BIRAC-Wellcome Trust Joint Call in Translational Medicine

FULL APPLICATION GUIDANCE NOTES

PLEASE NOTE THAT:

THE WELLCOME TRUST AND BIRAC (together, the "FUNDERS") RESERVE THE RIGHT NOT TO PROCESS YOUR APPLICATION SHOULD YOU BE INELIGIBLE TO BE AN APPLICANT OR SHOULD THE SUBJECT OF YOUR PROPOSAL NOT FALL WITHIN THE FUNDERS' REMIT.

THE FUNDERS' WILLINGNESS TO CONSIDER THE APPLICATION IN NO WAY IMPLIES THAT SUPPORT WILL BE FORTHCOMING.

These notes are for guidance in completing the BIRAC-Wellcome Trust Joint Call in Translational Medicine Full Application Form. They must be read by all those concerned with writing the application - the Principal Applicant, any Coapplicants, the Head of the Technology Transfer Office/Group (or its equivalent) and the Head of Department in which the work will be undertaken.

1. ELIGIBILITY

The Principal Applicant and Coapplicant(s) must check their eligibility to apply to the BIRAC-Wellcome Trust Joint Call in Translational Medicine before completing this form.

Definitions of Principal Applicants, Coapplicants, collaborators etc can be found in Section 7.

The Principal Applicant and Coapplicants are expected to be actively involved in the project. It is the expectation that no more than four Coapplicants will be associated with the application.

In addition it is essential for a member of the institution's Technology Transfer Office/Group or the company's Business Officer to be involved in submission of the application. A representative of the Technology Transfer Office/Group or the company Business Officer is required to take responsibility for information provided on commercial matters. The Wellcome Trust and BIRAC will require that they are also required to submit a letter with the application; the template letter for completion will be provided.

2. HOW TO COMPLETE THE FORM

Please follow these instructions when completing your form as this will help to avoid any unnecessary delay in the assessment of your application.

- You should ensure that all relevant sections of the form are completed.
- Answers should be entered in the text boxes provided, or uploaded as a PDF or Word document where indicated.
- Please adhere to word limits where they are specified to avoid your form being returned for amendment.
- If abbreviations are used, please ensure these are fully explained to assist the reader.
- The application must be complete in itself; no additional pages will be accepted unless otherwise notified.

3. HOW TO SUBMIT YOUR APPLICATION

Once you have completed all sections of the form, you are required to submit your application to:
techtransfer@wellcome.ac.uk **by 5pm local Indian time, 7 August 2014**.

4. RELATED APPLICATIONS

You are expected to inform the Wellcome Trust and BIRAC if you subsequently decide to submit this or a similar proposal to another funding body whilst this application is still being considered under the Joint Call. Non-compliance may lead to refusal to consider the application. If the applicants' request funding for the same costs on more than one application to the Wellcome Trust and BIRAC at any one time, they must make this clear in their application.

5. INFORMATION ON FUNDING OF AWARDS

Awards will be agreed by BIRAC-Wellcome Trust Joint-Call Committee and each successful application under the Joint Call may be funded by either BIRAC or the Trust in accordance with that Funder's standard funding terms and conditions.The decision as to which Funder will fund each successful application will be at the sole discretion of the Funders and will be final and binding on applicants.

6. OTHER IMPORTANT GENERAL INFORMATION – WELLCOME TRUST

a) Costing principles

- The Wellcome Trust will normally fund only the **directly incurred costs** of research. The Trust might consider funding **other costs** when it helps us to further our charitable mission.
- For details of the Trust's position on full economic costs, please refer to our website (www.wellcome.ac.uk/About-us/Policy/Policy-and-position-

statements/WTX026852.htm).

- The Wellcome Trust does not normally consider support for the extension of professional education or experience, nor for the care of patients.

- The Wellcome Trust does not provide top-up support for research currently active and supported by other funding bodies.

- The Wellcome Trust will not award grants to cover expenditure already incurred.

- Grants are cash-limited at the point of award.

b) Code of Conduct

The Wellcome Trust's Board of Governors and members of the Wellcome Trust's advisory committees are required to abide by a 'Code of Conduct' which is designed to protect and preserve the integrity of our advisers and our processes. Part of this code states that committee members may not discuss any aspect of the deliberations or recommendations of the committee with applicants. To avoid embarrassment and the possibility of further action by the Wellcome Trust, you should not contact committee members.

c) Eligibility

In view of the overwhelming evidence that both active and passive smoking of tobacco are injurious to health, the Wellcome Trust is unwilling to fund applications from individuals applying for, holding, or employed under, a research grant from the tobacco industry.

7. OTHER IMPORTANT GENERAL INFORMATION – BIRAC

a) Costing Principles

Costing principles refer to Guidelines for applicants under [Refer to BIRAC website www.birac.nic.in under Programmes click the Tab BIRAC-WT Joint Call]

b) Code of Conduct

The Applicants and the Co-applicants should observe the highest standards of ethics during the application and should avoid any corrupt and fraudulent practices. In pursuance of this Code of Conduct, BIRAC defines the terms set forth as follows:-

"Corrupt Practice" means offering, giving, receiving or soliciting of anything of value or any other action to influence the decision-making of the official in the process detrimental to free and open competition;

and

"Fraudulent Practice" means a misrepresentation of facts, in order to influence the funding process, and includes collusive practice among Applicants and Co-applicants (prior to or after proposal submission), designed to deprive BIRAC of the joint call benefits or enforceability of related agreements.

8. REFEREES

When your completed Full Application is received by the Funders, it will be sent to experts chosen by the Funders' scientific staff.

9. CONTACTS

If you have questions about the application procedure and content, please contact:

At the Wellcome Trust:

- E-mail Dr Shirshendu Mukherjee: s.mukherjee@wellcome.ac.uk

- Alternatively, call the Grants Management Helpdesk on +44 (0)20 7611 8202, or e-mail: techtransfer@wellcome.ac.uk

At BIRAC:

- [Dr Jyoti Shukla, Technical Manager at Email jshukla.birac@nic.in]

10 DEFINITION OF TERMS

A **principal applicant** is the lead investigator who will be the main contributor to, and have ownership of the project if the application is successful. This is the individual with whom the Wellcome Trust and BIRAC will correspond about the application.

The status of **joint-principal applicant** is given when there are two or more lead investigator who are based at different institutions. The administration and funds for the project are shared between the institutions. Individually, each of the joint-principal applicants fulfils the criteria of Principal Applicant above.

The **technology transfer office/group** is the term used to describe the technology transfer office or any group with delegated responsibility for the management of commercial matters arising from University based research. A Business Officer or equivalent should be named in applications from companies.

A **coapplicant** is a researcher who will make a significant contribution to, and have part ownership of, the project if the application is successful.

A **sponsor** is an individual who is able to guarantee that space and resources will be made available for the project if the Principal Applicant does not hold an established position. A Sponsor should be able to reassure the Wellcome Trust and BIRAC that the Principal Applicant will be welcomed into the host department. The Sponsor must hold an established post or hold a Wellcome Trust Senior/Principal Research Fellowship and have tenure beyond the duration of the grant.

A **collaborator** is an individual who will supply technical advice, reagents, samples or data for the project, but who would not normally be involved in the day-to-day execution of the project (unlike applicants and coapplicants). Collaborator involvement should be governed by appropriate legal agreements, e.g. material transfer agreements, confidentiality agreements and/or consultancy agreements. If such agreements are

already in place, copies should be provided with the application.

A **project milestone** is a key decision point within the project, and can be either scientific or commercial, e.g. completion of a specified set of experiments, or drafting of a business plan.

A **Gantt chart** is a project plan setting out the key tasks to be undertaken in parallel and sequentially together with timescales.

NOTES RELATING TO QUESTIONS ON THE FULL APPLICATION FORM

UNDERTAKINGS

These must be signed by:

- the Principal Applicant and all Coapplicants;
- the Head of Department in which the work will be undertaken;
- the Secretary or Finance Officer of the Institution on behalf of the Institution; and
- Head of the Technology Transfer Office/Group or the Company Business Officer.
- All applicants will need to provide an authorisation letter from the Institute or the Board resolution of the Company addressed to BIRAC..

If you are submitting a joint application involving more than one institution, you should duplicate this page and ensure that each institution signs it.

PROPOSED START DATE

Applications should normally be submitted at least six months before the proposed starting date.
In the case for BIRAC funded awards, Please note that the proposed start date of the project is the date of signing the agreement with the BIRAC

RELATED APPLICATIONS

The Funders will neither consider nor process an application for where the same or a related application is under consideration by another organisation.

COST OF MILESTONES

Please provide an approximate total cost for the application with an assessment of cost to each project milestone within the scientific proposal as a breakdown of the total cost. Costs provided to project milestones should sum to the total cost of the award. You should identify a minimum of three and a maximum of four project milestones within the scope of the project.

The Wellcome Trust will retain 10% of the total transferable funds budget up to a total of £100,000 until an End of Grant Spend Report and an End of Grant Report have been completed and returned to the Trust, unless the Trust agrees otherwise.
The project should have 5 milestones wherein 1st milestone is signing of the agreement

followed by three technical milestones and finally 5th milestone which is submission of report.

DETAILS OF THE INVESTIGATION

For a joint application, please indicate what work will be undertaken in each institution.

Please provide a projected total cost for the application with an assessment of cost to each project milestone within the scientific proposal as a breakdown of the total cost. Costs provided to project milestones should sum to the total cost of the award. You should identify a minimum of three and a maximum of four project milestones within the scope of the project. The project should have 5 milestones wherein 1st milestone is signing of the agreement followed by three technical milestones and finally 5th milestone which is submission of final report.

Graphs, figures and supporting unpublished data may be embedded in the text or included as an appendix. This data must not exceed the equivalent of five A4 pages in length.

Applicants must provide all information pertinent to their grant proposals within the application form (it is not acceptable to refer to additional unpublished information on personal websites).

Experimental design and methods to be used in investigating this problem

Where definitive experiments using animals are proposed, the experimental design should include the case for the number of animals required. You should estimate the number of animals needed, taking into account the likely magnitude of the effect and required statistical significance and power, and the factors that might affect this. It is unacceptable to base the number of animals to be used solely on a calculation of the number of experiments that can be carried out in a given time. It is also unacceptable to state that numbers are based on "previous experience" without additional justification, or to answer the question on numbers of animals to be used by paraphrasing the question in the form, for example: "these numbers are chosen as the minimum necessary to achieve statistical significance". Too few animals is just as unsatisfactory as too many. The sample size calculations used to estimate the number of animals required in the proposed experimental design should be stated where appropriate.

Animal studies usually present opportunities for random allocation and very efficient (for example, factorial) designs, and applicants should therefore pay particular attention to their experimental design. Some procedures are not definitive, for example, those to acquire tissue material or for preliminary estimation of the likely magnitude or frequency of an experimental effect. In such cases, a precise calculation of the number of animals needed cannot always be made, but the use of animals must still be optimised, and the number requested must be fully justified.

Project plan

Include a Gantt chart of the project plan setting out the key tasks to be undertaken in parallel and sequentially together with timescales.

Addressing unmet healthcare needs and target populations

You should identify and define the intended target population(s) for which the healthcare product and solution will benefit. Consider whether there are opportunities for extending the benefit your technology brings to other target populations that may exist within or outside India.

Affordability

You should summarise the technological and other considerations that have been made to ensure your product will be affordable for the Indian market for the maximum number of potential beneficiaries.

REFERENCES (Research Project)

A full citation, including the title of the paper and the name of all the authors, is to be provided. The preferred format is as follows: all authors' names (surname, initials); year of publication; title of article; journal name plus volume number, then page numbers.

Applicants will be asked to resubmit their references page if the citations are not provided in full and this might result in a delay to the processing of the proposal.

Applicants may refer to papers "in press"; copies of these papers should be submitted. Manuscripts that are "in preparation" or "submitted for publication" must not be included in the reference list but key data from these papers may be submitted as part of the allowed appendix/appendices of additional data.

COMMERCIAL MATTERS

This section should be completed with input from your Technology Transfer Office/Group (or the appointed University body with responsibility for this area) or Business Officer.

Patent information
Please provide details of all patent applications filed before the date of this application which relates directly to the research project outlined. State the funding sources that contributed to the development of the patented technology, e.g. company collaboration, research council and/or charity funding.

Intellectual property and freedom to operate

- Summarise the inventive step and key claims of patents or patent applications relating to the technology that have already been filed;
- Consider whether there are any freedom to operate issues in the area of the proposed technology and consider how these will be worked through during project management; including any IP that needs to be or has been in-licensed;
- Explain how the proposed experiments will add value to, or strengthen an existing intellectual property position;
- Outline the novel and inventive aspects of the Affordable Healthcare project being proposed for funding;
- Outline any likely new patent filings that may arise from this project and set out the main areas of likely claims.

Competitive position

- Summarise the competitors, competing technologies/products and stage of

development within the field.

- Describe the competitive advantage of this technology over others that are being developed and thoses that are already launched in the market, including an assessment of the advantages and disadvantages of these competitive technologies.
- Indicate the potential magnitude of the target healthcare market and in particular consider the market segment that this technology will target in India and potentially other markets outside of India.
- Describe the competitive advantage of the project team over other researchers in the field.

Commercialisation and/or adoption strategy

- What are the strategy and plans for attainment of a commercial exit, and how will this be implemented?
- What is the rationale behind this route?
- What are the outputs going to be (e.g. platform technology description, product descriptions)?
- Are there any clinical, manufacturing, regulatory or marketing issues known that may affect the ability to deliver the product to market and proposed solutions?

Current or downstream regulatory considerations or risks

Describe the regulatory approval and adoption strategy, and the elements that need to be in place in order for the healthcare product or solution to be made available to the relevant, greatest proportion of the target population in India within the shortest possible time.

Provide evidence that clinical and regulatory requirements that are known are being accounted for in the product development stages.

Describe the R&D strategy and portfolio/pipeline, in the case of companies

Briefly summarise the strategy, competencies and company portfolio and describe the portfolio fit for this proposal.

If there are any ties on intellectual property rights or publications arising from the research you undertake, please provide a written statement which details them.

For full details of Wellcome Trust policy in this area is found in Grant Condition 7.
For full details of BIRAC policy in above areas kindly refer to Guidelines for applicant regarding this Joint Call. Refer to BIRAC website www.birac.nic.in under Programmes click the Tab BIRAC-WT Joint Call

OUTLINE OF PUBLIC ENGAGEMENT PLANS

The Wellcome Trust is committed to engaging with society about the research it supports. We aim to raise awareness and understanding of biomedical science and place it within a societal, historical and cultural context. Further information is available on the Wellcome Trust's website under Engagement with your research.

We expect those researchers who receive funding from the Wellcome Trust or BIRAC to help foster an informed public climate within which biomedical science can flourish.

No more than 250 words should be used to describe what plans, if any, you have for engaging with the lay public about your work. State how the host organisation will support these plans.

CURRICULUM VITAE OF APPLICANT(S)

Source of personal salary support

Your source of salary may have an impact on your eligibility to apply for a Wellcome Trust grant. Please, therefore, state the source of funding of your salary, by indicating whether the salary is funded by a Higher Education Funding Council (HEFC) or another source (Indian or foreign). Please also be specific if your salary is being funded from more than one source and state the relative contributions of these sources.

If there are any ties on intellectual property rights or publications arising from the research you undertake, please contact the Wellcome Trust or BIRAC for advice. Restrictions on intellectual property may affect your ability to apply to the Wellcome Trust and BIRAC.

If the source of personal salary support is indicated as “other” and is commercial, please submit the following additional information with your application in order that Wellcome Trust and BIRAC staff may verify your eligibility:

(i) Copies of any agreements between the company, yourself and/or your employer;

(ii) A written statement from the commercial body indicating that there are no ties on intellectual property which arise from research you undertake, nor any restrictions on publications. If there are any ties, you may not be eligible to apply to the Wellcome Trust or BIRAC and should contact the appropriate Funding Committee for advice.

Summary of career to date, including key achievements

Please summarise what you consider to be your key achievements and state which period of your career they relate to. You do not need to list all your positions.

Wellcome Trust and/or BIRAC funded publications

The Wellcome Trust’s open access policy requires all original research papers, supported in whole or in part by Trust and/or BIRAC funding, to be made available through the PubMed Central (PMC) and Europe PMC repositories as soon as possible and in any event within six months of the journal publisher’s official date of final publication.

The PMCID reference is the unique ID assigned to an article in PubMed Central, e.g. PMCID: PMC3176834. The PubMed ID is not required.

Please note that:

- All Trust-funded papers published from October 2009 onwards, resulting from current or previous grants, must be compliant with this policy before any award can be activated.
- Applicants are advised not to include any non-compliant Wellcome-funded papers published from October 2009 onwards in their application submitted to the Trust; such papers will be discounted from consideration of a researcher's track record.

For further guidance, please refer to the Trust's open access policy statement and authors' FAQs

CURRENCY REQUESTED

Please note for the awards that will only bein India, costs will be considered in Indian currency.

It is expected that applications will be costed in the currency which, in the view of the applicant(s), best enables the activity to be undertaken. In the majority of cases, the currency specified is likely to be the local currency. Where this is not the case, the reasons for selecting the chosen currency must be clearly stated.

For full details of the implications of choosing a currency please refer to the Wellcome Trust's website.

If at any point, the Trust is unable to purchase the currency requested, discussions will be held with the Applicant Organisation to decide whether an alternative should be used. If you have any concerns that the currency you would like to request may not be readily available, please contact the Wellcome Trust by e-mailing: grantpayments@wellcome.ac.uk.

If the application is successful, the award will be made in the currency specified in the application, providing that the Wellcome Trust's currency requirements are met. Please refer to the Wellcome Trust's website for further information.

DETAILS OF FINANCIAL SUPPORT AND RESOURCES REQUESTED

The costs requested should exclude inflation in accordance with current Wellcome Trust policy (pay awards scheduled for Year 1 may be included in the costings). Please refer to the Wellcome Trust's website under Allowed costs for further information.

Please refer to the Wellcome Trust's website for details of allowed/disallowed costs and overseas allowances.

State clearly the currency used if not in UK £ Sterling (and exchange rate where appropriate).

Please also refer to Guidelines for applicant at www.birac.nic.in for details of allowed and disallowed cost.

Salaries

Please detail salaries requested for all staff to be funded on the grant. Salary support costings should be appropriate to local circumstances. Please refer to the Wellcome Trust's website for further information. Please also refer to Guidelines for applicant at www.birac.nic.in for details of allowed and disallowed cost in Personnel cost.

DEFINITION OF TERMS

Staff category: For example: “Postdoctoral research assistant”, “Technician”, “Fieldworker”.

Salary grade/scale: The national or local salary grade/scale on which the individual will be employed.

Basic starting salary: Salary to be paid to the individual upon their appointment to the post, exclusive of any allowances for which the individual is eligible. If the post is part-time, the salary should be quoted on a *pro rata* basis.

Total cost on grant: Total cost of the post, inclusive of any locally-recognised allowances (e.g. London allowance), employer’s contributions and increments, over the period of the grant. This total should include known pay awards that will take place during the first year (or an assumed percentage, equivalent to the Wellcome Trust's current inflation rate, where the scheduled pay award has not yet been confirmed).

Employer’s contributions should include any statutory obligations (e.g. for the UK, National Insurance contributions) and contributions towards an organisational pension scheme. (Please note that Employer’s contribution will not be applicable for awards funded by BIRAC)

Animals

In order to ensure animal experimentation costs are accurate, applicants are advised to complete this table after consultation with their animal house or biological services manager. The organisation is required to apply a consistent costing methodology when presenting cost details to the Wellcome Trust and BIRAC.

Source of supply
Details of intended source of supply (e.g. commercial company or in-house breeding programme) and the microbiological quality (e.g. barrier or non barrier-bred) should be provided.

Experimental procedures
State the experimental manipulations (e.g. injections, operations, blood sampling) which will be performed and the charge(s) levied for this.

Animals associated costs

These costs cover specific and relevant training and environmental enrichment, including training for animal husbandry, welfare and associated training for animal technicians. BIRAC will consider this cost based on the project’s justified need as well as on a case by case basis.

Details of total costs over the period of the grant should be provided; annual totals are not required. The costs requested should exclude inflation, in accordance with current Wellcome Trust policy. Please refer to the Wellcome Trust's website under Allowed costs for further information.

Equipment

The Organisation's Director of Procurement/Head of Purchasing (or equivalent) should be aware of all potential capital purchases.

Best procurement practice

The Organisation is required to use best procurement practice when purchasing equipment funded with Wellcome Trust and BIRAC funds.

Equipment purchase price

The estimated price of the equipment should cover all aspects including delivery, installation, maintenance and training, where appropriate. Discounted prices should be quoted wherever possible. A copy of at least one formal quote is required for each piece of equipment with a list price of £100,000 or more. The level of discount that has been negotiated should be clearly stated in the quote.

Maintenance costs

It is expected that the equipment requested will be covered by the manufacturer's warranty for the first year after it is purchased. The Wellcome Trust will fund reasonable maintenance costs for four years after the initial period of warranty on all equipment (irrespective of the length of award made) where this is negotiated as part of the capital purchase cost. BIRAC will consider on case basis specifically on high-end equipments.

Access charges

Access charges should be calculated on a cost-recovery basis and can include (i) a maintenance or service contract providing a basic level of service; (ii) running costs; (iii) materials and consumables; and (iv) staff time. BIRAC will consider this on case basis and project's justified need.

Value Added Tax (VAT)

For grants to be held in the UK, the costs of all equipment to be used for medical and veterinary research should be quoted exclusive of VAT. For equipment that does not fall within this definition, VAT costs should be shown.

Contract research organisation costs

Where there is a requirement for a project to outsource certain elements of the work to contract research organisations, please provide a breakdown of these costs.

Where possible, please include quotes with the application.

The applicants, through their Technology Transfer Office (or equivalent), will be responsible for the arrangements made with outsource suppliers. Such arrangements must be on a value for money, fee-for-service basis, and should not involve intellectual property sharing or joint-ownership unless such arrangements have been specifically agreed with the Wellcome Trust and BIRAC. Both background and arising intellectual property must be free of encumbrance for translation.

Miscellaneous

Travel costs

The Wellcome Trust will automatically provide an amount for the Principal Applicant and any research assistant to attend scientific meetings, either in India or abroad, on awards made to Universities. Requests for this purpose should not, therefore, be included. Only those Coapplicants requesting their own salary will be provided with a travel allowance.

If travel costs for collaborative travel are requested, please detail the airfare, and calculate subsistence costs based on the rates published on the Wellcome Trust's website. The need for the visit, and its duration, must be justified under **'Reasons for support requested'**.

ACCESS TO RADIATION SOURCES

Access to Synchrotron Radiation Sources
Applicants will be expected to apply directly to the synchrotron facility they wish to use (e.g. Diamond Light Source; European Synchrotron Radiation Facility) via the facility's normal peer review system.

The facility will normally fund the travel and subsistence costs of UK users. In instances where these costs will not be met by the facility, they may be requested from the Wellcome Trust, under the **Miscellaneous costs** heading.

Access to neutron sources
Applicants should apply directly to the relevant source for such access.
Where costs are being requested from the Wellcome Trust, justification of the proposed access, including the number of days requested, should be provided in this section. Costs required must be detailed in the Access Charges table on the preceding page.

REASONS FOR SUPPORT REQUESTED

Staff requested
Please give a justification for the type and seniority, including the level of salary requested, of each post sought.

Animals
Please ensure that a justification is provided for **both** the species and the numbers requested.

Equipment
Please indicate the intended use of each piece of equipment for which funding is sought.
Where equipment exceeds £50 000:

- describe the nature of the equipment and explain how the technology will enhance the scientific projects described in this application;
- details of similar equipment in the applicants' department and adjacent departments must be given and the reasons why it cannot be used for the particular project;
- if a particular manufacturer or supplier is favoured, the reason for this should be explained;
- provide details of any other individuals likely to benefit from use of the equipment.

Under BIRAC funding Equipment costs of up to 15% of project cost will be allowed. Please also refer to disallowed cost as stated in Guidelines for applicant.

Equipment maintenance
Equipment maintenance may be requested for the above equipment for up to five years. Other requests for maintenance of Wellcome Trust-funded equipment may be considered once the original grant period has expired. The Wellcome Trust will,

however, only consider providing maintenance funds for equipment more than five years old, if the applicant can demonstrate that it is cost-effective to do so.

Applicants outside the United Kingdom and Republic of Ireland may apply for maintenance costs for equipment originally funded by the Wellcome Trust or other sources.

Access charges
Access charges may be requested for the use of items of equipment or facilities, originally funded by the Wellcome Trust or other sources, once the initial funding period has ended. The use of the equipment/facilities must be essential to the proposed research.

Please detail how these charges have been calculated using the following headings: (i) a maintenance or service contract providing a basic level of service; (ii) running costs; (iii) materials and consumables; and (iv) staff time.

ETHICS AND REGULATORY ISSUES

All ethical (animal use and human trials) and regulatory guidelines must comply at all times with the relevant laws and regulation in the host country.

These notes are only intended to provide guidance and advice in completing the application form, rather than a comprehensive review of the legal and regulatory environment in which the application is made.

By providing funding, BIRAC shall not be considered as a Sponsor of the Clinical Trial as defined in the Drugs and Cosmetics Act 1940 and related Rules.

Applicant(s) shall be responsible to obtain all the necessary requisite approvals, clearance certificates, permissions and licenses from the Government/local authorities for conducting its activities/ operations in connection with the Project.

a. Any project that involves the use of animals must be compliant with Institutional Animal Ethics Committee
b. All projects having Clinical Trial Component shall comply with all applicable national and International regulatory frameworks.

RESEARCH INVOLVING HUMAN PARTICIPANTS, BIOLOGICAL SAMPLES AND PERSONAL DATA

Human participants, biological samples and personal data
The Wellcome Trust policy position on research involving human participants can be found on the Wellcome Trust website (http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTP052064.htm).

Approval from the appropriate research ethics committees is required for all Wellcome Trust-funded research involving human participants, biological samples or personal data. Personal data, in the context of the 1998 Data Protection Act (Section 3.2, and Annex 3) comprise information about living people who can be identified from the data, or from combinations of the data and other information which the person in control of the data has, or is likely to have in future. Any use of personal data or biological

samples should conform to MRC Guidelines available at http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420.

Approval from other regulatory bodies such as the Human Fertilisation and Embryology Authority (HFEA) or the Gene Therapy Advisory Committee in the UK should also be sought where necessary, e.g. research involving human embryos may require a licence from the HFEA (please refer to the website for more information: www.hfea.gov.uk). If your proposal involves research on gene therapy which requires regulatory approval, approval should be sought from your Local Research Ethics Committee, the University's Genetic Manipulation Committee, the Gene Therapy Advisory Committee and the Medicines and Healthcare products Regulatory Agency (MHRA).

For research undertaken outside of the UK, the relevant approvals should be sought from the equivalent regulatory bodies in the host country, as appropriate.

The organisation must ensure that ethical approval is in place at all relevant times during the project. For research carried out at multiple sites, ethics committee approval must cover each site.

Where the project, or part of the project, is to be performed outside the UK, independent ethics review must be obtained. For research involving people living in low- and middle-income countries, see www.wellcome.ac.uk.

Research using facilities or patients within the NHS and/or the public or private health service in India
By agreeing to fund work which requires NHS support, the Wellcome Trust is agreeing to abide by the Statement of Partnership on Non-commercial R&D in the NHS in England (and the corresponding statements in Northern Ireland, Scotland, and Wales). Researchers must therefore meet the obligations of the Partnership and may not carry out any research until the NHS has given its consent. The full report can be downloaded from the Department of Health website www.dh.gov.uk.

The Research Governance Framework for Health & Social Care, published by the Department of Health in England can be downloaded from the Department of Health website www.dh.gov.uk.

Researchers using facilities or patients within the public or private health service in India must meet the obligations of the relevant regulatory governance framework or healthcare legislation, and may not carry out the research until the relevant regulatory bodies have given their consent.

Please note that the Wellcome Trust cannot act as sponsor.

The Medicines for Human Use (Clinical Trials) Regulations 2004
Under the Medicines for Human Use (Clinical Trials) Regulations 2004, applicants must identify a sponsor (which will normally be either a university or NHS Trust) who fully understands the responsibilities and costs associated with assuming this role. Please note that the Wellcome Trust cannot act as sponsor.

EXPERIMENTS ON ANIMALS

Applicants must refer to the Wellcome Trust's policy on the use of animals in medical and veterinary research and the guidelines on 'Responsibility in the use of animals in bioscience research' on the Trust's website. In addition, applicants must also follow theCPCSEA guidelines when performing experiments in India

Experiments on animals in the UK
The Organisation must ensure that research involving the use of animals complies at all times with UK laws and regulations.

Experiments on animals outside the UK
If experiments are to be carried out on animals outside the UK, the experiments proposed must be performed to standards which accord with the principles of UK legislation. Furthermore, the housing and care of animals must similarly accord with the principles of the UK legislation.

When projects involve experiments on animals, all questions under **'Experiments on animals'** must be addressed. Failure to do so will result in delay in processing.

In all animal experiments supported by the Wellcome Trust, the principles of reduction, replacement and refinement will apply. In all experimental studies, it is the responsibility of the Applicant to actively consider:

- the complete replacement of live animals with tissues derived from either animals or humans;
- the possibilities of reducing the numbers of animals that need to be used;
- Refining the experimental design in order to obtain the maximum amount of information from the minimum number of animals.

Refined methods in animal research are those which alleviate or minimise any adverse effects for the animals involved, and/or enhance animal welfare. Refinements may be applied at any stage in the life of an animal. Thus, refinement encompasses all aspects of a procedure, including:

- the source, transport, husbandry and environment of the animals involved;
- the experimental design (e.g. the choice of species and the group size employed);
- the techniques applied;
- the end points of the procedures; and
- care of the animals before, during and after a procedure.

Monoclonal antibodies
The use of ascitic animals for monoclonal antibodies (mAb) production *in vivo* should only be proposed when *in vitro* attempts at mAb production have failed or the use of animals is considered justified for specific diagnostic or therapeutic products. If *in vitro* production methods are not considered to be suitable, a full explanation must be given. Details of the animals requested should be given.

Severity of procedures
Guidance on assessing the severity of a procedure is available from the Home Office website:
http://www.homeoffice.gov.uk/science-research/animal-research/

Why is animal use necessary: are there any other possible approaches?
Please specify if there are any other procedures of less severity that could be used.

Why is the species to be used the most appropriate?
It is particularly important to justify the species when an animal is being used as a model for a human physiological or pathological condition.

RISKS OF RESEARCH MISUSE

In preparing research proposals, the Wellcome Trust and BIRAC wishes to encourage applicants and their host institutions to consider carefully any ethical, safety or security implications associated with the research, including any risks that the potential outcomes could be misused for harmful purposes. Such purposes would include actions which lead to harm to humans, animals or the environment - including terrorist misuse.

Where there are judged to be **tangible** (i.e. real and non-hypothetical) risks that the proposed research **will itself** generate outcomes that could be misused to cause harm, institutions should take appropriate steps to monitor the research as it proceeds and minimise these risks. The Wellcome Trust recognises that most research could conceivably generate results that might hypothetically be misused at some point in the future, and is not asking applicants to appraise these kinds of remote and hypothetical risks.

Applicants should refer to the Wellcome Trust's position statement on bioterrorism and biomedical research, and guidelines on good research practice (http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/index.htm).

CONSULTANCIES AND EQUITIES

If this application is successful, confirmation will be sought that the researchers comply with the Wellcome Trust's and BIRAC policy document on the relationship between Wellcome Trust-funded researchers and commercial entities, which is reproduced on the Wellcome Trust's and BIRAC website.

TREASURY POLICY

Applicants should contact their organisation's Finance Department to supply this information. It is essential that applicants provide this Treasury Policy information with their application. **Applications will not be taken forward for consideration unless this information is given.**

Due to the instability of the banking system in recent years, where the Wellcome Trust is advancing significant funds, we request to see the treasury policy of the organisations we are funding. With advanced funding, funds will be placed with your bank until they are used and the Wellcome Trust has an interest in understanding how and where they will be held.

Applicants must provide us with a copy (in English) or details of your organisation's treasury policy. The treasury policy should outline how your organisation manages any risks associated with holding cash and other liquid funds. This should include:

- A list of banks and other financial institutions with which funds may be held (this may

be based on the ratings issued by credit rating organisations such as Standard & Poor's)

- Acceptable investment/deposit vehicles for holding funds
- Maximum allowable funds to be held in any one vehicle and with any one institution
- Time limits on investment/deposit holdings
- Authority for approving and reviewing the treasury policy
- The number of authorised signatories required to sign for expenditure payments out of the bank accounts together with any applicable limits.

Applicants must also provide us with the name and contact details of the person responsible for their organisation's Treasury Policy ("Treasury Policy Contact"). Applicants must promptly notify the Wellcome Trust in writing of any changes to the identity and/or contact details of the Treasury Policy Contact.

The Wellcome Trust must also be promptly notified of any changes in your treasury policy between application and receipt of an award (and throughout the duration of the award).

For BIRAC's due diligence process, applicants will need to provide necessary documents as stated under Eligibility heading in Guidelines for Applicant. Please attach those documents with the application. Visit www,birac.nic.in under Programmes click on BIRAC-WT Joint Call Tab.