BHIVA Research Awards 2021

Guidance Manual

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Contents

1. Background

Originally launched in 2006, the BHIVA Research Awards are open, through competitive application, to all BHIVA members for research projects that impact on the improvement of clinical care and management of people living with HIV in the UK.

A total of at least £30,000 per annum is available, to be distributed amongst the successful applicants according to the quality of the submitted proposals. The Awards panel is chaired by an appointed chair and the call for applications is open during March and April. Successful applicants are announced at the BHIVA Autumn Conference.

1.1 Purpose of the awards

BHIVA Research Awards provide funding for research projects that will improve the clinical care and management of people living with HIV in the UK or research towards a cure.

1.2 Application support and additional information

The BHIVA Research Awards programme provides support to all potential applicants, including queries on eligibility, the application process and scientific questions. In addition, BHIVA also provides registrars with access to senior doctors who can be contacted for advice on a particular project. For support with your application, or for information on the mentoring programme, please contact the BHIVA Secretariat at bhiva@bhiva.org.

2. Awards summary and timelines

The envisaged timeline for the BHIVA Research Awards is as follows:

Online applications open	**Friday 12 March 2021**
Application support and additional information available	12 March 2021–16 April 2021
Close online applications (at 1700)	**Friday 16 April 2021**
Submissions under review	April–August 2021
Research Awards Judging Panel meeting	**w/c 6 September 2021**
Notify applicants	w/c 4 October 2021
Appeals process window (see item 7.4)	11–22 October 2021
Notify applicants of results of any appeals	w/c 25 October 2021
Announce awards at Autumn Conference and on BHIVA website	**Oct/Nov 2021 (date TBC)**
Earliest possible start date for winners' projects	Wednesday 1 December 2021

3. Funding available for the 2021 award round

In 2021, a minimum of £30,000 is available to be distributed amongst the successful applicants. These funds will be distributed to several projects in categories of up to £10k and up to £30k. The allocation of all funds will depend on the funding available and the quality of applications received. Please see below for more information on the type of projects that will be accepted for review.

4. Eligibility

4.1 Who can apply

The Awards are only open to BHIVA members[1], either medical or non-medical, working on HIV infection in any capacity that contributes to improvement in HIV care and management within the UK.

BHIVA seeks to support clinical and non-clinical researchers who are developing and establishing themselves as independent researchers. Therefore, applications from persons who are not yet independent researchers or who do not hold an established academic or clinical post would be particularly welcomed and encouraged to apply for the BHIVA Research Awards.

Applicants may be asked to answer questions (remotely) during the Judging Panel meeting (w/c 6 September 2021) – please include your mobile contact number on the application form.

The earliest possible start date for projects is **1 December 2021** (subject to ethics/research and development approval).

4.2 Types of projects

BHIVA welcomes projects that may lead to improved patient care in the UK or studies that have the potential to translate into improvements in UK HIV clinical care and management. In addition, BHIVA is keen to fund small projects that undertake research towards a cure for HIV that would not attract funding from traditional sources.

4.3. NIHR non-commercial partner status

BHIVA is a National Institute for Health Research (NIHR) non-commercial partner in respect of its Research Awards funding stream. Appropriate research studies funded through this NIHR non-commercial partner funding stream are automatically eligible for inclusion in the NIHR Clinical Research Network (CRN) Portfolio and therefore entitled to:

- Use the NIHR Coordinated System for gaining NHS permissions (NIHR CSP), which is accessed via the Integrated Research Application System (IRAS)
- Access NHS support via the NIHR Clinical Research Network.

Please note that to gain inclusion on the NIHR CRN Portfolio research studies funded by BHIVA must meet the standard study eligibility criteria, namely that it:

- Is a discrete structure research project with an appropriate study protocol
- Is of clear value to the NHS
- Involves NHS patients, staff, premises, facilities or resources
- Requires NHS support via the NIHR Clinical Research Network.

Please refer to the following websites for further information about:

- NIHR CRN Portfolio https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/crn-portfolio.htm
- IRAS www.myresearchproject.org.uk (researchers use this site to begin the process of applying for NHS Permissions and for inclusion in the NIHR CRN Portfolio).

[1] Applications must be made online only. Only applications from BHIVA members will be accepted. If you are not a BHIVA member, please join at: www.bhiva.org/Membership and **allow up to 2 working days** for your application to be processed. In addition, successful applicants must retain their BHIVA membership during the entire period of any research project supported by the BHIVA Research Awards.

5. Application process

5.1 How to apply

- Download and read in its entirety the BHIVA Research Awards Guidance Manual (this document), which will guide you through the application process.
- Download the application form. The completed application must be submitted through the BHIVA Research Awards page on the BHIVA website: www.bhiva.org.
- Download and complete the declaration form. The completed form must be signed by both the applicant and the supervisor and email bhiva@bhiva.org.
- Applications will only be accepted in MS Word format submitted through the BHIVA Research Awards page on the BHIVA website: www.bhiva.org.
- Please pay particular attention to the stated word/page limits – applications that exceed these will be rejected.
- Supplementary information files (in MS Word format) may be included in support of the application (no longer than four (4) sides of A4 – documents longer than four (4) sides may be arbitrarily cut).
- All submissions will be acknowledged. If your application has not been acknowledged, please contact the Secretariat on 01462 530070 or email bhiva@bhiva.org.
- The guidance manual, application form and declaration form can be downloaded from the BHIVA website: www.bhiva.org.

5.2 Guidance notes on how to complete the application form

For detailed guidance on the completion of the application form please consider **each** of the guidance notes carefully. You will find within this section detailed points to consider for each section of the application form:

Name	Primary Investigator
Amount requested	Insert the amount requested in GBP (£)
Abstract	Provide a scientific abstract (maximum 250 words)
Lay summary (see notes below)	Provide a project overview in lay terms (maximum 250 words)

Please provide a lay summary of your project using non-technical language and avoiding any 'jargon'. Please provide a brief explanation of the problem, state your research question and then describe how you intend to answer this question. This information may be used on the BHIVA website and so should be understandable to anyone who may access this website.

Project outline

Start date of research project *(earliest start date is 1 December 2021)*	Click here to enter a start date
End date of research project	Click here to enter a date.
Duration of project (months)	Click here to enter text.
Is this project a sub-study?	Yes or No
If yes, please give title of relevant parent research project	
Click here to enter text.	
Is this project a pilot study? (see notes below)	Yes or No

If yes, please provide details of how the research findings will inform the design of the full-scale research study (maximum 500 words)

A pilot study is defined as a small-scale preliminary study conducted to evaluate feasibility, time, cost, adverse events and effect size (statistical variability) in an attempt to predict an appropriate sample size and improve upon the study design prior to performance of a full-scale research project. Therefore, pilot studies focus on one or more of the following:

- provision of estimates of key parameters for sample size calculations, such as estimates of the treatment effect itself, or the variability (standard deviation) of the outcome if measured as a continuous variable
- feasibility assessment – what are recruitment rates likely to be? Are there any barriers to participation? Why do trial participants drop-out before the end of the trial?
- validation of pre-test questionnaires, or
- reproducibility of study methodology.

Pilot studies are **not**, therefore:

- small exploratory, proof-of-principle or descriptive studies
- studies that aim to conduct preliminary work in an area that would then indicate whether further, larger, studies are required, or
- an excuse to conduct an under-powered study.

Thus, if your study is a pilot study, you will need to explain what you hope to achieve from your study. Are you performing the study to assess the feasibility of running a large-scale trial (for example, to assess whether patients would be willing to participate in such a study), say, or to obtain preliminary data that will inform the design of and sample-size calculations for a larger study? If so, what will the large-scale study look like and when do you anticipate conducting it? Who do you intend to approach to fund the larger study? And what are your timelines for conducting the larger study?

Note that the sample size for a pilot study **does** require careful consideration – although you are unlikely to require a formal power calculation, if you are performing the pilot study to estimate key study parameters, say, then the sample size should be large enough to ensure that any estimates are reliable.

Good example:

We aim to conduct a randomised controlled trial of drug X vs. standard of care among people living with HIV receiving antiretroviral therapy who have been diagnosed with hypertension. In order to power this trial appropriately, we require information on the distribution of the change in blood pressure levels that we might expect to see over a 12-week period (the duration of the intervention) among individuals with hypertension who receive standard of care (dietary and lifestyle advice) in the clinic. Thus, the pilot study will collect the preliminary data required for the power calculations. If successful, we would anticipate that we would submit a full application for funding to the MRC in Spring 2022.

Poor example:

This study will describe the immune response to xx vaccination in HIV-positive children. If this is deemed to be inadequate to protect the children, it may indicate that further studies are required to identify more appropriate vaccine dosing schedules.

Note that this study may still be an interesting (and important) study to do – it just is not a pilot study.

Has the application (or a related one) previously been submitted to BHIVA? (see notes below)	Yes or No

If yes, please explain how the present application has changed from the previously submitted version (maximum 150 words)

If you have received feedback (external reviewer or internal judge comments) on the previous application, please describe how you have amended the application in response to this feedback. Note that you do not need to describe any minor text or editorial changes that have been made, just more substantial changes relating to the study objectives, design or methods.

Detail whether ethics approval will be required and the prospective deadline for ethics approval (maximum 150 words) (see notes below)

It is expected that most research studies will require Ethics Approval, whereas audits and service evaluations may not always require this. The distinction between the different types of study may often be blurred. In general, the aim of a research study is to derive generalisable new knowledge (i.e., to find out what you should be doing), the principal mode of dissemination will be through research presentations and/or publications, and the target audience will be the wider clinical or research community. In contrast, the primary aim of audit/service evaluation is to find out whether you are doing planned activity and, if so, to assess whether it is working. Such studies would not consider using an intervention that does not already have a firm evidence base for its use, nor would they allocate treatment by protocol or randomisation. The principal mode of dissemination would be via internal reports and the target audience would be your colleagues and NHS management. Note that BHIVA research awards would not generally fund audit or service evaluation, unless specifically stated on the website.

It is recommended that you seek advice on your study design and/or the need for Ethics Approval from the National Research Ethics Service. https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/

If you do require Ethics Approval then whilst the panel will not expect you to have obtained this at the time of submission, it will expect you to be aware of the timelines for submission of your application and to be aware of the typical time it may take to obtain ethics approval. These timelines should be built into your own timelines for study completion. If you already have Ethics Approval (for example, if your study is a sub-study of a larger project and the existing Ethics Approval will cover this), then state this clearly.

Good example:

Full Ethics Approval for the parent study was received in January 2021 (reference: xxx). We will submit a request for an amendment to this approval to allow the present study to proceed as soon as funding is approved. We anticipate that this process will take no more than six weeks, and so would anticipate starting our project by the end of December 2021.

Provide details of your data sharing policy (maximum 150 words) (see notes below)

Most funders now require that you have an established plan for sharing your data with the wider scientific community with as few restrictions as possible. In addition to the transparency that this provides, data sharing increases the value of the data for research and for eventual patient and public benefit. Whilst such data must be shared in a timely manner, it must also be shared responsibly with the utmost regard for patient confidentiality. BHIVA would not expect you automatically to submit all data to an open-access repository with no control on subsequent use. However, it would expect you to seriously consider all requests for data access and to have an agreed and transparent policy for

deciding on how to respond. Note that it may be reasonable to withhold sharing data until your study is complete (so that you have an opportunity to publish your findings) if the delay is not unreasonable; if you anticipate receiving such requests, then the timelines should be clearly stated.

In some instances, there may be valid reasons why data cannot be shared, e.g., where the data may identify an individual and there is no way to securely anonymise the dataset. If so, this should be stated clearly.

What are your plans for sharing your dataset with others who may want to conduct their own analyses on the data? Have you established a policy for dealing with any such requests that are submitted? If you anticipate many such requests, do you have a plan for monitoring your responses?

Please note that data sharing is not the same as dissemination, which refers to the way in which your *research findings* are shared with the wider clinical, academic and patient communities and other stakeholders. Data sharing is also not about how you will store your data and protect it whilst in your own institution. Data should always be stored confidentially regardless of whether and when it is shared with other researchers.

Good example (Khoo *et al*. 2015):

Data sharing requests from external sources will be considered by the Steering Group. We will ensure that data-sharing is compliant with University policy. Relevant data will be made available to other researchers in a timely way, with as few restrictions as possible (some restrictions may be necessary, e.g., to protect IP, respect confidentiality, or honour third party agreements). It may be appropriate to allow a limited period of privileged access to the data for the research team that acquired or created it. All clinical studies aligned to our group have in the past, and will continue to, provide consent for study sample and data sharing with collaborators.

Poor example:

Our institution does not have a data sharing policy.

Provide brief details of the dissemination plan for this project (maximum 150 words) (see notes below)

Research is of no value if the findings are not shared with anyone outside the immediate study team (regardless of whether your findings are positive or negative). As clinicians and/or academics, our usual method of dissemination is through presentations at conferences and publications in academic journals. However, these methods of dissemination, whilst of importance for your own CV, may be of limited value. One of the criteria for acceptance of a BHIVA Research Award is that you will submit your findings as an abstract to one of the BHIVA annual (spring) conferences and you will attend and present the findings if accepted. Therefore, at the very least, you should identify the BHIVA conference that you would intend to submit your findings to. However, in addition to this, are there any other conferences that you will target? What journal would you expect to submit your paper to? Be realistic here – *Nature Medicine* or the *New England Journal of Medicine* are unlikely to accept results from a small pilot study, regardless of how excited you are with the results.

In addition, what other approaches will you take to disseminate your findings and to ensure that your research findings can be translated into clinical care? Who are the key stakeholders in your research (consider, for example, the patient community, academics, clinicians, other healthcare professionals, funders or commissioners, public health professionals and global health leaders)? What are your plans for engaging with each of these groups outside the normal academic route (for example, will you use a study website to promote your findings, study reports or social media)?

Good example:

Abstracts from the study will be submitted to the BHIVA Spring Conference in 2022, and to the World AIDS Conference 2023. A manuscript summarising our findings will be submitted to a clinical HIV journal (we anticipate submitting the manuscript to AIDS, HIV Medicine or JAIDS) and we will also present our findings locally at one of the regular meetings of the HIV and Infectious Diseases teams at our hospital. As the results of our study will be of particular interest to the HIV patient community, we will also work with our colleagues at UK-CAB and HIV i-Base to identify means to disseminate our findings to those living with HIV.

Poor example:

We hope to submit an abstract to the BHIVA Annual Conference in 2022.

Project aims/objectives

List the specific aims/objectives of this project (these can be listed as bullet points) (maximum 200 words) (see notes below)

The aims should be clearly stated although can be listed as bullet points if this is clearer. Whilst aim one (1) should generally contain quantifiable outcome measures, subsequent aims may be more exploratory. All the aims should relate directly to your hypothesis (Case for Support).

Good example:

We intend to perform whole genome sequencing (WGS) and phylogenomic analyses of HIV-1 from an established MSM cohort, which has been previously analysed using standard pol sequencing.

We aim to:

1. *Evaluate the WGS method by recording the number of samples fulfilling virological criteria (including analytical sensitivity, the success rate of generating full-length genomes, the accuracy of genome assembly at a sequencing depth of >1,000 reads).*
2. *Extend the findings of previous work by this group to identify the source of new HIV infections using integrated phylogenetic and epidemiological methods enhanced by WGS.*
3. *Compare WGS with pol gene sequencing to determining the advantages of this new technology in describing transmission networks and identify factors associated with onward transmission.*
4. *Provide the basis for further research in defining transmission networks, drug resistance and pathogenesis linked with the national UK resistance database; to extend the methodology to other at-risk populations and geographic locations; and enhance broader public health strategies to prevent onward transmission.*

Case for support

Provide detailed information about the proposed research, ensuring that you include the following sub-sections: background; proposed methodology (including statistical methods and sample size calculations, as appropriate); Importance of research to people living with HIV and/or other groups; wider benefits/implications of the research. Please ensure that your font is no smaller than Arial 11pt and your text is a maximum of three (3) sides of A4. (see notes below)

Background

This section should be concise and should convey the information simply and clearly. If you are citing the work of others, then you should include references to support your statements (you may include up to one (1) additional page of references in the next section). You should describe any relevant work that you have conducted in this area that has led you to the research question. The section should end with a clear hypothesis that should be plausible and testable with the methods proposed. Your study objectives (previous section) should directly address this hypothesis.

Good example:

We hypothesise whole genome sequencing will provide a much better understanding of the transmission networks driving the epidemic. In particular, newly acquired HIV infections in MSM will be predominantly transmitted by those with acute infection who are not yet receiving ART, and those with undiagnosed infection.

In your background section you should include a balanced discussion of the importance or novelty of your study. Why should BHIVA prioritise your research application over other studies? Why is it important that the study is completed now? What size of population might your research findings affect? Will it lead to other follow-on studies if successful?

Good example:

In 2014, 12,050 people living with HIV aged ≥55 years were seen for HIV care in England (SOPHID data). Whilst it is hypothesised that this group may have different healthcare needs to the younger HIV-positive population, there is little published evidence to support any change in guidelines for the management of this older group. If successful, our findings relating to the general health care needs of the older HIV-positive population could influence the design of interventional studies to prevent and treat the co-morbidities that are common in older age.

Study design and methodology

Make sure your overall methodology plan is consistent with your stated research aims/objectives. For example, if the question is 'how immunogenic is vaccine X in HIV-positive people?' then the methodology must include details of an assay that measures immunogenicity. The methodology needs to be precise and specific, for example, 'we will quantify parameter X using an antibody specific for target Y' is preferable to 'we will use a panel of antibodies against markers of interest'.

If you can, try to break the methodology down into sub-sections as this will make it easier to read (and will also allow you to check that nothing has been forgotten). Make sure that you describe the methodology that will address *all* the aims of your study. Try to identify and discuss any likely scientific and technical challenges – it is important that you recognise the limitations of your approach and be clear about what you would do to mitigate any risks. No study is perfect, and reviewers will accept that; however, it is far preferable that you identify the limitations of your study rather than they identify them.

You will need to state your study design in one clear sentence. Describe the study population (including any inclusion and exclusion criteria), any intervention, and provide any definitions that you will be using (for example, if your primary endpoint is the acceptability of a new vaccine, how will you define 'acceptability'?).

If you are using novel laboratory methods, please provide sufficient details of these such that a reviewer can judge whether they will provide reliable results. Have the methods already been developed? Are they validated? What is the inter-laboratory variability? Is special training required for those who will be performing the methods?

Preliminary data give you a massive advantage – if you have preliminary data that support your hypothesis or even show that your proposed method works, then include this (in the Appendix if necessary). This is particularly important if you are proposing a new method.

Consider contingency plans should you experience problems with any part of your study. For example, what will you do should your assay fail? What will you do should you fail to recruit sufficient patients to your study?

It is important to present your timelines. These must be realistic and should incorporate any time that will be required for obtaining the necessary ethics and R&D approvals (see earlier section). Please also note that it will generally take some time to sign contracts with BHIVA. A simple table with a list of tasks and time allocated to each can really help to demonstrate that your plan is feasible.

Good example:

We will perform whole genome sequencing and phylogenomic analyses on stored samples from a UK cohort of HIV positive MSM with linked clinical and epidemiological data. Data gathered from the full-length sequences will then be compared to previously obtained pol sequences enabling a direct comparison with standard technology.

Poor example:

This is a cross-sectional cohort study.

Statistical methodology

Many applications will involve statistical analyses of data. If this applies to you, then list any statistical tests that you will perform to test each of your hypotheses. Are any assumptions made when performing these tests? If so, how will you assess the validity of these assumptions? How will you compare your main outcomes? Will you use parametric or non-parametric tests? If you are performing an observational study, what method will you use to reduce the effects of any confounding that will be present? Will you perform any sensitivity analyses? How will you deal with missing data and/or inconsistent values (particularly important in an observational setting)?

Do not over-complicate your statistical methods. Each application will be reviewed by a statistician. You need to provide enough information to ensure that the reviewer can see what approach you will use.

Note that if you have consulted with a statistician in the development of your application then it is often wise to state this (although make sure that you have the approval of the statistician first).

Good examples:

We will estimate the incidence of MI in our cohort study and will provide a 95% confidence interval for this estimate. We will initially compare the incidence of MI in those who are and are not receiving cART using univariate Poisson regression; multivariable Poisson regression methods will then be used to assess whether any association with cART remains after adjustment for potential lifestyle and behavioural confounders.

The statistical analysis will be performed by the applicant under the supervision of Professor X.

Poor example:

We will compare groups using parametric and non-parametric tests, as appropriate, and P-values will be generated. Significant factors ($p<0.05$) will be included in multivariable regression models for the primary outcome using a stepwise selection procedure.

Sample size calculations:
An assessment of the appropriate sample size is required for almost all studies. If you are conducting a pilot study, a descriptive or exploratory study, or a qualitative study, then it may not always be necessary to perform a formal sample size calculation for a hypothesis test. However, you should still ensure that your sample size is enough to be able to estimate a parameter with enough precision or to fully describe the phenomenon of interest.

Good examples:

The response rate on drug A at 1 year has been estimated from clinic data to be 75%. To detect an improvement in this rate of 15% (i.e., a response rate in the intervention arm of 90%) with 80% power, and alpha=0.05, would require a sample size of 100 in each of the two arms of the study. As we anticipate that around 10% of patients will be lost-to-follow-up, we have inflated the total sample to allow for this. Our study will therefore recruit a total of 222 patients.

Although this is a pilot study, we do wish to obtain a relatively robust estimate of the variability in blood pressure change at 12 weeks for our subsequent sample size calculations. Based on our clinic records of patients attending for a follow-up visit in the past month, we anticipate that we will see 50 patients in the clinic over the first 8 weeks of the study who would meet the eligibility criteria for a full trial if it were to go ahead. Based on experience, we expect that 75% of these patients (37 patients) would be willing to return for a blood pressure measurement at 12 weeks. This will give us a reasonable sample size in a timely manner on which to estimate the mean change in blood pressure and the SD of this value.

Poor examples:

Our proposed sample size (n=5) is typical for studies such as these. Experience has told us that this sample size will be enough to detect any important effects.

Our sample size of 298 will allow us to detect a 10% increase in the rate of our primary endpoint with enough certainty.

As this is a pilot study, sample size calculations are irrelevant.

Importance of research to people living with HIV and/or other groups
Will your research lead to direct benefits for patients? If so, are there specific patient groups that will benefit? Or will your research lead to benefits for the wider general population (for example, if you are conducting a study around the topic of HIV prevention)? Are there other beneficiaries of your research, such as the wider scientific community or those working in other academic disciplines?

Good examples:

Outputs from this pilot study and the planned vaccination study will have broad-reaching benefits for all those involved in the health policy planning and care of older people, in particular, with respect to influenza vaccination delivery. This includes Public Health England, by informing the immunological approach in developing future seasonal influenza vaccinations and the best schedule of vaccination and the British HIV Association in developing guidelines for the health protection of older people with HIV infection. Individuals recommending (HIV clinicians) or offering (general practitioners) vaccination will benefit from improved strategies to combat infectious diseases in the ageing populations they are responsible for. Finally, both individuals with and without HIV infection will benefit from this research, which will provide new insights into both ageing and vaccine responses that can be directly translated to improving patient care.

We will extend the findings of our original phylogenetic study, which examined pol sequences from patients attending the clinic between 2000 and 2006 and will directly compare the two methods. By determining the factors associated with transmission and the proportional contribution of diagnosed (treated, untreated and lost-to-follow-up) and undiagnosed individuals to ongoing transmissions in the MSM group, we will provide data that can inform future public health interventions and strategy.

If our data suggest that primary HIV infection (PHI) is the driver of the UK MSM epidemic, then greater emphasis needs to be given to training of healthcare professionals and at-risk populations to identify acute infection. If undiagnosed infection is a major cause, then forthcoming updates to national HIV testing policy will be supported. If diagnosed but untreated individuals are significant contributors, this will further inform the debates of earlier ART initiation and Treatment as Prevention (TasP). Patients who are lost-to-follow-up may also sustain transmission, in which case an increasing emphasis on ensuring retention in care would be supported from a public health perspective.

Poor example:

Our findings will lead to improvements in the way that HIV-positive individuals are managed in the clinic.

Wider benefits/implications of the research

This section can be difficult to complete as research impact may be indirect and/or may only become apparent over the long term. However, it is important to describe the possible wider impacts of your study findings as fully as possible (whilst being realistic and precise). For example, how will your study drive the research into this field forward? Will you develop new methodologies and, if so, who will be likely to utilise these in the future?

Good example:

Statistical methodology to deal with missing data developed as part of our study will be presented at the International Workshop on Observational HIV Databases; this workshop is attended by methodologists working on all the major HIV cohorts in Europe and North America who will be likely to use our methodology in their own cohorts.

Although our project is focused on models of HIV infection, our findings will also have an impact on those working on mathematical models of hepatitis C virus infection and TB, as the methods will be easily applied to these other infections.

Final comments

There are many reasons why studies are not funded. In general, these fall into the following categories:

1. It is not clear how the research will add to what is going on internationally or will lead to health benefits
2. The project description is unfocused and/or over-ambitious
3. The study is unlikely to answer the research question and/or does not directly address the stated hypothesis
4. The methodology is not sufficiently detailed
5. There is no preliminary data to support the application, or
6. The applicant/research team lacks the appropriate experience to conduct the study.

By carefully writing your Case for Support, and by selecting your supervisor(s) and collaborators wisely, you can pre-empt these criticisms and thus maximise your chances of a successful application.

References (see notes below)

Provide full details of any references that are cited in the case for support. You have a maximum of one (1) side of A4 for this but please ensure that your font is no smaller than Arial 11 pt.

Funding and budget (see notes below)

This needs to be fully itemised and should be appropriately costed (i.e., it should be neither under- nor over-costed). The budget should represent good value for money and BHIVA does need to be sure that the money will be well spent. Please make sure that you have read the accompanying documentation about what BHIVA will and will not fund. Any subheading relating to direct costs (e.g., fieldwork, equipment or dissemination), which exceeds £1500 must be broken down and explained in detail.

Good examples:

Budget period	Item	Cost
	Fee for social scientist to attend and run 6 focus groups (£100 /hr x 6 groups x 2 hours)	£1200
	Transcription services for focus group interviews (6 focus groups of 90 minutes)	£450
	Dictaphone	£350
	Travel expenses for social scientist and HIV community member to attend and run six focus groups of 8 people (two in London, two in Birmingham, two in Edinburgh); costs based on the cheapest economy class train ticket between London and each town, and taxi costs between train station and venue.	£500
	Hall hire and refreshment costs for 6 focus groups of 8 people (£65 x 8)	£520

Poor example:

Budget period	Item	Cost
	Social science support	£8500
	Travel expenses	£1000
	Miscellaneous other expenses	£500

Give an itemised list of all costs and full financial information
Any subheading relating to direct costs (e.g., fieldwork, equipment or dissemination), which exceeds £1500 must be broken down and explained in detail

Budget period	Item	Cost
Budget period	Insert item	Insert the cost (£)
Budget period	Insert item	Insert the cost (£)
	Total (£)	Total Cost (£)

Is VAT payable?	Yes or No

Which institution will administer the grant?	Click here to enter text

Does your budget include any staff costs? (see notes below)	Yes or No
If yes, please justify why BHIVA should provide funding for these costs (maximum 250 words) (see notes below)	
Click here to enter text.	
Has additional funding been sourced for this project?	Yes or No
If yes, please specify the organisation(s) and amounts received	

Name of organisation(s)	Amount of funding received
Insert organisation	Insert the amount received in GBP (£)
Insert organisation	Insert the amount received in GBP (£)
Total (£)	Insert total received in GBP (£)

- A full itemised list of all costs and full financial information must be provided
- Use costings as advised by the NIHR Clinical Research Network Costing Group – see https://www.nihr.ac.uk/
- A detailed declaration of other sources of funding (names of organisations from which funding has been received and the amount of funding received from other organisations) must be provided
- The proportion of funds applied for from BHIVA should constitute most of the total funds required for this research project, i.e., BHIVA will be the major supporter of the project (>50%)
- Invoices for bought-in equipment where VAT is payable should be made out to BHIVA to allow the Association to reclaim the VAT
- The fund is intended to support operational costs, expenses (equipment and/or consumables) and essential travel
- The £30,000 award will require milestone delivery of funding on an annual basis. Funding for the second and subsequent years of the project will be contingent on satisfactory progress in the first year
- BHIVA will retain 10% of the grant, which will be released upon receipt of the final report and an abstract submitted to a BHIVA conference

Awards **may not** be used to fund:

- BHIVA or other conference attendance fees
- PhD or MD degree fees
- Salary costs. *Please note that a contribution to staff costs as a component of a service charge for provision of specific services is allowable. Staff costs that contribute to the support of an individual's salary and which incur overheads are not permissible. (Service charges account for delivery of specific services, e.g., lab tests, statistical analysis.)*
- Items which fall within the remit of routine NHS clinical care. *Please note that costs which fall under the remit of NHS clinical care, but are not routine, may be allowable. Applicants must provide a full explanation and justification of why the costs do not fall under routine NHS clinical care and why BHIVA should provide funding for NHS clinical care costs. The final decision will be made at the discretion of the BHIVA Research Awards Judging Panel.*
- Open access publication costs

Primary investigator, supervisor and collaborators (see notes below)

Please make sure that your team has all the relevant expertise to conduct the study. For example, if your study is a qualitative study, ensure that you have the appropriate social science support to conduct

the study. If your study is a laboratory study, ensure that you have the appropriate expertise in conducting this type of experiment in your laboratory.

Primary Investigator CV (see notes below)
Contact details required are name, mobile number, BHIVA membership number, job title, department, organisation, full address, telephone number, email address, qualifications, name of body, registration number, date of registration, and previous appointments in the last five (5) years and other current appointments.
Research experience: (see notes below)
Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.
Research training: (see notes below)
Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.
Relevant publications (list all publications in the last two (2) years plus other publications relevant to the current application:
Click here to enter text.
Briefly outline your future career objectives:
Click here to enter text.

Supervisor CV (see notes below)
Contact details required are name, job title, department, organisation, full address, telephone number, email address, qualifications, name of body, registration number, date of registration, previous appointments in the last five (5) years and other current appointments, and summary of research experience, including details of any research supervision.
Have you previously held, or supervised, a BHIVA Research Award? If so, please provide details of the award(s) and list all presentations and publications arising from the award:
Click here to enter text.
Relevant publications (list all publications in the last two (2) years plus other publications relevant to the current application:
Click here to enter text.

Details of other collaborators (up to six (6)) (see notes below)
Contact details required: name, job title, department, organisation and a brief statement about their contribution to the project.

Details of external reviewers who are experts in the relevant field (see notes below)

You are required to enter details of **four** (4) external reviewers. Note that an external reviewer should not be from the same institution as you or your proposed supervisor. You will also need to identify individuals who do not work closely with you on other projects, as these individuals are likely to have a conflict of interest.

Please do not include members of the BHIVA Education and Scientific Subcommittee in your list of suggested reviewers (see www.bhiva.org/educationandscientific).

The details required are name, job title, department, organisation, full address, email address and a brief explanation of your reason for suggesting this person.

Have you included a supplementary file in your submission?	Yes or No

Supplementary information files may be included, and documents should be in MS Word format and no longer than four (4) sides of A4 (documents longer than four sides may be arbitrarily cut).

5.3 Submission checklist

The following are required to submit your application:

- BHIVA website login username and password
- BHIVA membership number and paid up BHIVA membership for the year of the award
- **All sections** of the application form must be completed or be indicated as 'not applicable'. BHIVA reserves the right to refuse applications that are incomplete.
- Completed and signed **Declaration Form** (download from the BHIVA website):
    a. BHIVA must receive signed and scanned copies of the declaration form by email to bhiva@bhiva.org by the closing date of **1700 on Friday 16 April 2021**. Any declaration forms received after this date will result in your Research Awards application being rejected.
- Supplementary information files may be included in support of the application. These documents should in Microsoft Word format and no longer than four (4) sides of A4, (documents longer than four sides may be arbitrarily cut).

5.4 Submission deadline

Applications for the BHIVA Research Awards 2021 will open on **Friday 12 March 2021** and will close at **1700** on **Friday 16 April 2021**.

6. Post-award reporting requirements

6.1 Post-award requirements

- Payments will be made to institutions, not to individuals.
- Signed starting certificates should be submitted to BHIVA within one (1) month of the start date for payments to commence (invoices will not be accepted in lieu of a starting certificate).
- Successful applicants must retain their BHIVA membership during the entire period of research projects supported by the BHIVA Research Awards.
- Any awards made but not commenced within 12 months may be cancelled and the funds will be retained by or returned to BHIVA, unless an extension has been applied for and granted.

- The payments schedule will be defined by BHIVA in the awards letter (awards up to £10k usually an initial payment of 90% on receipt of a completed and signed starting certificate; awards of up to £30k usually an initial payment of 45% on receipt of a completed and signed starting certificate).
- Successful applicants are required to submit an interim report six months into a 12-month project or every 12 months on projects lasting two or more years as well as a financial status document at the same intervals.
- Successful applicants are required to submit an abstract to a BHIVA annual conference at the earliest opportunity following completion of their project. Acceptance of the abstract is subject to the normal conference judging procedures.
- Successful applicants are required to provide a final report, including a detailed financial report with a statement of itemised expenditure which is counter-signed by the Project Supervisor and the Finance Officer, within one month of the end of the project.
- Successful applicants will return any underspend to BHIVA within one month of receiving acceptance of the final report from BHIVA.
- Successful applicants must acknowledge BHIVA in their final report and in all publications related to the funded project. The BHIVA logo and acknowledgement to BHIVA, must also be included in any presentation (oral or poster) related to the funded project.
- Successful applicants are required to register and attend the BHIVA Autumn Conference and to be present at the awards ceremony in the year of the award.
- The remaining balance of up to 10% will only be paid on after the final report has been approved by BHIVA and an abstract submitted to a BHIVA conference.
- BHIVA reserves the right to withdraw funding if it is determined that a project is unable to provide the anticipated results.
- BHIVA reserves the right to withdraw funding if applicants are unable to fulfil the requirements of the award, including the submission of requested reports within the given deadline.
- When prioritising applications for funding, in addition to the quality of the proposed research, consideration will also be given to the track record of the applicant and supervisor in successfully completing previous BHIVA research awards to the agreed timelines. The Research Awards Judging Panel might decide to refuse a future application from an award winner who has had persistent delays in a previous project.

6.2 Post-award amendments

Any post award amendments will be reported to the BHIVA Education and Scientific Subcommittee at the earliest opportunity. The applicant must provide details of any amendment and email to bhiva@bhiva.org, together with a letter signed by the project supervisor. Amendments are subject to approval by the Committee and failure to fulfil requirements may lead to an award being revoked.

Post-award amendments include:

- Revision of original proposed research
- Requesting reallocation of funds
- Requesting a new start date or extension for your project
- Requesting a change of Primary Investigator
- Suspending and resuming a grant (sickness or maternity/paternity leave)

Please note that:

- Any reallocation from the original project budget must be requested and approved by BHIVA prior to reallocation of funds and must fall within the original project specification
- Delayed start dates or extensions for projects may be granted in exceptional circumstances, only subject to approval by the BHIVA Education and Scientific Subcommittee
- Funding is provided for the study as described at the time of application. Whereas it may occasionally be necessary to change aspects of the study design post-award, BHIVA must be consulted in the event of any changes to 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. If appropriate, a revised proposal may be required. Whilst BHIVA will aim to support all reasonable requests, where possible, to ensure projects are fruitful, BHIVA does reserve the right to revise, retain or terminate the existing award, particularly if the proposed revisions are major and have not been approved prior to being implemented. Re-allocation of funding may be allowed subject to prior approval from BHIVA and as long as this is to meet the cost of activity or activities that meet the agreed aims and objectives of the project. BHIVA reserves the right to query any expenditure outlined in the Final Report, which has not been incurred in line with the original (or revised and approved) application.

7. Assessment process

7.1 Judging

The assessment process is made up of three groups, who are invited to score applications and make comments for review at the panel meeting:

1. Internal judges are members of the BHIVA Education and Scientific Subcommittee and others, who act as the BHIVA Research Awards Judging Panel.
2. External reviewers are independent, expert assessors, who invited to judge the applications based on their expertise in the area covered by these applications.
3. Statisticians are independent, expert assessors, who are invited to conduct a statistical review of each application (where applicable).

These scores and comments will be used to help the Judging Panel decide which proposals are shortlisted for further assessment at the Panel meeting.

- The Judging Panel is led by an appointed Chair.

7.2 Scoring

The assessment of any research proposal is based on four core criteria:

1. **Importance:** how important are the questions, or gaps in knowledge, that are being addressed?
2. **Scientific potential:** what are the prospects for good scientific progress?
3. **Methodological robustness:** is the proposed study methodologically sound and are plans for analysis articulated clearly?
4. **Justification for resources:** are the funds requested essential for the work, and do the importance and scientific potential justify funding on the scale requested?

Each application will be assessed on the criteria specified below in items 7.2.1 and 7.2.2.

7.2.1 Internal judges' assessment criteria

Internal Judges will consider proposals against the following criteria:

1. Relates to an important question in HIV medicine
2. Impact on improvement of clinical care and management of people living with HIV in the UK
3. A clear research question is posed with appropriate methodology
4. Project is deliverable

7.2.2 External reviewers' assessment criteria

External Reviewers will consider proposals against the following criteria:

1. **The applicant:** Merit based on past career, current research standing, potential for independence, team leadership, ability to carry out proposed work, career intentions, high-flyer?

2. **The project:** Summary of assessment of the proposed research, significance of topic, hypothesis driven, details of proposal
3. **The research centre:** Standing in the field, appropriateness for the work proposed, appropriateness for career goals of the applicant, opportunities for training and career development, commitment to applicant and proposed research).
4. **Justification of support requested:** Appropriate to the needs of the proposal, fully justified, good value for money, expected benefits)
5. **Any other comments:** Any ethical, safety or security issues, or other potential adverse consequences, associated with the proposed research?

7.2.3 Marking scale

The ability of each applicant is marked on the following scale:

SCORE	INDICATORS
	Excellent quality research
10	**Exceptional**
9	Excellent – research that is (or will be) be at the forefront internationally. Addresses very important medical or scientific questions. Likely to have a high impact on medical practice, or on the relevant scientific field.
	Good quality research
8	Good, bordering on excellent
7	Good-quality research that is internationally competitive and at the forefront of UK work. Important research that will be highly productive, and likely to have a significant impact on medical practice, if applicable.
6	Good-quality research, on the border between national and international standing.
5	Good-quality research that is at least nationally competitive. Addresses reasonably important questions and will be productive. Good prospects of making some impact on medical practice, or on the relevant scientific field. Any significant concerns about the research approach can be corrected, easily.
	Potentially useful study
4	Potentially useful, bordering on good-quality research.
3	Research plans that contain some good ideas or opportunities, but which are very unlikely to be productive and/or successful. Major improvements would be needed to make the proposal competitive.
	Unacceptable
2	Potentially useful in some aspects, bordering on unacceptable in others.
1	Serious scientific or ethical concerns. Should not be funded.
0	**Ineligible for funding**

7.3 Feedback of comments to applicants

Following the decision of the BHIVA Research Awards Judging Panel, letters to all applicants will include comments made by the internal judges and external reviewers during the assessment process.

7.4 Appeals process

The competition for research awards is intense and therefore many high-quality applications may not receive support. All applications receive careful scrutiny by the BHIVA Research Awards Judging Panel and external reviewers.

- Appeals may not be made against the academic judgement of the BHIVA Research Awards Judging Panel, whose decision is final, and no appeal will be possible.

- Any applicant wishing to question a decision should write to the Chair of the BHIVA Research Awards Judging Panel no later than five working days after the results of the awards are announced.
- The sole ground on which an appeal may be made is to have the decision-making process reviewed to satisfy the applicant that all administrative procedures have been complied with.