activity or activities that meet the agreed aims and objectives of the project. While approval does not need to be sought from the Research Council for transfer of funds, the Research Councils reserve the right to query any expenditure outlined in the Final Expenditure Statement, which has not been incurred in line with the Grant Terms and Conditions.

GC 7 Extensions

Research Grants: After a research grant has started, the duration may be extended, subject to prior written approval, to cover staff absences (excluding the principal and co-investigators unless they are also research fellows or research assistants funded by the grant). The grant may be extended by a total of up to 6 months to cover breaks or delays in the appointment of staff, extended jury service or paid sick leave exceeding 3 months (or possibly shorter periods of sick leave if the member of staff is disabled for the purposes of the Equality Act 2010 or other exceptional circumstances with the agreement of the Research Council); or by an overall total of up to 12 months to cover periods of maternity, paternity, shared parental or adoption leave. In the case of other exceptional circumstances, the duration may be extended at the discretion of the Research Council.

Fellowship Grants: After a fellowship grant has started, the duration may be extended to cover maternity leave, paternity leave, adoption leave, shared parental leave, extended jury service or paid sick leave for a Research Fellow in line with the terms and conditions of the fellow's employment. Otherwise, the conditions for extending Fellowship grants are the same as apply to research grants.

Any request for an extension should be made via the Grant Maintenance facility in JeS once the required duration is known. All requests for extensions must be made before the grant ends.

GC 8 Staff

The Research Organisation must assume full responsibility for staff funded from the grant and, in consequence, accept all duties owed to and responsibilities for these staff, including, without limitation, their terms and conditions of employment and their training and supervision, arising from the employer/employee relationship.
The Research Organisation must provide research staff with a statement, at the outset of their employment, setting out the provisions for career management and development, including personal skills training, and ensure that they have access to appropriate training opportunities.
Provided it is related to the research project on which they are currently working, Research staff and Research Fellows may, during normal working hours, undertake teaching and demonstrating work, including associated training, preparatory, marking and examination duties, for up to an average of 6 hours a week (pro rata for part-time staff) calculated over the period that they are supported on the grant.

GC 9 Maternity, Paternity, Adoption and Parental Leave

The research organisation will be compensated at the end of the grant to cover any additional net costs, that cannot be met within the cash limit, of paid maternity, paternity, adoption and parental leave for staff within the Directly Incurred and Exceptions fund headings (excluding the principal and co-investigators, unless they are also research fellows or research assistants funded by the grant) if they fulfil the relevant qualifying conditions of the employing Research Organisation. The net cost is the amount paid to the individual less the amount the Research Organisation can recover for Statutory Maternity Pay and Statutory Adoption Pay from HMRC.

Maternity, paternity, adoption and parental pay is payable by the Research Council only for directly incurred staff that are funded for 100% of their contracted time on the grant (apart from staff acting as principal or co-investigators unless they are also research fellows or research assistants funded by the grant).

Grant funds, within the announced cash limit, may be used to meet the costs of making a substitute appointment and/or extending the grant to cover a period of maternity, paternity, adoption or parental leave for staff within the directly incurred and exceptions fund headings (excluding the principal and co-investigators, unless they are also research fellows or research assistants funded by the grant). The duration of a grant will be extended only if the period can be accommodated within the maximum period allowed for extensions. Directly Allocated and Indirect funds will not be increased as a result of such extensions.

Research Grants: Research Grant funds may be used to meet the costs of paid maternity, paternity, parental and adoption leave only to the extent that it is taken during the original period of the grant. The Research Organisation will be responsible for any liability for maternity, paternity, parental and adoption leave pay for staff supported by the grant outside the original period of the grant. If, for example, the original end date of a grant falls while a member of research staff is part-way through her maternity leave, the Research Organisation will be responsible for that part of the maternity leave which is taken after the original end date.

Fellowship Grants: Fellows are entitled to take maternity, paternity, adoption or parental leave in accordance with the terms and conditions of the fellow's employment. If requested, consideration will be given to allowing a fellowship grant to be placed in abeyance during the absence of the Research Fellow for maternity, paternity, adoption or parental leave, and the period of the fellowship extended by the period of leave. Consideration will be given to requests to continue the fellowship on a flexible or part-time basis to allow the Research Fellow to meet caring responsibilities.

GC 10 Sick Leave

The Research Organisation will be compensated at the end of the grant to cover any additional net costs, that cannot be met within the cash limit, of paid sick leave for staff within the Directly Incurred and Exceptions fund headings (excluding the Principal and Co-Investigators, unless they are also Research Fellows or Research Assistants funded by the grant) who fulfil the qualifying conditions of the Research Organisation. The net cost is the amount paid to the individual less the amount the Research Organisation can recover from HMRC.

Sick pay is payable by the Research Council only for directly incurred staff that are funded for 100% of their contracted time on the grant (apart from staff acting as principal or co-investigators unless they are also research fellows or research assistants funded by the grant).

Grant funds, within the announced cash limit, may be used to meet the approved costs of making a substitute appointment and/or extending the grant to cover a period of sick leave for staff within the directly incurred and exceptions fund headings (excluding the principal and co-investigators, unless they are also research fellows or research assistants funded by the grant). The duration of a grant will be extended only if the period can be accommodated within the maximum period allowed for extensions. Directly Allocated and Indirect funds will not be increased as a result of such extensions.

Research Grants: Research Grant funds may be used to meet the costs of paid sick leave only to the extent that it is taken during the original period of the grant. The Research Organisation will be responsible for any liability for sick leave pay for staff supported by the grant outside the original period of the grant. Where there is a continuous period of sick leave in excess of 3 months, the Research Organisation may apply to the Research Council to discuss the possibility of a substitute appointment to safeguard progress on the project. Where a Research Assistant has been on sick leave in excess of 3 months the Research Organisation must comply with all their obligations to consider reasonable adjustments before making a substitute appointment. Where a Research Assistant has been on sick leave for an aggregate (not necessarily continuous) period in excess of 3 months, where this is due to a single condition or a series of related conditions, the Research Organisation may request an extension to the duration of the project

Fellowship Grants: Fellows are entitled to take sick leave in accordance with the research organisation's terms and conditions. If requested, consideration will be given to allowing a fellowship grant to be placed in abeyance during the absence of the Research Fellow due to sick leave, and the period of the fellowship extended by the period of sick leave. The additional salary costs for the fellow (pro rata to their percentage FTE on the fellowship) should be claimed, as necessary, at the end of the extended period.

GC 11 Procurement of Equipment

The procurement of equipment, consumables and services, including maintenance, must comply with all relevant national and EU legislation and the Research Organisation's own financial policy and procedures. Accepted procurement best practice in the higher education sector must be observed. For all equipment and services where the contract value is more than £25,000, excluding VAT, professionally qualified procurement staff must be consulted before the procurement process begins, and, where appropriate, at the market research stage, and must approve the order/contract before it is placed with a supplier.

GC 12 Ownership and Use of Equipment

Equipment purchased from grant funds is primarily for use on the research project for which the research grant was awarded, and belongs to the Research Organisation. In certain circumstances the Research Council may wish to retain ownership throughout the period of the grant and possibly beyond. In such cases, the grant will be subject to an additional condition.

The Research Council must be informed if, during the life of the research grant, the need for the equipment diminishes substantially or it is not used for the purpose for which it was funded. The Research Council reserves the right to determine the disposal of such equipment and to claim the proceeds of any sale.

Any proposal to transfer ownership of the equipment during the period of the grant is subject to prior approval by the Research Council. After the research project has ended, the Research Organisation is free to use the equipment without reference to the Research Council, but it is nevertheless expected to maintain it for research purposes as long as is practicable.
Where there is spare capacity in the use of the equipment, the Research Council expects this to be made available to other users. Priority should be given to research supported by any of the Research Councils and to Research Council-funded students.

GC 13 Transfer of a Grant to another Research Organisation

The Research Organisation must send a request via the Grant Maintenance facility in Je-S if the Grant Holder intends to transfer to another organisation. If this organisation is eligible to hold grants, and is able to provide a suitable environment to enable the project to be successfully completed, the expectation is that the grant would be transferred with the Grant Holder. Written

agreement to this is required from both the relinquishing and receiving organisations; this will normally be triggered automatically by the initial request to JeS.

The Research Council will wish to be assured that satisfactory arrangements have been agreed that will enable the project to be undertaken, or to continue, in accordance with its research objectives. If suitable arrangements cannot be agreed, the Research Council will consider withdrawing its support or terminating the grant.

Where there is a basis for continuing involvement by the relinquishing organisation, agreement should be reached between both organisations on the apportionment of work and the distribution of related funding.

Grants will not be re-costed following transfer. The unspent balance of Directly Incurred and Exceptions costs will be transferred to the receiving Research Organisation. In the case of Directly Allocated and Indirect costs, a pro rata share, based on the time elapsed on the grant at the point of transfer, will be transferred to the receiving research organisation. The receiving organisation will be required to confirm, by return of an offer acceptance, that it will provide any additional resources needed to complete the project.

GC 14 Change of Grant Holder

Research Grants: The Research Organisation must consult the Research Council via the Grant Maintenance facility in JeS if it is proposed to change the Grant Holder, for example, following retirement or resignation. Where the Grant Holder is transferring to another organisation eligible to hold a grant, the provisions of GC 13 will apply. In other circumstances, the Research Organisation may nominate a replacement Grant Holder. The Research Council will wish to be assured that the replacement meets the eligibility criteria and has the expertise and experience to lead the project to a successful conclusion, in accordance with its research objectives.

Fellowship Grants: A fellowship grant is awarded on the basis of a named individual's suitability to undertake and benefit from the period of research: therefore changes to the Grant Holder are not permitted. The resignation of the Research Fellow, or the termination of their employment, constitutes the end of the grant for the purpose of submitting a final report and the Council's financial liabilities.

GC 15 Annual Statement

The Research Organisation may be sent a statement to return each year showing payments made by the Research Council during the previous financial year for all the grants it holds. Where a statement is required, the Research Organisation must certify, by returning the statement, that:
* Expenditure has been incurred in accordance with the grant conditions, and
* Those grants shown as current are continuing.

No further payments will be made until the annual statement has been received and accepted by the Research Council.

GC 16 Expenditure Statements

The Research Organisation must complete and return an expenditure statement within 3 months of the end date of a grant. Once an expenditure statement has been received and the expenditure incurred has been reconciled against payments made, it will be considered as final.

Expenditure shown in the Directly Incurred and Exceptions headings must show the actual expenditure incurred by the project. Settlement by the Research Council will reflect the proportion of fEC stated in the award letter applied to actual expenditure, within the cash limit.

For the Directly Allocated and Indirect Costs headings, the Research Council will pay the amount shown as spent, within the cash limit, provided that the grant ran its full course. Where a grant is terminated more than 6 months before the planned end date, a pro rata share will be paid. Where a grant terminates within 6 months of the planned end date, estates and Indirect Costs will be paid in full, but Investigators' costs and Other Directly Allocated Costs will be paid pro rata.

Costs arising from maternity, paternity, adoption or sick leave should be identified in the Absence heading of the statement.

The Research Council reserves the right to require the Research Organisation to complete and submit a statement of expenditure at any time during the course of a grant, or to provide supplementary information in support of an interim or final expenditure statement.

If there are exceptional reasons that will prevent submission of the expenditure statement within the period allowed, a written request may be made via the Grant Maintenance facility in JeS, before the due date passes, for the submission period to be extended.

GC 17 Inspection

The Research Council reserves the right to have reasonable access to inspect the records and financial procedures associated with grants or to appoint any other body or individual for the purpose of such inspection.

The Research Organisation must, if required by the Research Council, provide a statement of account for the grant, independently examined by an auditor who is a member of a recognised professional body, certifying that the expenditure has been incurred in accordance with the research grant terms and conditions.

Research Councils will undertake periodic reviews of Research Organisations within the Funding Assurance Programme to seek assurance that grants are managed in accordance with the terms and conditions under which they are awarded.

GC 18 Reporting on the conduct and results of research

Exceptionally, the Research Council may require a separate final report on the conduct and outcome of the project. If so, it must be submitted by the Research Organisation within three months of the end of the grant, on the form provided. No further application from a Grant Holder will be considered while a final report is overdue. If there are exceptional reasons that will prevent submission of the final report within the period allowed, a written request may be made via the Grant Maintenance facility in JeS, before the due date passes, for the submission period to be extended.

The Research Councils use an online system to collect information on the outputs and outcomes of research, and provide guidance on the use of the system and the timing and scope of reporting that is required. The Research Organisation must ensure that the system is used in accordance with the guidance provided. The Research Councils also reserve the right not to consider further proposals from a grant holder where the reporting requirements on previously awarded grants are not observed.

GC 19 Sanctions

The Research Councils reserve the right to impose financial sanctions where they identify areas of non compliance in relation to the terms and conditions of grants.
If the final report or the financial expenditure statement is not received within the period allowed, the research council may recover 20% of expenditure incurred on the grant. All payments may be recovered if the report or statement is not received within 6 months of the end of the grant. Research organisations may appeal against a sanction, but must do so within 60 days of the pay run in which the sanction was imposed.
In relation to the current Quality Assurance and validation project for TRAC implementation in universities, the Research Councils reserve the right to apply sanctions of 75% of the non-compliant rate where an institution is found to be using rates which are materially inaccurate (>10% variance on any single rate). These sanctions would only apply to future applications although Councils may exercise a higher sanction where there has been evidence of significant overpayments to research organisation based on inaccurate rates.

GC 20 Public Engagement

It is the responsibility of the Research Organisation and the Grant Holder and Co-Investigators to communicate the research to the public at both local and national level, and to raise awareness of the role of science and research in any related issues of public interest. Special schemes exist in some Research Councils providing additional support for these activities.

GC 21 Exploitation and Impact

It is the responsibility of the Research Organisation, and all engaged in the research, to make every reasonable effort to ensure that the intellectual assets obtained in the course of the research, whether protected by intellectual property rights or not, are used to the benefit of society and the economy. Research outcomes should be disseminated to both research and more widespread audiences

- for example to inform potential users and beneficiaries of the research.

Unless stated otherwise, the ownership of all intellectual assets, including intellectual property, and responsibility for their application, rests with the organisation that generates them.

Where the grant is associated with more than one research organisation and/or other project partners, the basis of collaboration between the organisations, including ownership of intellectual property and rights to exploitation, is expected to be set out in a formal collaboration agreement. It is the responsibility of the Research Organisation to put such an agreement in place before the research begins. The terms of collaboration agreements must not conflict with the Research Councils' terms and conditions.

Arrangements for collaboration and/or exploitation must not prevent the future progression of research and the dissemination of research results in accordance with academic custom and practice. A temporary delay in publication is acceptable in order to allow commercial and collaborative arrangements to be established.

The Research Council may, in individual cases, reserve the right to retain ownership of intellectual assets, including intellectual property (or assign it to a third party under an exploitation agreement) and to arrange for it to be exploited for the national benefit and that of the Research Organisation involved. This right, if exercised, will be set out in an additional grant condition.

There should be suitable recognition and reward to researchers who undertake activities that deliver benefit through the application of research outcomes. The Research Organisation must ensure that all those associated with the research are aware of, and accept, these arrangements.

GC 22 Research Monitoring and Evaluation

While it is the responsibility of the Research Organisation to manage the research, the Research Council reserves the right to call for periodic information on progress or to visit the project team. The Grant Holder may also be asked to attend meetings to exchange information and ideas with others undertaking research in the same or similar fields.

The Grant Holder must make all reasonable efforts, if so invited, to respond to requests for information or to attend events or activities organised by the Research Council concerning the research undertaken. Such events may be held after a grant has finished.

GC 23 Publication and Acknowledgement of Support

The Grant Holder should, subject to the procedures laid down by the Research Organisation, publish the results of the research in accordance with normal academic practice and the RCUK policy on open access http://www.rcuk.ac.uk/documents/documents/RCUKOpenAccessPolicy.pdf.

Publications and other forms of media communication, including media appearances, press releases and conferences, must acknowledge the support received from the Research Council (or Councils, in the case of grants funded by more than one) quoting the grant reference number if appropriate.

Journal publications should acknowledge the funding source using the standard format agreed by funders and publishers and detailed in the additional information accompanying this grant.

GC 24 Disclaimer

The Research Councils accept no liability, financial or otherwise, for expenditure or liability arising from the research funded by the grant, except as set out in these terms and conditions, or otherwise agreed in writing.

Where studies are carried out in an NHS Trust, the Trust has a duty of care to its patients. The Research Council does not accept liability for any failure in the Trust's duty of care, or any negligence on the part of its employees.

The Research Councils reserve the right to terminate the grant at any time, subject to reasonable notice and to any payment that may be necessary to cover outstanding and unavoidable commitments.

Further to GC3, the Research Councils reserve the right to amend the payment profile at their discretion. The Research Organisation will be advised, in advance, of any such a change. Changes to payment profiles may affect the overall value of the grant.

If a grant is terminated or reduced in value, no liability for payment or redundancy or any other compensatory payment for the dismissal of staff funded by the grant will be accepted, but, subject to the provisions of GC16, negotiations will be held with regard to other contractual commitments and concerning the disposal of assets acquired under the research grant.

GC 25 Status

These terms and conditions will be governed by the laws of England and Wales; all matters relating to the terms and conditions will be subject to the exclusive jurisdiction of the courts of England and Wales.

If any provision of these terms and conditions is found by a court or other legitimate body to be illegal, invalid or unreasonable, it will not affect the remaining terms and conditions which will continue in force.

These terms and conditions, together with any additional conditions set out in the grant; contain the whole agreement between the Research Council and the Research Organisation in relation to the stated research grant. The Research Council and the Research Organisation do not intend that any of these terms and conditions should be enforceable by any third party.

UNIVERSITY OF GHANA

OFFICE OF RESEARCH, INNOVATION AND DEVELOPMENT

UNIVERSITY OF GHANA RESEARCH FUND

5TH CALL FOR PROPOSALS

THIS DOCUMENT MUST BE TYPED!! Please take note that hand written applications shall not be considered

PLEASE INDICATE TYPE OF GRANT APPLICATION BY TICKING THE APPROPRIATE BOX:

1. SEED FUNDING (UP TO GHC 5,000)	
2. INVESTIGATOR-LED GRANTS (UP TO GHC 30,000)	✓
3. LARGE MULTI-DISCIPLINARY GRANT (UP TO GHC 100,000)	

LEAD FACULTY AND DEPARTMENT:
University of Ghana Medical School (UGMS), College of Health Sciences
Department of Medicine and Therapeutics

COLLABORATING FACULTIES AND DEPARTMENTS:
School of Allied Health Sciences (SAHS)
Department of Pathology, UGMS
Department of Microbiology, UGMS
Department of Medical Laboratory Sciences, SAHS

NAME OF PROJECT PI/ CONTACT PERSON/ COORDINATOR (PLEASE CIRCLE AS APPROPRIATE):
Dr. Timothy Archampong

APPLICATION DEADLINE: 5PM ON FRIDAY MARCH 30, 2012

Electronic copy of application and all accompanying documents to be submitted as a single PDF file to proposalsubmission@ug.edu.gh by the deadline indicated above. One original hard copy also to be submitted to the Office of the Pro Vice-Chancellor (RID) on the ground floor of the LECIAD Building addressed to:

THE RESEARCH ADMINISTRATOR, OFFICE OF RESEARCH, INNOVATION AND DEVELOPMENT, GROUND FLOOR LECIAD BUILDING, UNIVERSITY OF GHANA, LEGON

UNIVERSITY OF GHANA RESEARCH FUND

managed by the

OFFICE OF RESEARCH, INNOVATION AND DEVELOPMENT

5TH CALL FOR PROPOSALS

PROPOSAL SUBMISSION CHECKLIST

To be completed by Principal Investigator (PI) and attached to application form

- **PLEASE CHECK (√) TO CONFIRM THAT DOCUMENT DESCRIBED IS ATTACHED**

Application form signed by Principal Investigator and endorsed (with signature and stamp) by Head of Department and Provost/ Dean of College or Faculty.	✓
Abridged CV of PI (3 pages max.)	✓
Completed Ethical Review and Research Assurance Form	✓
*Proposal does not exceed 17 pages	✓
Proposal prepared using Times New Roman (Font Size 1o) and is single spaced	✓

Please see proposal page length guide below

- **PROPOSAL PAGE LENGTH GUIDE**

SECTION	MAXIMUM PAGE LENGTH
Title page	1
Proposal Summary	1
Problem Statement	2
Detailed Project Description	6
Budget statement (including budget justification)	1
Full budget table	1
Summary of PIs experience	1
Abridged CV of PI	3
Ethical Review and Research Assurance Form	1
TOTAL NUMBER OF PAGES	**17**

UNIVERSITY OF GHANA

UG RESEARCH FUND

APPLICATION FORM FOR 5TH CALL FOR PROPOSALS

THIS DOCUMENT MUST BE TYPED!! Please take note that hand written applications shall not be considered

Project Title: *Helicobacter pylori*-related gastro-duodenal disease in Greater Accra, Ghana			
Faculty: University of Ghana Medical School, College of Health Sciences	Department: Medicine and Therapeutics		
Total Budget Requested: GHC 29,688.75			
Principal Investigator (PI) Information:			
Name: Dr. Timothy Archampong			
Email Address(es): tnaa@doctors.net.uk; tarchampong@chs.ug.edu.gh	Cell Phone No: 0249966209/0203039841	Office Phone:	
Years of Service with UG: 3 yrs	Position: Lecturer		
Collaborator Information:			

Name	Department	Email	Telephone no.
1. Prof. E.K. Wiredu	Pathology & SAHS	ekwiredu @chs.edu.gh	0244664184
2. Prof. R. Gyasi	Pathology	rkg539us@yahoo.com	0244632427
3. Mr. Richard Harry Asmah	Medical laboratory Sciences, SAHS	rhasmah@chs.edu.gh	0244266529
4. Dr. Japheth Opintan	Microbiology	japh_opintan@yahoo.com	0244789209
5.			

Signatures:		
Principal Investigator's signature: T Archampong		Date: 15/3/12
Head of Department's signature: A Foon.	Seal/Stamp: DEPT. OF MEDICINE & THERAPEUTICS KORLE-BU TEACHING HOSPITAL P. O. BOX 77, KORLEBU	Date: 16/3/12
Faculty Dean's signature:	Seal/Stamp: OFFICE OF THE DEAN UNIVERSITY OF GHANA MEDICAL SCHOOL P. O. BOX 4236 ACCRA	Date: 19/03/2012

For official use only

Date received:	Seal/Stamp:

1. SUMMARY (Max. 1 page)

Brief statement of the project, including what it proposes to do what it seeks to achieve and the total funds needed**. (Maximum 1 page)**

Helicobacter pylori infection is the primary aetiologic agent in the development of gastritis, gastric and duodenal ulceration, gastric B-cell lymphoma and distal gastric cancer. Distal gastric cancer is strongly associated with lifelong *Helicobacter pylori* infection and relative socio-economic deprivation. The bacterium *Helicobacter pylori* is a spiral-shaped gram-negative urease-producing pathogen found in the stomach and in areas of gastric metaplasia in the duodenum. The exact mode of transmission of the pathogen is unclear but intra-familial clustering suggests person-to-person spread mainly in childhood. Overcrowded conditions associated with childhood poverty leads to increased transmission and higher prevalence rates.

The best understood bacterial virulence factor is the cagA pathogenicity island. *Helicobacter pylori* strains possessing this factor induce more inflammation, ulceration and oncogenesis when compared with cag-negative strains. Another virulence factor is the vacuolating cytotoxin, VacA. The bacterial strains producing more active forms are more closely associated with gastro-duodenal disease. It remains unclear whether these patterns of *Helicobacter pylori* virulence will be reflected in the African population.

This research study received ethical approval from the University of Ghana Medical School Protocol and Ethical Review Board in April, 2010. The study target population were Clinical Outpatients undergoing Upper-Gastro-Intestinal Endoscopy at the Korle-Bu Teaching Hospital Endoscopy Unit, Accra. Between July, 2010 and December, 2011, a total of two-hundred and thirty nine (239) dyspeptic patients with endoscopic evidence of *Helicobacter pylori*-gastro-duodenal disease were recruited consecutively into our sample population. They were all taken through an informed consent process and completed our questionnaire. This gathered demographic and clinical data on selected patients. *Helicobacter* status was defined by Rapid-Urease-CLO testing on gastric antral biopsies. This yielded our study *Helicobacter pylori* prevalence of 73.2%. Following Upper-Gastro-Intestinal endoscopy, three systematic gastric antral biopsies per patient were stored in DNA-gard solution in the School of Allied Health Sciences (SAHS) Laboratory. The SAHS Laboratory currently has two-hundred and thirty nine (239) stored patient-biopsy sets for further evaluation.

This research project therefore proposes to perform histological, microbiologic and molecular assessments on gastric antral biopsies stored in DNAgard. It will provide the opportunity to carry out clinical, epidemiological, microbiologic and subsequent molecular assessments of *Helicobacter pylori* infection in patients presenting to Korle-bu Teaching Hospital, the main tertiary referral centre for Southern Ghana. It will investigate clinical and genotypic differences seen in *Helicobacter pylori* infection thereby providing compelling data on its expression in Ghana. It has also provided an opportunity for post-graduate study for an MPhil Student in Microbiology.

It is expected that at the end of the project we will be able to categorize and risk stratify symptomatic patients thereby prioritising and promoting optimum treatment strategies against *Helicobacter pylori* disease in Ghana. There is likely to be a geographical and dietary basis for the prevalence of *Helicobacter pylori* in Ghana which will be clarified. There is also increasing *Helicobacter pylori* anti-microbial resistance in Ghana which will need defining. This will be very relevant as there are a number of commonly used triple therapy *Helicobacter pylori* eradication regimens. Molecular characterization will be done to evaluate if cagA and vacA *Helicobacter* strains would prove to be very ulcerogenic and carcinogenic in Ghana as reported in the developed world.

Funds sought from University of Ghana Research Fund: 29,688.75 Ghana Cedis.

2. PROBLEM STATEMENT (Max. 2 pages)

Briefly state how important your project is and why it should be funded, in relation to other works done or proposed in this area. Show how it will contribute to the attainment of UGs mission, state opportunities for post-graduate training, show contribution to development issues in Ghana **(Maximum 2 pages)**

Levels of *Helicobacter pylori* infection are very high in Ghana. The incidence of *Helicobacter pylori* infection in Ghanaian patients with dyspeptic symptoms referred for upper gastrointestinal endoscopy was 75.4%.[1] While 23.5% of *Helicobacter* pylori-positive patients had active peptic ulceration, 19% of *Helicobacter pylori*-negative patients also had the ulcer.[1] Of patients with normal gastroscopies, (74.4%) were *Helicobacter pylori* positive and so were 66% of patients with gastric malignancies, therefore specific host or environmental factors are important in its continued clinical expression.[1] *Helicobacter pylori* has been linked with peptic ulceration and gastric malignancy [2,3] with virulent strains such as the vacA/cagA[4], Oipa/BabA[5] causing more intense gastric inflammation and disease. These molecular associations are yet to be characterised in the Ghanaian host. Transmission routes and socio-cultural implications also vary across populations.[6,7]

It is clear from current data in Ghana that Gastro-duodenal disease has a high incidence with its attendant morbidity and mortality.[1] It will therefore be important to address the following questions with regard to *Helicobacter pylori* infection and its clinical manifestations in Ghanaians.
Who gets *Helicobacter pylori* gastro-duodenal disease in Ghana and *why* is it endemic?
What are the important aetiological factors to blame for its continued prevalence in Ghana?
Which strains of *Helicobacter pylori* are more virulent and carcinogenic in Ghana?
What is the anti-microbial susceptibility pattern across *Helicobacter pylori* strains in Ghana?

A review of endoscopies at the Endoscopy Unit in Korle-Bu Hospital, the largest tertiary centre in Ghana, (6,977 upper GI endoscopies between January 1995 and December 2002) looked at the indications for endoscopy.[8] Epigastric pain (42.5%), dyspepsia (32.8%), haematemesis and melaena (14.2%) were the commonest reasons for endoscopy. Chronic duodenal ulcer (19.6%), acute gastritis (12.7%), duodenitis (10.2%) and oesophagitis (7.5%) were the most frequent diagnoses.[8] Normal endoscopy was reported in 41.1%. This was higher in the younger age group. [8] In a Nigerian study, detection of *H. pylori* was done on gastric mucosal biopsies either by the Campylobacter-Like Organism (CLO)-urease test or by histo-pathology. A total of 834 patients were studied, out of which 268 were investigated for *H. pylori*. [9] A hundred and ninety-five patients (73%) were positive for *H. pylori* and the peak age was in the fourth decade. Duodenal ulcer was the most common endoscopic finding (38.7%).[9] The incidence of *H. pylori* infection was 76% among patients with duodenal ulceration, gastritis, gastro-duodenitis and gastric outlet obstruction. [9] *H. pylori* was significantly associated with gastric ulceration occurring with gastritis. Gastric carcinoma was diagnosed in 52 patients (6.2%) and 50% of these tested for *H. pylori* were positive.[9] These studies emphasize the important role *Helicobacter pylori* continues to play in the pathogenesis of peptic ulcer disease in our West African sub-region.

There are now rising numbers of patients seen with *Helicobacter pylori* eradication failure in Korle-bu, Accra. This implies changing patterns of anti-microbial susceptibilities and heterogeneity of prescribed antibiotic brands. The proposed study will also throw more light on the important role of antibiotic compliance in Ghanaians. Patients who do not take their prescribed medications at the specified times due to lack of information may develop *Helicobacter pylori* treatment failure and resistance. Between October 2003 and April 2004, the anti-microbial susceptibility pattern of 138 male and 129 female Kenyan patients aged 15-85 years were studied.[10] The MIC90 (minimum inhibitory concentration) was 256 mg/l for metronidazole, 1.5 mg/l for clarithromycin, 1.5 mg/l for tetracycline and 0.75 mg/l for amoxicillin. The MIC values for amoxicillin were significantly higher in the female patients ($p = 0.02$) but showed no significant variation for age. The MIC values for metronidazole, tetracycline and clarithromycin showed no significant difference for age or gender. MIC values for tetracycline were significantly higher for patients with duodenitis and duodenal ulcer $p = 0.009$ and 0.02, respectively.[10] All isolated *Helicobacter pylori* organisms were resistant to metronidazole. [10] The susceptibility of the *Helicobacter pylori* isolates was 93.6% for clarithromycin, 95.4% for amoxicillin and 98.1% for tetracycline.[10] The MIC90 for amoxicillin and clarithromycin were found to be close to the

upper limit of the susceptibility range. There was a rising MIC90 for tetracycline and metronidazole compared to that found in a previous study in 1991.[10] A similar pattern of metronidazole and tetracycline *H. Pylori* resistance was noted in a study on Nigerian patients in Jos. [11]

In Ghana, the high level of metronidazole and co-amoxiclav (augmentin) use in primary and tertiary care will impact on our *Helicobacter pylori* anti-microbial sensitivities. It will be important to define these resistance patterns to improve our treatment outcomes and inform clinicians about the emergence and consequences of these trends. This will ultimately lead to an effective evidence-based protocol for the management and eradication of *Helicobacter pylori* in the Ghanaian population.

Contribution to the attainment of University of Ghana's Mission and Opportunities for Post-graduate Training

Funding of this research project will go a long way in answering these pressing questions and significantly improve our understanding of the Ghanaian *Helicobacter pylori* infection from the clinical, epidemiological, microbiologic to the molecular level. It will help in the promotion of research in the University of Ghana by partaking in the rapidly developing world of molecular genetics in health and disease. It will further stimulate the development of specific teaching and learning skills in the University by the dissemination of molecular techniques in a variety of fora and workshops during the project.

A BSc student (Department of Medical Laboratory Sciences, School of Allied Health Sciences) recently completed work on isolation of *Helicobacter pylori* DNA in line with our current preliminary work on *Helicobacter pylori*. We have recruited a post-graduate (M.Phil) student to focus on the molecular spectrum of *Helicobacter* isolates in the gastric antrum. He has had his proposal approved by the Ethical Committee, University of Ghana Medical School and the Post-Graduate Division of The College of Health Sciences, University of Ghana. He is currently undergoing training in molecular methods under the supervision of Mr. Richard H. Asmah, Department of Medical Laboratory Sciences, SAHS.

This *Helicobacter pylori* research project on Gastro-duodenal disease is attracting further interest from aspiring post-graduate (M.Phil) students keen to study DNA analysis and molecular biology. It provides immediate clinical relevance for the students due to the integrated approach encompassing clinicians, molecular biologists, microbiologists and pathologists. It therefore offers a unique opportunity to discuss clinico-pathological issues at inter-departmental level fostering important relationships and ultimately improving the efficiency of *Helicobacter pylori* investigative processes.

Contribution to development issues in Ghana

Gastro-duodenal disease is a significant burden on the Ghanaian with a substantial impact on quality of life. Medical complaints pertaining to the upper gastrointestinal tract are common and lead to loss of productivity from repeated excuse duty and sick leave. Funding of this project will result in effective *Helicobacter* eradication programs specific to the Ghanaian population. These will reduce the morbidity associated with gastro-duodenal diseases and improve the general wellbeing of the Ghanaian citizenry living with these ailments. A healthier workforce will lead to a more productive economy. Its impact will be felt at the Public Health level as specific community initiatives can be directed at preventing *Helicobacter pylori* transmission thereby contributing to health and socio-economic development.

3. DETAILED PROJECT DESCRIPTION (Max. 6 pages)

a) Goals

To investigate *Helicobacter pylori* associated gastro-duodenal disease in Ghana.

b) Objectives

1. To determine the histological severity of *Helicobacter pylori* infection in the gastro-duodenum of Ghanaian patients
2. To analyse the range of molecular strains of *Helicobacter pylori* prevalent in Ghanaian patients undergoing Upper Gastro-Intestinal Endoscopy
3. To identify the anti-microbial susceptibilities of the various strains of *Helicobacter pylori* in gastric antral biopsy specimens

c) Specific Activities to achieve the objectives indicated above

1. Histological severity of *Helicobacter pylori* infection will be determined by performing histological evaluation of gastric antral biopsy for density of *Helicobacter* organisms and degree of inflammation.
2. Molecular strains of *Helicobacter pylori infection* will be determined by performing genomic DNA extraction and genetic DNA sequencing on gastric antral biopsies.
3. *Helicobacter pylori* anti-microbial susceptibilities will be determined by microscopy, culture and antibiotic sensitivity testing on gastric antral biopsies.

d) Methodology

Give a brief description of methods including why a particular method was selected, provide details of equipment/ resources needed and how these would be sourced.

Overview:

This study uses a cross-sectional design to investigate *Helicobacter pylori*-related gastro-duodenal disease seen at the Endoscopy Unit, Korle-Bu Teaching Hospital, Accra, Ghana.

Study Setting:

Korle-Bu Teaching Hospital has 2,500 beds and is the main tertiary referral centre in Accra serving the majority of the southern half of Ghana. The Endoscopy Unit is the principal referral centre for Gastro-Intestinal (GI) endoscopic services in Accra performing approximately 20 – 30 upper GI endoscopies between 9am and 5pm on weekdays. It has endoscopy nurses, gastroenterologists and GI surgeons involved in GI endoscopy. The target population in question were patients referred from the Korle-Bu Polyclinic, Accra, In-patients/ clinic outpatients in Korle-Bu Teaching Hospital with upper gastrointestinal symptoms for upper-gastrointestinal endoscopy. Gastric antral biopsies were performed in the Endoscopy Unit, Korle-Bu Teaching Hospital and gastric antral samples were stored in the School of Allied Health Sciences Laboratory for further evaluation.

Study design:

This research study received ethical approval from the University of Ghana Medical School Protocol and Ethical Review Board in April, 2010. Patients undergoing upper gastrointestinal endoscopy at the Korle-Bu Teaching Hospital Endoscopy Unit, based on clinical need were considered for the proposed study. Between July, 2010 and December, 2011, a total of two-hundred and thirty nine (239) dyspeptic patients with endoscopic evidence of *Helicobacter pylori*-gastro-duodenal disease who met the inclusion criteria below were recruited consecutively into our sample population. They were all taken through an informed consent process with an explanatory statement and completed our questionnaire (page 11). This gathered patients' demographics, biodata, associated symptoms, lifestyle/dietary habits, signs and relevant background history. *Helicobacter* status was immediately defined by Rapid-Urease-CLO testing on gastric antral biopsies performed at endoscopy. This yielded our study *Helicobacter pylori* prevalence of 73.2%. Following upper-Gastro-Intestinal

endoscopy, three systematic gastric antral biopsies per patient were preserved in 0.2ml DNA-gard solution and transferred to the School of Allied Health Sciences (SAHS) Laboratory for storage. The School of Allied Health Sciences Laboratory currently has all 239 patient sample sets stored in DNA-gard solution in preparation for histological, microbiologic and *Helicobacter pylori* strain analysis. Histological evaluation will take place in the Pathology Laboratory, UGMS while Microbiologic and *Helicobacter pylori* strain analysis will be performed in the SAHS Laboratory.

Inclusion criteria:

- Patients presenting to the Medical Outpatient Clinic with dyspeptic symptoms
- In-patients with dyspeptic symptoms on General Medical wards, Korle-bu
- Patients consenting to participate in the above study on *Helicobacter* disease
- Patients with a clinical need for upper gastro-intestinal endoscopy
- Patients with rapid urease CLO positive results

Exclusion criteria:

- Patients with prior *Helicobacter* eradication treatment or proton-pump inhibitor use two weeks preceding endoscopic analysis
- Patients refusing consent to participate in the study
- Patients with rapid urease CLO negative results

Endoscopy and Clinical Studies

Patients were examined by the Principal Investigator prior to endoscopy. They were then consented for upper gastro-intestinal endoscopy. Upper GI endoscopy is a test which allows direct visualization of the lining of the oesophagus (the gullet), the stomach and around the first bend of the small intestine - the duodenum. They were given the option of sedation with (midazolam 1-2mg; pethidine 25-50mg) or lignocaine throat spray. Samples of tissue were removed through the endoscope, using tiny forceps.

Determination of *Helicobacter pylori* status with rapid urease testing

In the Endoscopy Unit, Korle-Bu Teaching Hospital, a gastric antral biopsy sample following upper gastrointestinal endoscopy was tested by the rapid urease CLO test to determine the presence of *Helicobacter pylori* in samples. (Source: Cambridge Life Sciences Ltd, 14 St. Thomas Place, Cambridge, UK).

Determination of *Helicobacter* infection using microscopy, culture and sensitivity

A gastric antral biopsy specimen obtained during endoscopy will be drawn from DNAgard and cultured in agar medium to isolate *H. pylori*. The E test, a quantitative method for antimicrobial susceptibility testing applies both the dilution of antibiotic and diffusion of antibiotic into the culture medium. A predefined stable antimicrobial gradient is present on a thin inert carrier strip. When this E test strip is applied onto an inoculated agar plate, there is an immediate release of the drug. It is a preferred method due to its reliability and sensitivity.[12,13] (Source: Qiagen House, Fleming Way, Crawley, West Sussex, UK). Work will be done in the SAHS Laboratory under Mr. Richard H. Asmah and Dr. Japheth Opintan.

Determination of the severity of endoscopic *Helicobacter* infection using histology

A gastric antral biopsy specimen in DNAgard solution will be immediately drawn and introduced into a fixative of 10% phosphate buffered formalin. *Preparation of histological slides:* an orientation of the biopsy specimens will be made before paraffin embedding to have sections which show the surface epithelium where bacteria are essentially located. Three thin sections will be cut at different levels and the preparations stained with Haematoxylin and Eosin. Work will be done in the Pathology Services Department under Prof. R Gyasi and Prof. E.K. Wiredu.

Molecular Analysis of strains of *Helicobacter pylori for pathogenic factors*

Gastric antral biopsies obtained at endoscopy will be immediately inserted into specimen tubes containing DNAgard which preserves DNA at room temperature for at least twelve months. (DNAgard will be sourced from Biomatrica, Inc, Oberlin Drive, San Diego, USA). There are two main pathogenic factors: the *cag*A and

the polymorphism of the *vacA* gene. We will use the methods described below by Rudi *et al* [14,15] to amplify the genes involved in pathogenicity.

Genomic DNA Extraction
Genomic DNA will be extracted from stored tissue samples collected from patients using QIAGEN DNeasy tissue kit. (The Qiagen DNeasy tissue kits will be sourced from Qiagen House, Fleming Way, Crawley, West Sussex, UK). After extraction, genomic DNA will be stored frozen at -20^{o}C for further analysis in the SAHS Laboratory.

PCR Analysis of *VacA* and *CagA* genes
For *vacA gene*, primers vac1F and vac1R will be used to amplify the signal sequence region[14] with amplification fragments of 201 and 228 bp expected. *Helicobacter* gene primers and enzymes will be sourced from Qiagen House, Fleming Way, Crawley, West Sussex, UK. The middle region of the *vacA* gene will be analyzed with 2 primer sets vac3F and vac3R, vac4F and vac4R, to amplify 388-bp fragments and 346-bp fragments respectively. For the amplification of *cagA* sequences, two primer sets will also be used. The first set, cag1 and cag3, will amplify a fragment of 612 to 615 bp from the hydrophilic region of *cagA*[14]. Primers cag2 and cag4 are derived from a region of internal duplications and will amplify DNA with expected fragment lengths of 450 and 558bp.
PCR amplification will be performed under the following conditions: initial denaturation at 95°C for 3 min followed by 35 cycles of denaturation at 95°C for 50 s, annealing and extension for 160 s, and final extension at 72°C for 2 min. Annealing temperatures will be set at 55°C for vac1F-vac1R, at 60°C for vac3F-vac3R and vac4F-vac4R, and at 50°C for primers cag1-cag3 and cag2-cag4[14]. Negative and positive controls (DNA of strain *H. pylori*) will be assayed in each run. Thirty microlitres of each PCR mixture will be subjected to gel electrophoresis on 2% agarose gels. Aliquots of the PCR products obtained with primers vac1F-vac1R and cag2-cag4 will be taken through restriction endonuclease digestion with the enzyme *Nla*III for 2 hours at 37°C prior to electrophoresis. The restriction products will be analyzed directly by electrophoresis on 3% agarose gel stained with ethidium bromide (Source: Qiagen House, Fleming Way, Crawley, West Sussex, UK). Work will be done in the SAHS Laboratory under Mr. Richard H. Asmah.

Data Handling and Statistical Analysis
Data will be initially entered into excel spreadsheet by the study research fellow and Principal Investigator. Data will be subsequently coded into the statistical program SPSS 16 by the principal investigator and the study research fellow continuously throughout the study timeline (December, 2011-August 2013). The Principal investigator will have an electronic copy of data entered with a back-up copy drawn up and updated after each entry session by the study research fellow. This will occur on Friday afternoons 2-4pm with collation of questionnaires. Data checking will be arranged on Wednesday afternoons (1-3pm) by the principal investigator for quality assurance purposes. Descriptive analysis will be based on the spectrum of endoscopic diagnoses, histological changes, anti-microbial susceptibilities and strain patterns in Helicobacter pylori infection. Data will be further analyzed to determine statistical significance between predictor variables (e.g. *Helicobacter strain*), correlates (e.g. age, gender) and outcomes (histological grade, stage of antral inflammation, anti-microbial susceptibility, endoscopic diagnoses) by the chi-square for the binary predictor variables and the student t-test for the continuous predictor variables.

e) Expected Outputs/ Deliverables

State expected outputs/ deliverables.

There is likely to be a geographic distribution of *Helicobacter-pylori*-induced gastro-duodenal disease in Ghana. Dietary, environmental and strain factors will be sought to explain this.

There may be a correlation between household structure, density, location, socio-economic status and *Helicobacter pylori*-related disease thereby raising pertinent issues regarding Public Health and transmission routes.

The endoscopic spectrum of disease will be varied and may not reflect the disease burden in some patient groups.

Anti-microbial resistance will contribute toward the continued prevalence of *Helicobacter pylori* infection and the variable success rates of *Helicobacter pylori* eradication therapy in Ghana. This may be a result of an increasing *Helicobacter pylori* resistance to (e.g. metronidazole, amoxicillin) in Ghana.

The cagA and vacA *Helicobacter pylori* strains have been proven to be more ulcerogenic and carcinogenic in Western subjects. They are likely to be responsible for the severity of *Helicobacter*-induced Gastro-duodenal disease although the degree of correlation remains undiscovered.

f) Work plan and Implementation Plan

Provide a work and implementation plan showing when each activity will be delivered.

Project Work Plan

Time line

Start date: July 2010

Proposed ending date: August 2013

Project Implementation Plan

Activity Time line

Collection of Questionnaire Data and Samples:	July, 2010 – December, 2011
Preparation of Laboratory reagent and processes:	August, 2012 – September, 2012
Laboratory Analysis:	September, 2012 – February, 2013
Analysis of Results:	February, 2013 – April, 2013
Report Writing:	May, 2013 – June, 2013
Presentation of Project Report:	July, 2013 – August, 2013

g) Administrative/ Management Arrangements

Give details of administrative / management arrangements which would be put in place to ensure successful project delivery.

There will be regular weekly (Thursday) meetings of the Core Investigation team in the School of Allied Health Laboratory, 4-5pm, to discuss project issues, procurement, update investigators as well as administration. The Principal Investigator will be responsible for all correspondence with the Ethical and Protocol Review committee, patient sampling and informed consenting. Research assistants will support the Principal Investigator with questionnaires and consenting. The Principal Investigator, in conjunction with the co-investigators, will ensure all consumables e.g. questionnaires, stationary, DNAgard and CLO rapid-urease testing are available during the requisite project periods. Questionnaires and all confidential data will be stored in a secure cabinet in the Department of Medicine, UGMS.

The School of Allied Sciences Molecular Biology team (Richard H. Asmah) will arrange storage of gastric specimen in DNAgard, quotations, ordering of reagents and report to the Principal Investigator at the Thursday Project meeting. They will also be in charge of DNA extraction, primers, and PCR analysis of antral samples. The Principal Investigator will take stock weekly by tracking reagent use and update the Investigation team. Research assistance will be required in delivering specimens to the SAHS laboratory from the Korle-Bu Hospital Endoscopy Unit. The Pathology Team (Prof. R. Gyasi, Prof. E.K. Wiredu) will be in charge of histological assessments on antral samples received. The Microbiology Team (Dr. Japheth Opintan) will be in charge of microscopy, culture and sensitivity on antral samples received. The Community Health Department will assist in questionnaire development and data analysis.

h) Monitoring and Evaluation

Statement for monitoring and evaluation of the project.

Continuous review of project processes involved in sampling, delivery, storage and testing will be the responsibility of the Principal Investigator. Reporting on these will be mandatory at the weekly project meeting. To ensure quality, there will be data checking and evaluation of methods periodically. The Principal

Investigator will update the Ethical and Protocol Review Committee six-monthly on progress and development of the Research.

***HELICOBACTER PYLORI* QUESTIONNAIRE**

Name:	Age	Sex:
Occupation:	Address:	Hometown:
Medical Complaint?		
Do you smoke? Yes.....no..... If YES, how many cigarettes/day.....		
Do you drink alcohol? Yes.....no..... If YES, how much alcohol/week? Beer/lager.....Spirits.....Wine..... How long have you been drinking?		
Do you take any herbal preparations? Yes.....no..... If YES, which preparation?		
Household structure: Detached..... Semi-detached..... Compound House..... Number in entire household..... Toileting: communal..... household.....		
How many meals/day do you have?		
Do you prefer spicy foods? Yes.....no..... If NOT, what are your dietary preferences?		
Do you take pain killers Yes.....no..... If YES, which agent(s)? How often? I..... II..... III..... Why?.....		
Do you take other medications? Yes.....no..... If YES, which drugs?		
Have you had any antibiotics over the past two (2) weeks? Yes..... no..... If YES, which antibiotics?(duration).....		
Have you been treated for a previous *Helicobacter* infection? Yes.....no..... If YES, which antibiotics?(duration).....		
Data Collection (Physical signs) sheet (tick when present and describe findings)		
General examination General appearance: cachexia....., obesity....., abdominal distension..... Hands, nails, conjunctivae: pallor....., jaundice....., clubbing..... Mouth, tongue: cyanosis....., candida infection....., ulcers....., glossitis....., stomatitis (cheilitis)....., lymphadenopathy & region.....		
Abdominal examination Abdominal scars..... Abdominal tenderness (region)..... Mass (region).....Hepatomegaly.....Ascites.....		
FOR OFFICE/LAB USE *CLO Helicobacter result*..... *Gastric antral biopsy result*..... *Microbiological analysis*..... *Molecular strain analysis*.....		

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4. BUDGET STATEMENT (Max. 1 page)

State total budget required, complete summary table below covering main budget lines, and provide justification for key budget items
GHC 29,688.75

a) Summary budget table

Budget item	Yr 1 (GHS)	Yr 2 (GHS)	Total (GHS)
1. Project personnel	10,000	0	10,000
2. Equipment	1,700	0	1,700
3. Consumables	12,375	0	12,375
4. Field Costs	0	0	0
5. Local Travel	400	0	400
6. External/ International Travel	0	2,500	2,500
7. Dissemination (including publications)	400	400	800
8. Office & Administrative Expenditure	500	0	500
9. Contingency (5%)			1,413.75
GRAND TOTAL			29,688.75

b) Justification of key budget lines *(as indicated above)*

1. **Project personnel**: Two research assistants will be working full-time during the study period providing 50% effort respectively. This will attract a cumulative salary of GHC 3000 each. Research Assistant 1

	will be responsible for histological and microbiological analysis in the Pathology & SAHS Laboratory, UGMS under the supervision of Prof. R. Gyasi and Dr. Japheth Opintan. Research Assistant 2 will be responsible for all molecular analysis in the SAHS Laboratory under the supervision of Mr. Harry Asmah of the Department of Medical Laboratory Sciences, SAHS. They will be assisted by two laboratory support staff (50% effort each) during the study period attracting a cumulative salary of GHC 2000 each.
2.	**Equipment:** A personal computer with installed data-processing programs (excel, Microsoft access) and statistical software (SPSS Inc.) will be required on site for the weekly updating of data by the Principal Investigator. It is envisaged study data will also be stored on pen drive to facilitate data transfer with co-investigators and also to facilitate data collation and statistical analysis. This will require internet access on-site to ensure efficiency of data handling. These costs will amount to GHC 1700.
3.	**Consumables:** DNAgard agent is a necessary consumable for preserving sampled gastric tissue for over 12 months. It will cost GHC 5 per patient sample amounting to GHC 1250 for 250 patient sample sets. DNA extraction will the initial step in molecular analysis with an extraction kit at GHC 8 per patient sample amounting to GHC 2000 for 250 patient samples sets. CagA and vacA primers will be used to amplify the signal sequence region during molecular genetic analysis and will cost GHC 10 per patient sample set amounting to GHC 2500 for 250 patient sample sets. Also required in the amplification process (denaturation, restriction endonuclease digestion) will be DNA Taq polymerase (GHC 7 per patient sample amounting to GHC 1750 for 250 samples sets), the *dNTP Set* (GHC 5.5 per patient sample set, GHC 1375 for 250 patient sample sets), agarose gels (GHC 2 per patient sample, GHC 500 for 250 patient sample sets) and DNA molecular weight markers (GHC 2 per patient sample, GHC 500 for 250 patient sample sets). A fixative of 10% phosphate buffered formalin will be required for histological analysis of gastric antral biopsies at a unit cost of GHC 2, GHC 500 for 250 patient sample sets. The preparation of the histological slides will cost GHC 2 per patient sample set, GHC 500 for 250 patient sample sets. E strip preparation will be necessary for anti-microbial sensitivities of antral *Helicobacter pylori* with a unit cost of GHC 6 per patient sample, GHC 1500 for 250 patient sample sets.
4.	**Field Costs:** No field costs will be required as all 239 patient gastric samples have been collected.
5.	**Local Travel:** Local travel for acquisition of reagents, supplies, seminars as well as visits to the main campus, University of Ghana for administrative reasons will approximately amount to GHC 400.
6.	**External/ International Travel**: International conference travel will be required in the dissemination of results so as to stimulate collaboration for further multi-disciplinary grants. This will amount to GHC 2500.
7.	**Dissemination** (including publications): The cost of manuscript preparation, online submission and local presentations will amount to GHC 800.
8.	**Office & Administrative Expenditure**: Pens, pencils, printing paper and communication costs between staff will be necessary. These administrative costs will be approximately GHC 500
9.	**Contingency (5%):** To cater for inflation and future price adjustments it is envisaged that GHC 1413.75 will be required to offset their impact on the project processes and supplies.

APPENDIX 1: FULL BUDGET TABLE (Max. 1 page)

OFFICE OF RESEARCH, INNOVATION AND DEVELOPMENT

BUDGET TEMPLATE FOR UNIVERSITY OF GHANA RESEARCH GRANTS

BUDGET ITEM	Unit Cost	Units	Year 1		Year 2		TOTAL COST
			No. of units	Cost	No. of units	Cost	
1. Project Personnel							
Research Assistants	3000	2	2	600	0	0	6000
Graduate Assistants				0		0	0
Teaching Assistants				0		0	0
Laboratory support staff	2000	2	2	400	0	0	4000
Students				0		0	0
Pls. add on as many rows as needed				0		0	0
2. Equipment* (please itemize all equipment needed)							

Computers etc.	1200	1	1	120	0	0	1200
Computer programs (SPSS, Microsoft work,	500	1	1	500	0	0	500
				0		0	0
3. Other Research Costs (Consumables)							
DNAgard preserving agent	5	250	250	125	0	0	1250
CagA & VacA primers	10	250	250	250	0	0	2500
Agar medium; E test strips	6	250	250	150	0	0	1500
DNA Extraction Kit	8	250	250	200	0	0	2000
DNA Taq polymerase	7	250	250	175	0	0	1750
dNTP Set (dATP, dGTP, dTTP, dCTP)	5.5	250	250	137	0	0	1375
Histological slides	2	250	250	500	0	0	500
Formaldehyde reagent	2	250	250	500	0	0	500
Agarose gel	2	250	250	500	0	0	500
DNA Molecular weight marker (100 bp)	2	250	250	500	0	0	500
4. Field Costs							
e.g Data Collection			0		0	0	0
			0		0	0	0
5. Travel (Local)							
	200	2	2	400	0	0	400
				0		0	0
6. Travel (International)							
	2500	1	0	0	1	2500	2500
				0		0	0
7. Dissemination (including publications)							
	400	2	1	400	1	400	800
				0		0	0
8. Office and Administrative Expenditure							
	500	1	1	500	0	0	500
				0		0	0
9. Contingency (5 percent)							
							1413.75
10. *Please add on as needed……*							
GRAND TOTAL							29,688.7

APPENDIX 2: INFORMATION ON INVESTIGATOR (s) (Max. 1 page for sum. of PI(s) experience & 3 pages for abridged CV)

a) SUMMARY OF PI(s) EXPERIENCE

Provide a summary of the PI's experience and expertise that show that he/she can deliver the project successfully. **Max. 1 page**

My interest in Research started at undergraduate level. As part of the Special Study Research Modules of Phase 1 MBChB (Leicester), I took up research projects in the following areas of study culminating in the Award of Distinction. In Biochemistry of Inflammation, I studied the role of superoxide dismutase in the inflammatory process in cells. Superoxide dismutase is an enzyme that repairs cells and reduces the damage done to them by superoxide, the most common free radical in the body. The outcome was that superoxide dismutase plays a pivotal role in maintaining the health of tissues and has an anti-inflammatory and anti-oxidant role in this process. Physiological Measurement covered the quantitative assessment and visualization of physiological function in clinical research and practice, with an emphasis on the development of new methods of measurement and their validation.

I have successfully collated retrospective data on patients with Inflammatory bowel disease (IBD) and Irritable bowel syndrome (IBS) seen at the Korle-Bu Teaching Hospital over the past six years and have been able to draw up trends on IBD/IBS disease expression in Accra, Ghana.
In 2010, I collaborated with Kwamin F, Sackeyfio J. T. et al in the review of the ethical implications in the screening of health care students For Hepatitis B/HIV at the College of Health Sciences, Korle-Bu, Accra. It elicited the need for an emphasis on pre-screening counseling for health care students about the implications of Hepatitis B and HIV screening.

I have shown keen interest in Research Audit resulting in the development and completion of a number of projects as the key investigator leading to important inferences drawn on management and assessment methods in Northampton General Hospital (NGH) and University of Leicester NHS Trust (UHL), UK.
The Research Audit on the delay in the diagnosis of colo-rectal cancer in Northampton General Hospital led to a specialized follow-up pathway for the reporting of low ferritin levels in the Health Trust.
The study of the outcome of Clostridium Difficile diarrhoea in the University of Leicester Hospital Trust (UHL) Elderly Care Ward led to the need to optimise treatment early (after 48 hrs) to ensure rapid resolution.
The role of pre-dosing virology testing was emphasized in the Beri-plex Audit into warfarin-related life-threatening haemorrhage (UHL). This was as a result of the risk of blood borne transmission of viruses and its medico-legal consequences.

I have been actively involved in developing my research skills by participating in the eight-week Brown University Summer Clinical and Translational Research Course, 2011 as an NIH Fogarty Fellow, June-July, 2011. I have also made a significant contribution to the development of my specialty area, gastroenterology such that our department elected me Head of the Gastroenterology Unit and Medical Unit 1. I have continued to show keen interest in research and have recently had the study on Hepatitis B Viral Resistance to Lamivudine (3TC) Therapy in Hepatitis B-HIV Co-infected Ghanaian Patients approved by the department and our medical school's protocol and ethical review panel.

b) Abridged CV of PI

Please attach an abridged CV of not more than 3 pages as part of Appendix 2.

CURRICULUM VITAE

Name: Timothy Nii Akushe Archampong

Date of Birth: 10.02.1976

Address: Department of Medicine and Therapeutics, University of Ghana Medical School, Box 4236, Accra, Ghana
MDC (Gh) Number: 0004633

Tel: Home: 0302685161
Mobile: 0249966209
E-mail:tnaa@doctors.org.uk
GMC Number: 6063275

EDUCATION

UNDERGRADUATE

From	To	Institution attended	Qualification
6.9.97 -	8.11.02	University of Leicester Medical School, UK	MBChB (Leicester)

Distinction 06.2002
Achievements in the Science Skills Special Study Research Modules of the MBChB Course:
Biochemistry of Inflammation Physiological Measurement

Merit Award 04.2002
Achievements in the Core Medical Science Modules of the MBChB Course
Excellent in Gastro-Intestinal System, Respiratory System, Musculo-skeletal System, Cardiovascular System, Mechanisms of Disease & Histology, Human Diversity, Clinical Pharmacology, Neurobiology, Metabolism and Biological Molecules

PROFESSIONAL QUALIFICATIONS

Date	Institution	Qualification
21.09.2011	Federation of Royal Colleges of Physicians of the United Kingdom & The British Society of Gastroenterology	Specialist Certificate in Gastroenterology
20.10.2005	Royal College of Physicians of London & the United Kingdom	MRCP(UK), MRCP(London)

PROFESSIONAL APPOINTMENT

16. 02. 2009 - **Gastroenterologist & Physician Specialist**
Korle-bu Teaching Hospital, Korle-bu/Accra

ACADEMIC APPOINTMENT

16. 02. 2009 - **Lecturer**
Division of Gastroenterology and Hepatology, Department of Medicine, University of Ghana Medical School (UGMS), Box 4236, Korle-bu/Accra

- Head, Medical Unit 1, Gastroenterology & Hepatology Unit
- Examinations Officer, Undergraduate Medical Education, Department of Medicine and Therapeutics
- Introductory Clinical Course Coordinator, Graduate Entry Medical Program (MBChB)
- Vice-Chair, Endoscopy Committee, Korle-bu Teaching Hospital
- Member, Quality Assurance Committee (UGMS)

PREVIOUS MEDICAL APPOINTMENTS

From	To	Post Description	
4. 8. 2006	1. 11. 2008	Medical Registrar	Gastroenterology & General Medicine (Dr Watts) Wythenshawe Hospital/South Manchester University Hospitals NHS Trust; Gastroenterology & General Medicine (Dr Sherwood/Dr Shah) Northampton General Hospital NHS Trust (NGH)
1. 2. 2004	3. 8. 2006	SHO Rotational Posts	University of Leicester NHS Trust Senior House Officer Medical Rotation (Gastroenterology, Cardiology, Respiratory, Neurology/Elderly Care/Stroke Medicine, Haematology) (UHL)
2. 2. 2003	1.2 2004	Medical House Officer	Southampton General Hospital Pre-Registration House Officer in General Medicine, (Dr D G Waller/Dr Zaman) William Harvey Hospital (WHH) Pre-Registration House Officer in General Surgery/Urology(Mr Basnyat)

CURRENT RESEARCH EXPERIENCE & PROJECTS

	Topic/Role
06-08. 2011	**Fogarty Fellow (NIH), Research Training:** Brown University Summer Clinical and Translational Research Course, Rhode Island, USA
06. 2010 (Project started)	**Helicobacter pylori-related gastro-duodenal disease in Accra.** **Principal Investigator** To investigate *Helicobacter pylori* associated gastro-duodenal disease in Ghana. To determine the severity of endoscopic and microscopic *Helicobacter pylori* infection. To analyse the range of strains of *Helicobacter pylori.*To identify the virulent and oncogenic *Helicobacter pylori* strains endemic in Accra, Ghana.
11. 2011	**Hepatitis B viral resistance to 3TC (Lamivudine) in Hepatitis B-HIV co-infected Ghanaian patients.** **Principal Investigator** This study will provide the basis for information on the spectrum of 3TC resistance in treatment-naïve and treated HIV-HBV co-infected patients thereby investigating contributing intrinsic (host) factors.

PUBLICATIONS

F. Kwamin, J.T. Sackeyfio, J. S. Acquah, T. Archampong, A.A. Boateng. Ethical Implications in the screening of Health Care Students For Hepatitis B/HIV at the College of Health Sciences, Korle-Bu. Ghana Dental Journal 2011; 8:20-23.

PUBLICATIONS IN PREPARATION

1. Archampong TNA, Asmah H, Wiredu, EK, Nkrumah KN. The Clinical Epidemiology *of Helicobacter pylori*-related gastroduodenal disease in Accra
2. Archampong TNA, Nkrumah KN. Functional Bowel Diseases at the Korle-bu Teaching hospital
3. Archampong TNA, Nkrumah KN, Acquaye E. Lamin J. Patterns of Inflammatory Bowel Disease in Accra: Is there a new trend?

APPENDIX 3: RESEARCH ASSURANCE

University of Ghana Research Fund
Ethical Review and Research Assurance Form
Please take note that proposals which are not accompanied by this form shall not be considered

I. Ethical Review
Please indicate in the corresponding box if any of the following are involved in the research:

- Human Subjects ☑
- Animal Subjects ☐ *(Please specify)* _____
- Radioactive Material ☐ *(Please specify)* _____
- Potential Biological Hazards ☐
- Hazardous Chemicals ☐

Have you obtained the required ethical clearance to enable you conduct the research? **Yes** ☑ **No** ☐

If the answer to the above question is No, please give an indication of when you expect to receive the required ethical clearance _____

II. Research Assurance

"I DR. TIMOTHY ARCHAMPONG *(Please insert name of PI)* of the Department/ ~~School/ Institute~~ OF MEDICINE of the University of Ghana, agree to accept responsibility for the scientific, ethical and technical conduct of the research proposal above. I shall provide a regular progress report if a grant is awarded as a result of this application in accordance with the rules and regulations of the grant.

I further declare that I shall be at post during the period when this research grant is operating. I understand that the University may apply any sanctions against me should I abandon this project without submitting appropriate accounts and reports".

Signature: T Archampong

Date: 15/3/12

III. Endorsement by Head of Department Ag.

I DR AUDREY G. FORSON *(Please insert name of Head of Department)* confirm my support for this proposal and give assurance that the Principal Investigator will remain at post during the period in which the research grant is operating.

Signature: A Forson

Date: 16/3/12

DEPT. OF MEDICINE & THERAPEUTICS
KORLE-BU TEACHING HOSPITAL
P. O. BOX 77, KORLEBU