# NIHR Global Health Due Diligence Questionnaire (DDQ)

**Instructions**

* The form must be completed in English.
* Where possible attachments should also be in English. If policies are not available in English, please provide a summary in English of what the policy covers alongside the policy in its original language.
* All organisations **MUST** complete the following sections of the form as these are project specific.
  + Section 2 (Ability to Deliver)
  + Section 4 (Subcontractor Management)
  + Section 5 (IP Management)
* If your organisation has completed a due diligence form on behalf of NIHR or another UK funder, there is no need to complete Sections 1 and 3 if the following points are met:
  + The completed due diligence form, and links to any policies is attached.
  + It has been completed in the last 3 years and includes all the required information.
  + NIHR or UKRI Funding Assurance reports completed in the last 3 years will also be accepted in lieu of Sections 1 and 3.

Please complete the form as comprehensively as possible. Each section should be completed by the most appropriate person eg Finance Manager for Finance information, project team for project-related information.

If you have any questions or require clarification, contact your NIHR Manager.

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## 

## Summary

| **Required information** | **Response** |
| --- | --- |
| Organisation Name |  |
| Description of Organisation - What is the main purpose of the organisation? |  |
| Organisational Postal Address |  |
| Named Head of Organisation |  |
| Name and Contact Details of Main Contact Person (who can deal with queries in relation to this questionnaire). |  |

## Questionnaire

### Section 1 - Governance and Internal Control

#### Governance

| **Ref.** | **Area to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 1.1 | What is the legal status of the organisation? | Copy of registration/ incorporation certificate |  |  |
| 1.2 | Is the organisation affiliated to any other organisation?  If Yes, please provide details. | None |  |  |
| 1.3 | Does the organisation have a fully functioning non-executive Board, which is separate from executive management? | Organisational Organogram  **or**  Link to list of current board members |  |  |

#### Policies and procedures

| **Ref.** | **Area to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 1.4 | Please confirm whether the organisation has the following policies:  i. Anti-fraud, corruption & bribery  ii. Whistleblowing  iii. Travel & subsistence  iv. Conflict of interest  v. Human Resources  vi. Procurement | Copy of policy(ies)  **or**  Link to existing policies if held on a publicly accessible website |  |  |
| 1.5 | If any policies in Section 1.4 do not exist at your organisation, please provide copies of any regulations or other rules your staff need to comply with to meet these requirements e.g. relevant legislation/ any other documents that state the requirement for compliance. | Regulations, legislation or other rules, as applicable. |  |  |
| 1.6 | What is the process for reviewing each of these policies and how often are they reviewed? |  |  |  |
| 1.7 | How are staff made aware of each of these policies? |  |  |  |
| 1.8(a) | Please provide a description of how your organisation manages financial and non-financial risk. | Organisational Risk Management Policy, Risk Register |  |  |
| 1.8(b) | Are risk registers kept at a corporate/organisational level, for individual projects or both? |  |  |  |
| 1.8(c) | Who is responsible for updating the risk register?  What is the frequency of review? |  |  |  |

#### Safeguarding and Ethics

| **Ref.** | **Area to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 1.9 | Does the organisation have a formal Safeguarding policy or policies which cover the following:   * anti-bullying and harassment * staff conduct in respect of children and vulnerable adults * staff safety * prevention of exploitation | Copies of relevant safeguarding policies |  |  |
| 1.10 (a) | How are Safeguarding and related policies disseminated among staff? |  |  |  |
| 1.10 (b) | Have staff received any training on safeguarding?  If Yes, please provide details. |  |  |  |
| 1.11 | In the last 3 years, have there been any reported Safeguarding incidents within the organisation?  If Yes, how was this managed and what was the outcome? |  |  |  |
| 1.12 (a) | Does your organisation (and all subcontractors) have documented labour standards, and do all operate in line with the UK Modern Slavery Act (MSA) 2015. | Copies of relevant policies |  |  |
| 1.12 (b) | How does your organisation ensure that employees and those in your supply chains are not subject to exploitation through any of the forms of modern slavery listed below?  i. Slavery, servitude, and forced or compulsory labour  ii. Sexual exploitation  iii. Organ donorship  iv. Force, threats or deception  v. By virtue of them being a child or other vulnerable person | Copies of relevant policies |  |  |
| 1.13 | How does your organisation ensure that research complies with relevant legislation, regulations and other ethical requirements? | Copies of relevant ethics and scientific policies |  |  |
| 1.14 (a) | What process does your organisation follow when allegations of fraud are made either against staff at your organisation, or any downstream partners? | Any fraud investigation reports, organisational operating processes, relevant policies |  |  |
| 1.14 (b) | How many times have you had to instigate this/these process(es) in the last 3 years?  Were any of the allegations upheld? |  |  |  |
| 1.15 (a) | Are there any current, pending or threatened arbitration proceedings (as a claimant or defendant), or any prosecution or inquiry pending by a government or official body? |  |  |  |
| 1.15 (b) | If Yes, please provide details of the nature and status of proceedings. |  |  |  |

### Section 2 - Ability to Deliver

#### Science Delivery and Impact

| **Ref.** | **Area to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 2.1 (a) | How many staff are employed to do research at:  (i) your organisation?  (ii) within your faculty (where relevant) |  |  |  |
| 2.1 (b) | What facilities are provided to support the research eg labs, space for clinics etc |  |  |  |
| 2.2 | Please provide examples of how you have maximised the wider impact and value of research for the benefit of local economies and /or societies. | Copies or links to press articles/internal reports |  |  |

#### Award Administration

| **Ref.** | **Area to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 2.3 | How is research award administration organised and managed within your organisation? Is this done centrally across the organisation or are their separate teams within each faculty/department?  Who has overall responsibility for the management of research awards and contracts? | Research Administration Organogram (if not covered by the Organisational Organogram requested in 1.3) |  |  |
| 2.4 | Describe the structure of the finance team who will be supporting this project and allocated full-time equivalent (FTE). | Finance Organogram (if not covered by Organisational Organogram requested in 1.3) |  |  |
| 2.5 | Does the organisation have financial management procedures / or a finance manual which clearly sets out accounting, reporting, internal control and administrative tasks?  Please note this should include Accrual Management - please see [NIHR Global Health Research - Financial Management Guidance for Awards funded through Official Development Assistance (ODA)](https://www.nihr.ac.uk/documents/nihr-global-health-research-financial-management-guidance-for-awards-funded-through-official-development-assistance-oda/29396#accrual-management) | Copy of financial management procedures/ finance manual |  |  |
| 2.6 (a) | How is project expenditure authorised, processed and paid for, and who is responsible for each stage? |  |  |  |
| 2.6 (b) | Does each transaction have a unique system generated transaction number? |  |  |  |
| 2.7 | How is expenditure on research awards and contracts monitored? - Both for expenditure against budget and for eligibility of expenditure. |  |  |  |
| 2.8 (a) | Do you have systems in place to provide quarterly detailed transaction listings for all expenditure incurred on the award? |  |  |  |
| (b) | What documents are kept to evidence expenditure and how do you ensure they can be linked to the lines on the transaction list, especially if they are in different currencies? |  |  |  |
| (c) | How long do you retain documents which evidence expenditure on awards? |  |  |  |
| 2.9 | How are staff project hours monitored to ensure the actual amount of hours worked are charged to the project? | Copy of timesheet template where relevant |  |  |

### Section 3 - Financial Stability

#### Financial Viability

| **Ref** | **Area to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 3.1 | Please provide information about your total research income along with supporting audited accounts (or financial statements) for the past 3 years. | Audited accounts or financial statements for the past 3 years. |  |  |
| 3.2 | How would any deficit within the organisation be managed? |  |  |  |
| 3.3 | Is the organisation experiencing a period of financial growth or decline? |  |  |  |

#### Financial Management

| **Ref** | **Area to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 3.4 | Does the organisation have a bank account with a reputable bank, held in the organisation’s name, which can receive award funds in GBP? | Bank “Letter of Good Standing” for this account confirming account holder and account details |  |  |
| 3.5 | Does your organisation/bank need any permissions to pay funds from the award to subcontractors that are based in another country?  If Yes, please provide details |  |  |  |
| 3.7 | Does your organisation need any licenses (or other permissions) to receive funds in GBP?  If Yes, does your organisation have all the necessary licenses and permissions in order to receive funding and undertake the required research?  Will the licenses/permissions need to be renewed during the lifetime of the award? | Copy of any relevant license(s) and additional information |  |  |
| 3.8 | How does your organisation record assets both at a project and an organisational level? | Copy of Asset Register template or documented processes |  |  |

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#### Insurance

| **Ref** | **Area to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 3.9 (a) | Does your organisation hold public liability insurance that covers work relating to externally funded research projects? | Copy of insurance policy |  |  |
| 3.9 (b) | What is the policy value or limit? | . |  |  |
| 3.10 | Please provide justification that the amount of public liability insurance is sufficient to cover the work required on this award. |  |  |  |
| 3.11 (a) | Do you have professional indemnity insurance that extends beyond the life of the project? |  |  |  |
| 3.11 (b) | If Yes, what is the value or limit? |  |  |  |
| 3.12 | Please provide justification that the amount of professional indemnity insurance is sufficient to cover the work required on this award. |  |  |  |

#### Strength of Audit

| **Ref** | **Area to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 3.13 (a) | Are your organisation’s annual financial statements audited externally?  What is the organisational policy for tendering services of external auditors? |  |  |  |
| 3.13 (b) | Who are your external auditors, and who do they report to? |  |  |  |
| 3.14 (a) | Do you have an internal audit service? |  |  |  |
| 3.14 (b) | How regular does audit review research award management? | If relevant, copy of most recent report on research award management. |  |  |

### Section 4 - Sub-contract and collaborator[[1]](#footnote-0) management

| **Ref** | **Areas to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 4.1 | How were the subcontractors / collaborators identified? |  |  |  |
| 4.2 | What due diligence has been undertaken (or do you intend to undertake) on your sub-contractors / collaborators to assess their ability and suitability to undertake the required research | Copy of due diligence reports on relevant partners.  Relevant due diligence approach/processes if not yet undertaken. |  |  |

#### Management Frameworks and Contracts

| **Ref** | **Areas to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 4.3 | How is the relationship with subcontractors / collaborators managed, for instance do you put in place a contract or collaboration agreement? | Copy of agreement template or sample document |  |  |
| 4.4 | What financial reporting arrangements have been agreed with sub-contractors / collaborators to ensure your organisation has sufficient control of expenditure? |  |  |  |
| 4.5 | Do any of the named sub-contractors require any licenses, permissions etc to receive funding from the award? | Copies of any licenses, permissions etc |  |  |
| 4.6 | What arrangements do you have in place to monitor the progress sub-contractors / collaborators are making on the project | Examples of any monitoring documents |  |  |
| 4.7 | Have there been any reported incidents of fraud in any subcontractor / collaborator organisations in the last 3 years? |  |  |  |
| 4.8 | How does your organisation ensure subcontractors have appropriate policies and procedures in place to manage safeguarding issues? |  |  |  |
| 4.9 | What safeguarding training will be provided for subcontractors / collaborators? For example: safeguarding, start-up workshop etc. |  |  |  |

### Section 5 - Intellectual Property Management

The following section is aimed at making sure the organisation has controls in place to prevent unauthorised use of outputs from the research such as data, designs, inventions, written publications, films etc.

| **Ref** | **Areas to be assessed** | **Document required** | **Applicant responses and comments** | **Reviewer’s comments** |
| --- | --- | --- | --- | --- |
| 5.1 (a) | Please provide a copy of any policy (or similar) your organisation has in place which provides the protection outlined above. If this is covered in more than one policy, please provide a copy/link to each of these. | IP Policy (or similar) |  |  |
| 5.1 (b) | Please describe what outputs your project is expecting to produce that will require protection. |  |  |  |
| 5.2 (a) | Does your country (or any of the countries that are involved in the project) have any legislation in place which may impact on publications or on the ability to undertake clinical trials where these are required for the project? |  |  |  |
| 5.2 (b) | If Yes, please describe what they are and anything which has been put in place to mitigate them. |  |  |  |
| 5.3 (a) | Will any of the outputs deliver Patient, Care User and Public Benefit (see [Appendix 2: Terminology](#_heading=h.4z7t6v7zyeje) for more detail) |  |  |  |
| 5.3 (b) | If Yes, please describe which outputs will deliver the above, how this will be delivered, and what the expected impact of these outputs will be. |  |  |  |
| 5.4 | What steps does your organisation plan to put in place to protect any patents or other outputs resulting from this project? |  |  |  |
| 5.5 | Is there any legislation governing IP creation, ownership and exploitation in any of the jurisdictions in which the research is being undertaken that will addect the use of the Research outputs by all parties? |  |  |  |
| 5.5 | Briefly describe the security measures you have in place to protect personal, clinical and research data. | Cyber Security Policy  Data/Information Management Plan  Other relevant policies |  |  |
| 5.6 | Are you likely to be using any material which is covered by the [Nagoya Protocol](https://www.gov.uk/guidance/abs)? |  |  |  |

### Appendix 1: Document Checklist

Please complete this table to indicate whether you have included the documentation required as part of this assessment. If you are unable to supply certain documents (for instance a policy not currently in existence in your organisation) please indicate that this is the case.

| **No.** | **Document** | **Enclosed (Y/N)** | **Comments** |
| --- | --- | --- | --- |
| 1 | Evidence of legal status |  |  |
| 2 | Organogram |  |  |
| 3 | Anti-fraud, corruption & bribery policy |  |  |
| 4 | Whistleblowing Policy |  |  |
| 5 | Travel & subsistence Policy |  |  |
| 6 | Conflict of interest Policy |  |  |
| 7 | Risk Management Policy (including Risk Register) |  |  |
| 8 | Safeguarding Policy |  |  |
| 9 | Ethics / Scientific Misconduct Policies |  |  |
| 10 | HR Policy |  |  |
| 11 | Procurement Policy |  |  |
| 12 | Fraud investigation Reports |  |  |
| 13 | Sample Timesheet |  |  |
| 14 | Last 3 years’ Audited Accounts or Financial Statements / Latest Audit Management Letter |  |  |
| 15 | Financial Manual |  |  |
| 16 | Bank ‘Letter of Good Standing’ |  |  |
| 17 | License to receive international funding (if relevant) |  |  |
| 18 | Insurance Certificate |  |  |
| 19 | Asset Register template |  |  |
| 20 | Most recent internal audit report |  |  |
| 21 | Internal Audit Report on award / contract management (if available) |  |  |
| 22 | Due Diligence report on Sub-contractors / Collaborators |  |  |
| 23 | Contracts / agreement templates with Sub-contractors / Collaborators |  |  |
| 24 | Examples of Sub-contractor/ Collaborator monitoring documents |  |  |
| 25 | IP Policy |  |  |
| 26 | Cyber Security Policy |  |  |

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### Appendix 2: Terminology

| **Term** | **Definition** |
| --- | --- |
| **Affiliated** | Is the organisation owned by another company or has for example shared-governance etc |
| **Asset** | Any resource owned or controlled by the organisation which has monetary value eg property, vehicles, equipment |
| **Conflict of Interest** | A situation in which an individual's ability to exercise judgement or act in one role is, could be, or is seen to be impaired or otherwise influenced by their involvement in another role or relationship |
| **Intellectual Property** | Intellectual property is a broad categorical description for the set of intangible assets owned and legally protected by a company or individual from outside use or implementation without consent. An intangible asset is a non-physical asset that a company or person owns. Examples could include data, designs etc |
| **Legal Status** | Examples include public university, private university, limited company, charity non-government organisation etc |
| **Patient, Care User and Public Benefit** | Achieving any one or more of the following:   1. identifiable improvements in the quality of Health Care or Social Care offered by any Health Service Provider in any LMIC or in the United Kingdom; 2. identifiable improvements in the experience of patients receiving by any Health Service Provider in any LMIC or in the United Kingdom; 3. identifiable improvements in patient health outcomes; 4. identifiable improvements in the efficiency of Health Care, Social Care or Public Health services in any LMIC or in the United Kingdom; 5. identifiable and measurable cost savings achieved in any LMIC or in the United Kingdom; 6. generating revenue for any Health Service Provider in any LMIC or in the United Kingdom; 7. or any other outcome that has been accepted in writing by the Authority and that is designed to benefit any Health Service Provider in any LMIC or in the United Kingdom,   Except that where the Health Service Provider is a commercial for profit entity, that Health Service Provider may not rely on (d), (e) or (f) above. |
| **Safeguarding** | Measures to protect the well-being and human rights of individuals, which allow people, including children, young people and vulnerable adults—to live free from abuse, harm and neglect. [NIHR Safeguarding Guidance](https://www.nihr.ac.uk/documents/nihr-safeguarding-guidance/25744) |
| **Whistleblower** | A whistleblower is a person, often an employee, who reveals information about activity within a private or public organization that is deemed illegal, immoral, illicit, unsafe or fraudulent |

## Declaration

**PLEASE NOTE** - To avoid any conflict of interest, this section should be signed by someone who is not directly involved in the project. This could be a member of the research management, contracts team (or similar) or a senior member of staff.

The information provided in this questionnaire should be a true representation of your organisation. If false information has been provided there is a chance this will affect your funding.

Please sign below to confirm.

Signed ………………………………………………………………

Position ……………………………………………………………...

Date ………………………………………………………………….

1. Subcontractors and collaborators in receipt of award funds [↑](#footnote-ref-0)