KEMRI Wellcome Trust Research Programme

Guidelines for Research Data Sharing

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1.1	Addition of sentence to indicate policy on deposit of datasets with the programme upon departure from the programme.	31st July 2015
1.2	Expansion of information on processes for sharing of study specific data and update of the title of the document.	4th January 2018

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Abbreviations used

CSC	KEMRI CGMR-C Centre Scientific Committee
DGC	Data Governance Committee
ERC	KEMRI Ethics Review Committee (Nairobi)
KCH	Kilifi County Hospital
KHDSS	Kilifi Health and Demographic Surveillance System
KIDMS	Kilifi Integrated Data Management System (KHDSS/KCH clinical surveillance data)
KWTRP	KEMRI Wellcome Trust Research Programme
MoH	Ministry of Health
NACOSTI	National Council for Science, Technology and Innovation
PF	Programme Forum: midcareer and senior researchers in the programme, including grant holders
SERU[1]	KEMRI Scientific and Ethics Review Unit (SERU)
SSC	KEMRI Scientific Steering Committee (Nairobi)

[1] SERU is a new committee that replaces SSC and ERC. In this document SSC/ERC is referenced but from 1st March 2015 all protocols will be reviewed and approved through submission to SERU.

1. Background and Key Principles for Research Data Sharing in KWTRP

1.1 Sharing research data is a necessary component of scientific investigation, traditionally in the form of publication of findings in the scientific literature. More recently, the benefits of greater data sharing between scientists, including prepublication data, have been increasingly recognised as a means of strengthening the **scientific utility**[2,3] of research. At the same time, there is a clear requirement to ensure that the **rights and interests of research participants, investigators and other stakeholders are not compromised through data sharing practices**, leading to the need for institutions to develop governance policies responsive to local interests and national and international data sharing guidance/policies that are tailored to the types of research data scientists generate in that setting[4].

1.2 Within the KEMRI Wellcome Trust research programme (KWTRP), a range of different types of data, summarised in three groups in Table 1, are collected from study participants or generated through research on primary data and/or samples collected. Drawing on national and international guidance[5], this document summarises key principles underpinning research data sharing in the KWTRP for all forms of data (paragraphs 1.4 to 1.7).

1.3 This document further describes detailed processes for requests for data from **i) the Kilifi Integrated Data Management system (KIDMS)[6] alone and ii) mixed KIDMS and study data.**

[2] Forms of utility include preventing unnecessary duplication of research, reducing the costs of answering new study questions and supporting the development of important forms of meta-analysis across studies.
[3] Pisani and AbouZahr(2010) Sharing Health Data; Good Intentions are Not Enough. Bull WHO, 88; 462-455; Sharing Data from Large-scale Biological Research Projects: A System of Tripartite Responsibility. Report of a meeting organized by the Wellcome Trust and held on 14–15 January 2003 at Fort Lauderdale, USA
[4] BBSRC Data Sharing Policy: version 1.1 (June 2010 update) www.bbsrc.ac.uk/datasharing
[5] Including: i) National guidance from KEMRI ERC SOPs 2009; NCST Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (2004); Draft Kenya Data Protection Bill (2012), Kenya Freedom of Information Bill (2012) and MoH Standards and Guidelines for Electronic Medical Records in Kenya; and ii) International guidance from the Wellcome Trust, MRC, BBSRC (2010) and Organisation of Economic Cooperation and Development (OECD) Best Practices for Biological Resource centre (2007) and National Institutes of Health (Final NIH Statement on Sharing Research Data, 2003).
[6] KIDMS includes linked data from routine clinical surveillance at Kilifi County Hospital (KCH) and the Kilifi Health and Demographic Surveillance System (KHDSS). KIDMS is an active database with boundaries defined by the DGC under the Data Curation Policy. KHDSS includes approximately 260,000 people living around KCH and accounting for 60% admissions to this hospital researchers. The focus was chosen because most data requests currently include KIDMS data, given its function to support research and health service delivery.

Key Principles

1.4 In addition to a responsibility to promote the **scientific utility** of research they conduct, **researchers have a responsibility to protect and as far as possible promote the rights and interests of research participants (Data Subjects[7]) and groups of research participants**, including confidentiality and autonomy, through appropriate forms of benefit sharing. The nature of informed consent provided by Data Subjects is central to decisions on data and sample sharing. Secondary researchers and data governance bodies operating at institutional, national or international levels share this responsibility.

1.5 Given the global reach of many forms of data sharing, governance practices should safeguard the **rights and interests of primary researchers in the Programme**, particularly given potential international inequities in resources available to support analysis and publishing[8]. This may include applying temporary embargos on data sharing and/or publishing to give priority to local analysis and publication of findings in some situations.

1.6 A concept of data **custodianship** underpins governance policy for research data sharing. In the KWTRP, custodianship of data collected by researchers is held by the Programme[9], devolved to the Principal Investigator for the duration of a study in which data are collected. Exceptions occur where researchers collect information as part of collaborations with other institutions or researchers, in which case custodianship is defined by the terms of the agreement underpinning this partnership (see Table 1). When PIs leave the programme, a copy of all datasets generated from research conducted within the programme should be deposited either i) within the programme, including with a named current PI or ICT; or ii) with an external open access or managed access repository. The choice of repository and type of access will depend on the conditions described during informed consent processes, conditions approved in the study protocol and funding requirements. The DGC should be notified when data is archived outside the programme. The research office will be responsible for ensuring copies of datasets have been deposited into an internal or external repository that meets the required criteria and will maintain a log of where datasets are held.

1.7 Given the importance of balancing goals of strengthening scientific utility with protecting the rights and interests of research participants and primary researchers, principles of **transparency** and **accountability** are central to governance of data sharing, and have prominence in these guidelines. Within the KEMRI Wellcome Trust research programme, requests from internal and external researchers for access to data for which the programme has custodianship are made to a programme Data Governance Committee (DGC)[10].

[7] Data Subjects are the individuals who have contributed their data to the Database

[8] Parker et al (2009) Ethical Data Release in Genome-wide Association Studies in Developing Countries. PLoS Medicine, 6, 11, e1000143

[9] Custodianship: By default, custodianship of all data collected within the Programme is held by the Programme through DGC. During the course of specific studies, custodianship of data collected in that study is devolved to the PI. At the end of a study, custodianship is transferred from the PI to the Programme at the PI's initiation through discussion with the Programme Director or Head of ICT. In some instances, the PI and the Programme may continue to share custodianship by arrangement.

[10] The DGC is a subcommittee of the programme's CSC, and has representation from scientific and community liaison programme staff and the Kilifi Ministry of Health. CSC is under the governance of the national KEMRI SSC and ERC, in turn accredited by NaCOSTI. See section 4.1-4.5 on DGC, including makeup and ways of working

Table 1. A summary of the types of data and data sharing in the KEMRI Wellcome Trust programme

Data type[11]	How collected	Custodianship	Data sharing
ROUTINE CLINICAL/ HEALTH DATA	Collected by MoH in Kenya and other parts of Africa *[e.g. Malaria Public Health department's use of malaria indicator data from Malaria Control Programmes]*	Custodianship is held by relevant MoH. Programme researchers are recipients of data under the terms of a Data Transfer Agreement (DTA) or Memorandum of Understanding (MOU).	A copy of the fully executed/authorised DTA/MOU should be submitted to the research office. Programme researchers may not consider requests for data sharing unless described in the DTA/MOU. This restriction applies to requests from other researchers within the Programme who were not party to the original DTA.
	Collected by programme researchers or MoH in Kenya or other parts of Africa, including through collaborations between these parties *[e.g. DPHR collection of clinical data in collaboration with Kenyan MoH]*	Custodianship is held by the relevant MoH. Programme researchers' use of data is governed by a Memorandum of Understanding (MOU) or DTA developed to support the collaboration.	Requests for data sharing should be approved by the relevant MoH, including: i) Applications from researchers within the Programme for uses not described in the MoU/DTA; ii) Applications from researchers external to the Programme.
STUDY SPECIFIC DATA	Data collected by programme researchers under KEMRI SSC/ERC approved proposals; including in collaboration with other research institutions.	Custodianship is held by the Programme, devolved to the study PI while working in the Programme[12].	Requests for data sharing should be made first to the PI while they hold custodianship[9]. The PI will then forward the request to DGC with their recommendation in access, outlining any relevant funding or publishing requirements.
KILIFI INTEGRATED DATA MANAGEMENT SYSTEM (KIDMS)	Integrated data archive comprising: i) Routine and study specific clinical data collected at KCH and surrounding health facilities; and ii) Data collected under KHDSS to support public health and research systems.	Custodianship is jointly held by the Programme and Kilifi MoH, under terms of informed consent for its collection, unless specified otherwise.	For internal requests, routine requests[13] and those covered by an SSC proposal are released through an automated audited system. Non-routine internal and external requests are released after DGC review. These requests may be reviewed by CSC if this is recommended by

[11] Some data requests may occur across these three categories. For those including study specific and KIDMS data, since custodianship of these datasets is separate, both the PI and the DGC should be involved in decisions about access, as described in section 3.12.

[12] PI holds custodianship on behalf of KWTRP while they are working within the programme; on leaving, custodianship should be held jointly by the PI and KWTRP.

[13] Routine requests are those already approved by SSC or are for preliminary enquiries involving non sensitive data; non routine requests are for preliminary enquiries involving potentially sensitive data or for new studies not under an SSC number, including pilot studies, as described in section 3.6

			DGC and may be referred to SSC where a new proposal/external review is recommended.

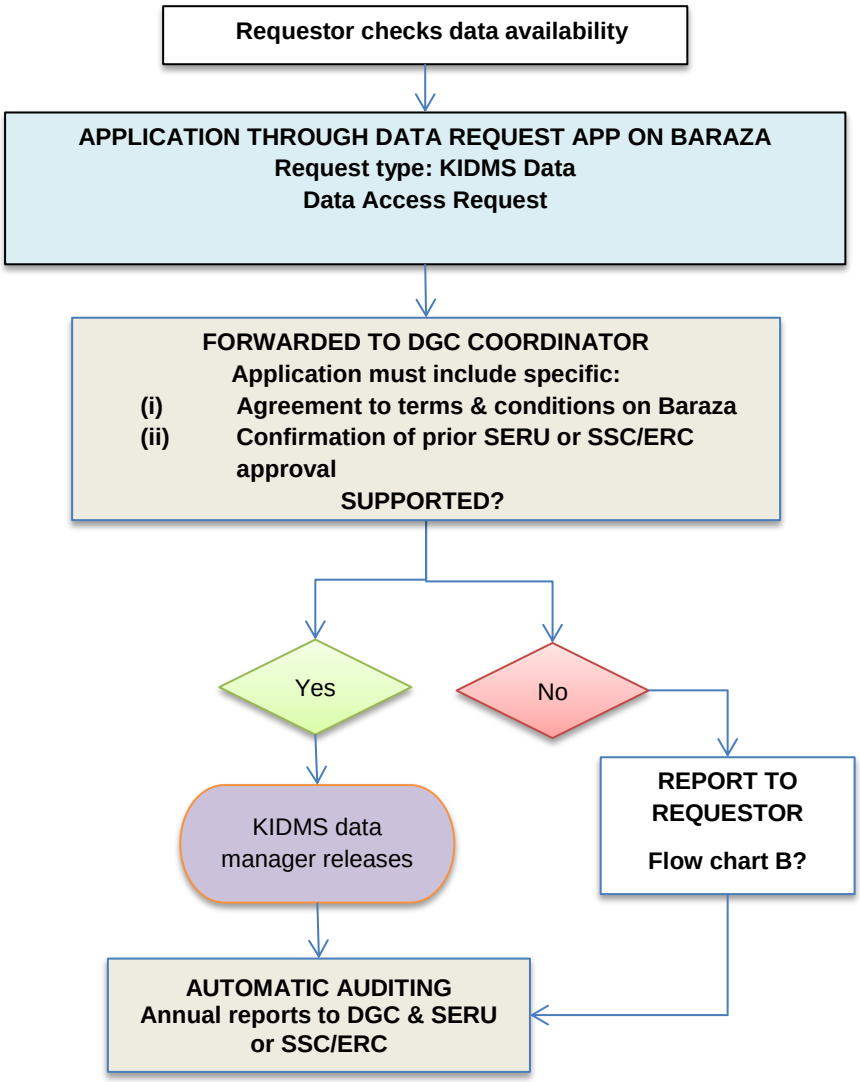
2. Overview of processes for KIDMS and study specific data sharing

The main pathways for sharing KIDMS and study specific data are summarised below, with details in flow charts A to D.

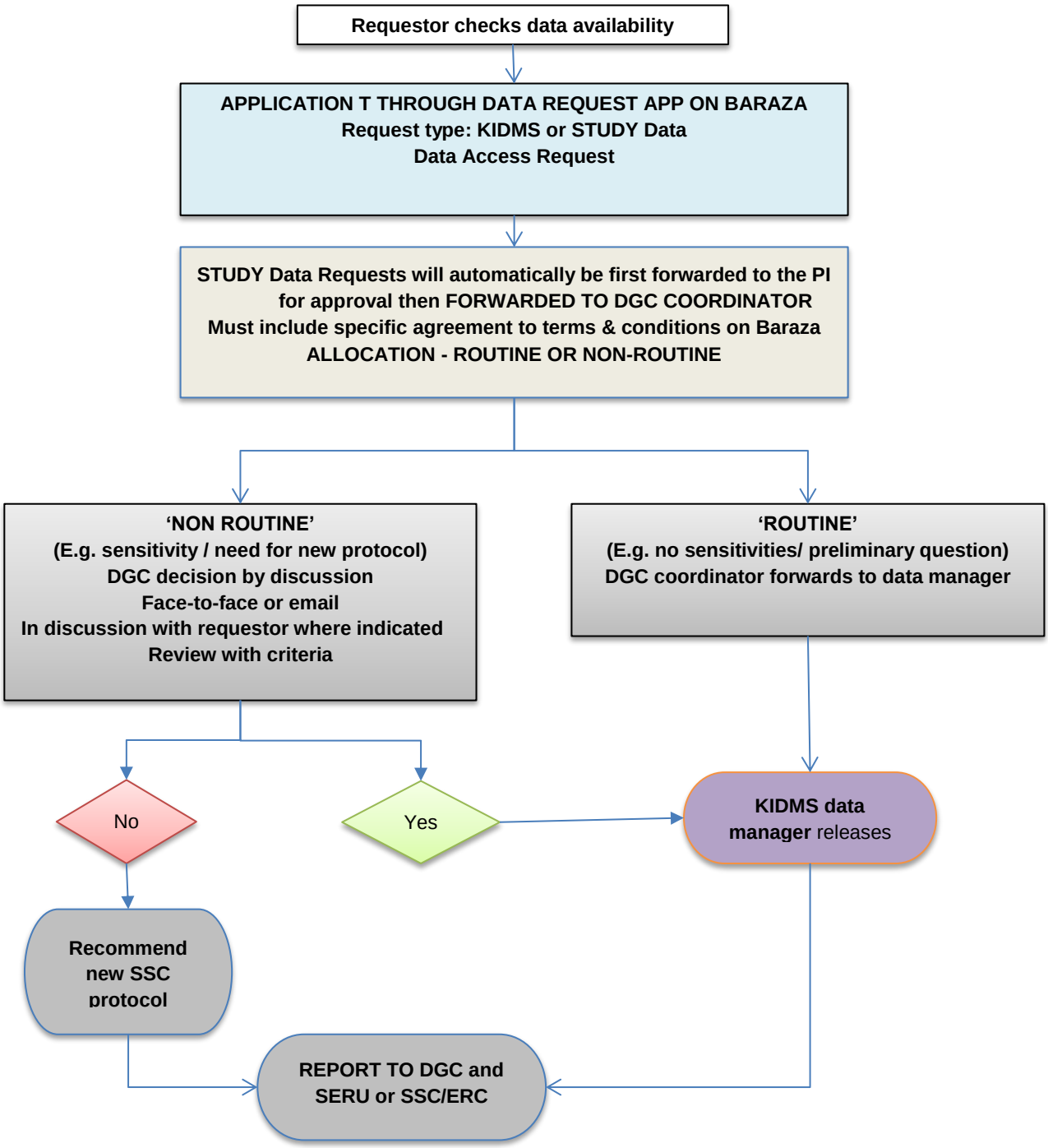
Pathway	Type of data/identity of requestor	Flow chart
KIDMS DATA		
1. Direct access through Data Request Application on the KWTRP intranet	• **Internal** requests[14] for KIDMS data/data use already described and approved in SSC proposal • **Internal** requests for *non-sensitive*[15] KIDMS data/data use not already described and approved in an SSC proposal, which constitute a preliminary enquiry and NOT a new study (full or pilot)	A
2. Access through Programme Data Governance Committee (DGC)	• **Internal** requests for *sensitive*[13] KIDMS data not already described and approved in an SSC proposal, which constitute a preliminary enquiry and NOT a new study[16] • Any **external** request[17] for data/data use	B
3. Access through new SSC proposal	• **Internal** requests for data/data use that constitute a new study (full or pilot) [18]	C
MIXED KIDMS & STUDY DATA		
4. Access through PI[10] and DGC[19]	• **Internal** and **external** requests	B

[14] Internal requests are made by a Programme Researcher, and may involve collaborations with outside researchers where the PI is internal.
[15] See Appendix A for an explanation of sensitive & non-sensitive data
[16] Examples of preliminary enquiries are for data to inform protocol development, research/MoH planning and sampling strategies.
[17] External requests are made by researchers external to the Programme, including those working in collaborations with internal researchers but where the PI is external.
[18] For example (but not exclusively) where ethical approval will be needed for publication of the analysis
[19] To support independence. Funders & journals increasingly stipulate that requests for data access should be handled by a data governance group, not the PI alone.
(e.g. http://blogs.plos.org/everyone/2014/02/24/plos-new-data-policy-public-access-data-2/)

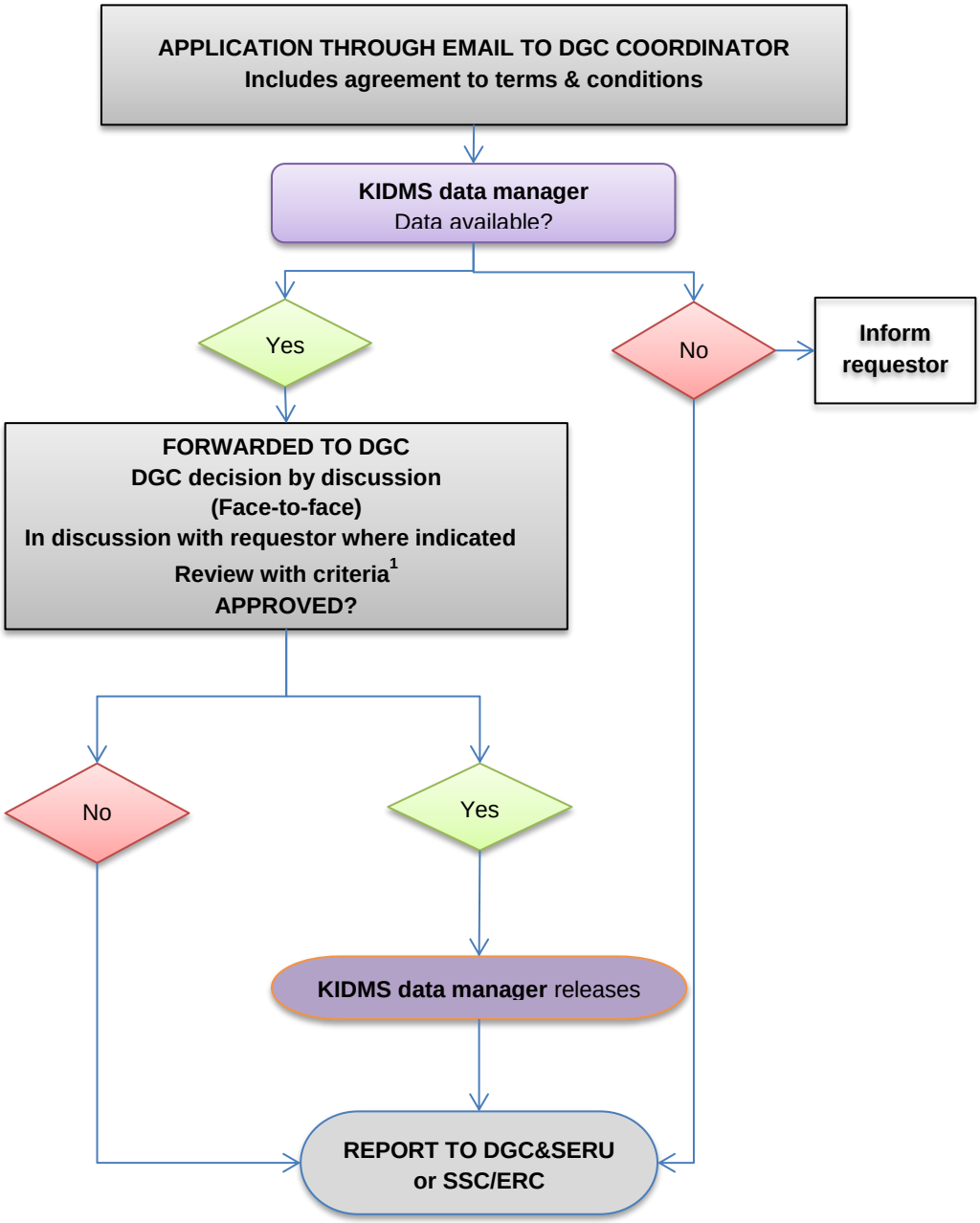
Flow chart A. Internal requests for KIDMS data under an approved SERU or SSC/ERC protocol



Flow chart B. Internal requests for KIDMS or mixed KIDMS/study data NOT under an approved SERU or SSC/ERC protocol



Flow chart C. External applications for KIDMS or mixed KIDMS/study data



3. Data sharing processes

The Data Governance Committee (DGC)

3.1 Oversight for data and sample sharing within the Programme is the function of the Data Governance Committee (DGC), a subcommittee of the Centre's Scientific Coordinating Committee (CSC). The DGC has two main roles: i) Advising the CSC on policies for and issues related to data sharing; and ii) Making decisions on, or recommendations to CSC on, responses to specific data sharing applications. In doing this, the DGC aims to work actively towards resolving issues that limit data sharing, while taking careful account of criteria in Appendix A.

3.2 The DGC includes the Centre Director, the Programme Scientific Director and representatives from the Community Liaison Group, all scientific departments, ICT and laboratory managers, and the Kilifi County Health and Hospital Management Teams. The DGC has a chairperson, a secretary and a coordinator.

3.3 The DGC will meet as required through face-to-face or email conferencing to make recommendations on applications for data sharing, using the criteria in Appendix A. Routine DGC meetings are held on the first Friday of each month. The format of DGC discussions will depend on the complexity of issues emerging from the application and the degree of consensus reached. The format for meetings will be proposed by the DGC coordinator and confirmed by the DGC chair. Face-to-face meetings will be held where earlier automatic voting[20] or email correspondence following requests do not lead to consensus. Meetings may also be face-to-face where significant resources are needed to make data available, or when stronger collaborative arrangements are needed to support data sharing. Decision-making within the DGC is through consensus building.

3.4 The DGC meeting minutes are uploaded onto the Protocol Tracking System and available for review at monthly CSC meetings. The minutes include a summary of the final recommendations on data request applications. CSC minutes are shared with KEMRI DDRT on a monthly basis. The Data Request App produces summary statistics on number of requests submitted and their outcomes. Audit reports can also be generated on data release.

3.5 Given cross departmental representation in DGC, in reviewing applications for data sharing, DCG members will seek to ensure any additional forms of **cross-programme collaboration** that would be beneficial scientifically or for scientific capacity building, or any **conflicts of interest** that might exist for other Programme Researchers across the programme, are raised and discussed at DGC. Where necessary, resolution of any such issues will draw on discussions with the requestor and any other advisors within the programme.

Applications for access to KIDMS data

Approved, routine and non-routine applications

3.6 For internal applications, the DGC coordinator will allocate the request to a provisional category of **approved**, **routine or non-routine, using criteria below:**

[20] Through on-line Data Access platform for internal researchers on programme intranet (Baraza)

- *Approved:* Applications made under an existing approved SERU or SSC protocol, in relation to the nature of data requested, the type and purpose of the analysis intended and the timing[21] of the analysis (Figure 1).
- *Routine*: Given that KIDMS has a primarily research and clinical/public health support function, **routine** applications are those requesting **non-sensitive** KIDMS data for **support purposes**, such as preliminary analyses to support the development of a future proposal/test early research concepts, or to undertake clinical or public health audit activities, often in collaboration with the MoH. Decisions about routine applications are made by DGC.
- *Non-routine*: Other internal applications are seen **as non-routine.** These include applications for **sensitive data** or where the application may be classed as **new research.** Recommendations for decisions on non-routine applications are made by DGC, before circulation to CSC[22] for notification.

Application through Data Request App for internal KIDMS requests

3.7 All internal applications are made via the Data Request App on Baraza (programme intranet); see user guide: http://baraza/sites/doc/_layouts/15/WopiFrame2.aspx?sourcedoc=/sites/doc/Documents/Baraza%202.0%20Internal%20Data%20Request%20Application%20-%20User%20Guide.docx&action=default.

3.8 For all internal applications, the app application form includes a radio buttonx for requestors to indicate they have read and agreed the Terms & Conditions of data sharing posted on the Baraza site, under the following link: http://baraza1/intranet/sites/default/files/faq/Datasharing/Terms-and-Conditions.pdf . Agreement to the data sharing terms and conditions on Baraza is legally binding under Kenyan Law. Limitations, prioritisation and conditions for data sharing are described in section 4.0 of this document.

Process for internal KIDMS applications with SSC/ERC approval

3.9 The service desk application for approved requests will begin by asking the requestor:

i) To provide the SSC number under which the protocol was approved, and confirm the status of the application as approved (that is, covered by the nature of data requested, the type and purpose of analysis and the timing of the analysis).

ii) To confirm that they have read and agreed to the terms and conditions of data sharing on Baraza.

Requests are automatically forwarded to the DGC coordinator to check the conditions i) and ii) above. If confirmed, the approved request will be assigned to a data manager on line, copied to requestor to support data access in discussion with the requestor. If the DGC coordinator has queries about any aspects of the application, s/he will refer the request to the DGC.

Process for internal KIDMS applications without SSC/ERC approval

[21] It is accepted that the exact timing may differ from that in the protocol since the scheduling of research procedures may often change from that originally planned.

[22] A primary reason for circulating non-routine applications to SCC is to ensure that other Programme scientists do not have existing plans to undertake analyses described in the application, in which case a collaborative project would be preferred.

3.10 Internal applications include those from researchers within the KWTRP or where KWTRP researchers make applications in collaboration with researchers from external institutions. The category will not include collaborations where the KWTRP researcher has a minor/non-substantial role[23].

3.11 For internal requests not included in an existing SSC protocol, the application will begin by asking the requestor to confirm that they have read and agreed to the terms and conditions of data sharing on Baraza; and indicate the type of data requested and intended data use. Requests are automatically forwarded to the DGC coordinator to check the agreement to the terms and conditions, and to allocate a provisional status of either 'routine' or 'non-routine' (see paragraph 4.5).

3.12 **Where applications are for Study data or include access to study data as well as KIDMS data**, the requestor should select Study Data as the type of request as this will first be forwarded to the PI of the study involved in primary data collection to seek agreement to data sharing. If approved, the request will then be automatically forwarded to the DGC coordinator.

3.13 **Where applications are classified as routine** (i.e. non sensitive data or use, and a preliminary question) these will be forwarded to the KIDMS data manager for release under the agreed Terms & Conditions. Notification of the decision will be sent automatically to DGC members.

3.14 **Where applications are classified as non-routine** (i.e. potentially sensitive data or use, or may require a new SSC proposal to be developed) a vote by DGC members will be required, this can be done through the app or a face to face meeting, depending on the timing of the application in relation to the next DGC meeting and the urgency of the application. The DGC can decide to accept or reject the application directly, or to request input from PF members. The involvement of a wider scientific group may, for example, be appropriate when DGC assesses that there are potential missed opportunities for greater collaboration between programme researchers. Any issues raised by DGC may be discussed with the requestor to seek a resolution where possible. DGC approval may be based on amendment of the application to address any issues preventing or limiting approval, including challenges for confidentiality or sensitivity of data (see limitations in sections 4.3, 4.4 and 4.5). Decisions will be made with reference to the criteria in Appendix A.

3.15 Discussions and decisions made about access to data by internal requestors will be documented through: the online system; emails and minutes of meetings for DGC. Voting and comments will also be saved on the Data Request app on Baraza other discussions will be documented through minutes of meetings or emails exchanged.

Process for external KIDMS applications

3.16 Applications will include those from researchers who work outside the KWTRP, including the PI, but will also include applications where one or more KWTRP researchers are included but have a minor/non-substantial role.

3.17 Applications are made to the DGC coordinator by email, using the on line form in Appendix Bii. The form specifies the Terms & Conditions of data sharing[24] and should be signed by the requestor at the point of making the application. Since the signed application form, including Term & Conditions, will act as the Data Transfer Agreement, the requestor should submit a

[23] For example, it would not be appropriate for this grouping of internal and external collaborators to forward a new protocol to KEMRI SSC/ERC

[24] For external applications, the wording of Terms & Conditions is taken from the MalariaGEN Data Transfer Agreement.

scanned application with an original signature. The DGC coordinator will check with the KIDMS or relevant Data Manager/Departmental Committee if the requested data are available. If data are not available, the DGC coordinator will communicate this information to the requestor. If data are/can be made available, the request will be forwarded to the DGC.

3.18 Following referral to DGC, the DGC will make provisional recommendations to accept or refuse the application at a face-to-face meeting, based on considering the criteria in Appendix A. The DGC decision will be circulated to CSC for information to ensure that views of community liaison staff, and representatives from the Ministry of Health and KEMRI at national level (particularly the Centre Director) can be taken into account, noting potential community sensitivities for requests from researchers outside Kenya[25].

4. Limitations, prioritisation and conditions of use in data sharing

4.1 Applications for use of data that address current **prominent healthcare needs in sub Saharan Africa will be given priority**, particularly for uses in Kenya or East Africa. The outcomes of research should be likely to lead to relevant and sustainable health benefits in the short or long term for people in the areas where the research was undertaken[26].

4.2 Applications for use of data are limited by the terms under which **informed consent were obtained from Data Subjects, where applicable[27].** The condition of informed consent should be made explicit to data managers at the point of storage, to custodians to support decisions on sharing, and to requestors or recipients as part of DTAs.

4.3 **Data will only be shared in a pseudo-anonymised or anonymised form, without access to personal identifiers, including names, specialised roles and geographic identifiers**. Geographic data in the KHDSS will routinely be aggregated to the level of the sub location, or otherwise de-identified. Geographic identifiers for small populations (such as villages or sub locations) will be shared in a pseudo-anonymised form (e.g. village 'A', sub location 'B'). Where finer granularity is needed (e.g. household GPS coordinates or names of places) are requested, the DGC will consider the appropriateness of meeting this request based on the importance of the research question and the ability to ensure the confidentiality of individuals and groups of individuals in any public use (e.g. publications, reports and presentations at scientific meetings). The Terms & Conditions of data sharing on Baraza (internal applications) or the application form (external applications) will support these restrictions.

4.4 In addition to the situations described in 4.3, **certain types of data are deemed sensitive** and sharing will be restricted. These include information on HIV status, sexual behaviour, ethnicity and potentially stigmatising conditions. All such data sharing requests will be carefully considered on an application by application basis to minimise any potential risks of harm. See Appendix A for more information on sensitivity of data.

4.5 Sensitivity may be related to the use of data rather than to its nature *per se*. In considering applications for data access (where not approved under a SERU protocol) the DGC coordinator

[25] From recent community consultations (May to June 2014) recommendations were made that requests from researchers outside Kenya should involve national level overview. In these situation, the DGC should ensure that there is adequate discussion of the application including the views of the Centre Director, community liaison staff and Kilifi Ministry of Health representatives.

[26] http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/wtd015295.htm

[27] 'Where applicable' refers to situations in which consent for data sharing has been explicitly given or withheld.

& DGC should consider **sensitivity in relation to use** of all data. See Appendix A for more information on sensitivity of data use.

4.6 Data can only be used for the purposes proposed in the application and agreed in the DTA (where applicable), and may not be used in such a way that damage or distress is or is reasonably likely to be caused to any Data Subjects.

4.7 The data relates directly to individual Data Subjects and is strictly confidential. Data can only be disclosed to Data Users[28], and cannot be transferred or disclosed in any part to any other person or body.

4.8 Recipients must agree not to attempt to link anonymised data and/or samples provided with any other data set without the permission of the custodian. Recipients must not attempt to identify any individual from the data and/or samples provided. Should recipients believe that they have inadvertently identified any individual, they must i) inform the custodian and provide details of the circumstances under which this occurred; and ii) must not record this, share the identification with any other person or attempt to contact the individual. If identifiable samples or data are provided then there should be no attempt to contact the donors or data subjects unless this is covered by consent and has been agreed as part of the study protocol. If subjects will be re-contacted then this should be done via the custodian or the team that created the collection.

4.9 Data are protected by and subject to national and international laws (e.g. Kenya Data Protection Bill 2013).

4.10 Within the limitations described in 4.1, priority in applications will be given to requestors who are researchers employed within the programme or existing collaborators of researchers employed within the programme. Other researchers affiliated to recognised research institutions who are willing to pursue the research in collaboration with programme researchers or who have a satisfactory record of publication in the field are eligible but may be given lower priority. In the latter case, registration with an appropriate professional body may be required to ensure accountability in the event of non-compliance.

4.11 There may be an embargo/fair use period in which data are not accessible to requestors to allow primary researchers (originators) within the programme to complete planned research. The period of time needed, and the reasons for this, will be decided by the primary researcher and the DGC/CSC. The justification for any embargos used will be shared with requestors, who may also submit an appeal to the DGC/CSC.

4.12 Recipients of data are free to use these in their research from the point of release, under the conditions of the DTA, but are asked to respect the originator's interests in conducting the primary research. They should discuss any overlapping uses with the originator in advance. Where more than one originator is involved, discussions on any overlapping interests should be held with relevant scientific administrative groupings (e.g. EDC and CRG management groups in the programme).

[28] "Data Users" means those officers, employees and students of the Recipient Institution, who work directly with the Recipient and have a need to use the Data for the performance of their work with respect to the Agreed Purpose, and have agreed to comply with this Agreement.

4.13 The handling of intellectual property rights from data sharing will be governed by Intellectual Property policies of KEMRI[29], the Wellcome Trust[30] and/or other funders involved in supporting the originators' research, as described in the Terms & Conditions of data sharing

4.14 Recipients may publish results arising from their use of the data for the agreed purpose providing the data itself is not disclosed. Aggregate or generic information generated from the Data may be published on the provisos that: i) Such aggregate or generic information does not allow Data Subjects or groups of Data Subjects to be identified with reasonable effort; ii) No damage or distress is or is reasonably likely to be caused to any Data Subjects, groups of Data Subjects or communities from which they are drawn; and iii) No attempt will be made to identify the Data Subjects.

4.15 Recipients' publications based on use of the Data must be deposited in the UK PubMed Central data base within 6 months of publication. A copy of any publication based on data and/or samples from the Programme should be sent to the PI and/or DGC. Such publications or presentation using data and/or sample from the Programme should include an acknowledgement using the text as follows: *"This paper/publication has used data and/or biological samples provided by the KEMRI Wellcome Trust Research programme in accordance with the consent provided by participants and approved by the KEMRI Ethics Review Committee".*

4.16 Recipients are required to give feedback to the DGC on the outcome of their use of this data, including positive and negative outcomes.

4.17 The Custodian reserves the right to audit the recipients' use of data if this is considered necessary. Recipients found to be in breach of the DTA will be denied future access to data in the programme and their institutions and funders will be informed.

4.18 Data Subjects have the right to request access to or withdrawal of their own identifiable information, where there is no conflict with the protocol or other regulations.

[29] The KEMRI Intellectual Property Policy 2006

[30] See footnote 14

Appendix A. Criteria to support decision-making on applications to DGC on data sharing: Non routine internal and external applications

Criteria	Limitations/comments
1. Exactly what data are needed?	Check if available
2. Does this request have prior scientific/ethics approval? If so, from which governance body?	Prior SCC/ERC approval can be automatically shared. External requests with prior approval from SCC/ERC or another recognised research governance body can be given greater priority than those without this approval. Any request without approval may require PI to develop a new protocol for SSC/ERC review (see Appendix H)
3. Do we have these data (in a clean form)?	Resources required to make data available will affect prioritisation of application.
4. Is the application compatible with limiting third party access, or will these be future/public access to the data shared?	Data sharing with third party or public access can only be for aggregated and fully anonymised data with appropriate consent, and would be prioritised for uses relevant to health issues in Kenya/Africa.
5. What sensitivities are there for specific data requested?	Key influence on form in which data can be shared. Sharing sensitive data should be limited to applications of high social value and can only be shared with appropriate consent and in fully anonymised and aggregated forms, including risks that roles (e.g. nurse in charge of named dispensary), names of places (e.g. named village) or geographic positioning data (e.g. to household level) may compromise confidentiality. Where geo-positioning data is shared, this should be aggregated to the level of a sub-location or higher, and as far as possible place names replaced by codes. Sensitivities may arise in relation to nature of data or the way it is used. Data that have been reported as sensitive by the community include those on: HIV status, potentially stigmatising conditions such as sickle cell disease or epilepsy, sexual orientation, gender violence, sexual abuse and socioeconomic status. All are particularly sensitive where associated with individuals, groups or communities who may be recognisable.
6. What consent has been given by participants for this use of data (broad or specific)?	Data sharing is contingent on appropriate levels and forms of consent being given. This can include informed written and verbal consent, but not assent.
7. What are (all) the objectives of the proposed secondary analysis, and what outputs planned? Overall, what is the potential social value of the analysis to research stakeholders in Kenya/East Africa/Africa including scientific capacity building?	The intended purpose of data sharing is key to prioritising applications.
8. Who's asking for the data? If external, what evidence of their scientific integrity? Is there any existing/ planned scientific collaboration with the programme?	Data sharing is prioritised within the programme and with collaborators. Data should only be shared with external scientists or research institutions with a track record of scientific integrity. Recent community consultations (May to June 2014) have indicated particular sensitivities for community members where data is shared with researchers outside Kenya. For international forms of data sharing, it will be important to ensure that a reasonably broad range of views have been taken into account in making a decision, including national level authorisation (e.g. from the Centre Director's role in SCC), support from Kilifi representatives of the Ministry of Health and community representation (e.g. through inputs of community facilitators or –where indicated – consultation with KCRs/chiefs about specific requests).
9. Is there an existing plan to undertake this/similar analysis within the programme? Who/when?	Where there are competing interests between internal and external applications, internal researchers' requests will be prioritised. Where there are competing interests between internal researchers, resolution will be sought through the programmes usual scientific governance mechanisms (PF, SCC, departmental management groups)

10. Do methods support scientific validity?	Data sharing cannot have utility if applications are based on methods without scientific validity; in this case data should not be shared. PIs/DGC must take care not to overly promote particular methodological approaches where others have scientifically recognised value.
11. What risks of loss of privacy/confidentiality for individuals and communities? How has data been anonymised?	All data sharing must be based on full protection of the confidentiality and interests of Data Subjects and groups of Data Subjects (also see question 5 above)
12. What risks of harms to individuals/communities e.g. stigmatisation, impacts on family/community relations/cultural identity?	The potential for harm to individuals/communities involved in research is a key ethical issue; researchers have an obligation to share data in ways cause harm. The likelihood of harm may be difficult to predict but question 5 (on sensitivities) explains what data are particularly implicated. If there is doubt, DGC members should consider consulting community opinion leaders and representatives before making a decision on data sharing.
13. Any risks to trust between the research programme and the community from sharing this data?	The extent to which Data Subjects and groups of Data Subjects (communities) are aware of and support the use of their data in data sharing processes has an important influence on trust between Data Subjects and researchers. Loss of trust has an implication for other concurrent and future research as well as particular studies. Of particular importance is that participants/communities were aware at the time data was collected that this form of data sharing could occur in future, or there have been subsequent efforts to seek community input into a decision to share data not supported by any form of prior consent or awareness.
14. Is data available from elsewhere? If so, why are our data the better source?	Where a request is given low priority, it may be possible to direct requestors to other data sources.
15. What resources do we need to invest in order to share this data?	The level and availability of resources in the Programme to make the required data available to requestors is a key criterion in decision making. Where applications are prioritised but resources are not available, new scientific collaborations may be formed to support data sharing and a new SSC protocol is highly likely to be needed.

Appendix Bi. Application form/Data Transfer Agreement for internal requests

KEMRI/WELLCOME TRUST RESEARCH PROGRAMME
INTERNAL REQUEST FORM FOR KIDMS AND STUDY-SPECIFIC DATA
Conditions and Limitations of Data Sharing

1. REQUESTOR DETAILS			
Name		**Department**	
2. INVESTIGATORS Names of all investigators who will have access to data (begin with Principal Investigator)			
Names	**Roles**	**Institutions**	
1. 2. 3. 4.			
3. IS THIS APPLICATION COMPLETELY COVERED BY AN EXISITING APPROVED PROPOSAL OR PROPOSAL REVIEWED BY ANOTHER SCIENTIFIC AND/OR ETHICS REVIEW COMMITTEE?			
If yes: Give name of scientific/ethics review committee, date of approval, title of proposal, name of PI and end date of proposal:			
If no: outline any plans to apply for scientific/ethical approval:			
4. DESCRIPTION TYPE OF DATA REQUIRED (INCLUDE DETAILS OF STUDY THAT HOLDS THE DATA YOU REQUIRE IF APPLICABLE i.e. study number, study title and PI name)			
5. OBJECTIVES OF DATA USE INCLUDING TIME FRAME			
6.ANY RISKS/SENSITIVITIES OR BENEFITS OF ANALYSIS, including to Data Subjects and groups of Data Subjects			
7. PLANNED OUTPUTS OF ANALYSIS			

Conditions and limitations for data sharing

1. You understand and acknowledge that custodianship of the Data is held jointly by the Programme and the Ministry of Health in Kilifi, and will be retained by the Programme and the Ministry of Health in Kilifi in case of any data transfer to a Recipient.
2. You understand and acknowledge that the Data is experimental in nature, and that access to the Data is provided without any representations or warranties of any kind in relation to the Database or the Data.
3. You will only access the Database and use the Data for the Agreed Purpose and shall not use the Data in such a way that damage or distress is or is reasonably likely to be caused to any Data Subjects.
4. The Data relates directly to individual Data Subjects and is strictly confidential. Data from subjects will be shared in a fully anonymised form without access to personal identifiers, including names and/or specialised roles. Geographic identifiers for subjects will routinely be aggregated to the level of the sub location or similarly de-identified. Consideration of requests for data with greater granularity will be informed by the local importance of the research question and the ability to protect the confidentiality of individuals and communities.
5. You shall only disclose the Data to your Data Users. You shall take all reasonable measures to ensure that your Data Users shall not make copies of the whole or any part of the Data without your consent, and shall keep a written record of any such copies sufficient to permit you to fulfil your obligations under clauses 3 and 7 of this Agreement. You shall not transfer or disclose any part of the Data to any other person or body.
6. You understand and acknowledge that the Data is protected by copyright and other intellectual property rights. Except as reasonably required to carry out Your research with the Data for the Agreed Purpose You shall not duplicate, or sell, or offer for sale or transfer or offer to transfer all or part of the Data, on any media.
7. You agree at all times to keep strictly confidential, and ensure that the Data Users keep confidential the information and Data pertaining to Data Subjects. In particular, You undertake not to use, or attempt to use, or permit anyone other than the Data Users to use the Data on its own or in conjunction with other data, to seek to discover the identity of any Data Subjects, to compromise or otherwise infringe the confidentiality of information on Data Subjects and their right to privacy.
8. You accept that the Data is protected by and subject to national and international laws, and that You are responsible for ensuring compliance with any applicable laws.
9. You agree that you will submit a summary report and any other information reasonably requested to the KEMRI Wellcome Trust Research Programme for the purposes of monitoring data use on the understanding that such information, data, results, and conclusions contained within will be treated as confidential information belonging to the Recipient.
10. This agreement is not transferable and You may not purport to assign it (in whole or in part) without the written consent of the KEMRI Wellcome Trust Research Programme.
11. If You commit a material breach of this Agreement or for any persistent breach of this Agreement, the KEMRI Wellcome Trust may terminate this Agreement immediately by notice in writing, without prejudice to its accrued rights and remedies.
12. You accept that it may be necessary for the KEMRI Wellcome Trust Research Programme to alter the terms of this Agreement from time to time in order to address new concerns. In this event, the KEMRI Wellcome Trust Research Programme will contact You to inform You of any changes and You agree that Your continued use of the Data shall be dependent on the parties entering into a variation of the Agreement.
13. If requested to do so by the Data Governance Committee, the KEMRI Wellcome Trust Research Programme may terminate this Agreement at any time by giving one month's notice in writing to You.
14. Your duty to protect the confidentiality of the Data received under this agreement shall survive termination of this Agreement and shall continue in full force and effect indefinitely.
15. Upon termination of this Agreement you will permanently delete all copies of the Data from your computer systems and storage devices and will ensure that all Your Data Users shall also permanently delete such copies. You may retain aggregate information on the proviso that such aggregate information does not allow any individuals or groups of individuals who are the subject of the Data to be identified with reasonable effort.
16. You may publish Your results arising from the use of the Data for the Agreed Purpose providing the Data itself is not disclosed. Aggregate or generic information generated from the Data may be published on the provisos that: i) such aggregate or generic information does not allow Data Subjects or groups of Data Subjects to be identified with reasonable effort; ii) no damage or distress is or is reasonably likely to be caused to any Data Subjects or groups of Data Subjects; iii) the Data will not be used in any way that could reasonably be expected to lead to ethnic stigmatisation; and iv) no attempt will be made to identify the Data Subjects.
17. You agree to acknowledge the KEMRI Wellcome Trust Research Programme or appropriate Programme researchers (via authorship or an acknowledgment statement) in any work based in whole or part on the Data publications arising from the use of the Data.
18. You agree that if your application is approved, information about the proposed research use can be posted on the KEMRI Wellcome Trust Research Programme's public website. The information may include Your name and institution, the title of the project, and a non-technical summary of the research question.
19. You recognise that nothing in this Agreement shall operate to transfer to You any intellectual property rights relating to the Data. You have the right to develop intellectual property based on comparisons with Your own data.

Definitions in the agreement above:

"Recipient" means the principal researcher named above; "Recipient Institution" means the organisation named above at which the Recipient is employed, affiliated or enrolled; "Data Users" means those officers, employees and students of the Recipient Institution, who work directly with the Recipient and have a need to use the Data for the performance of their work with respect to the Agreed Purpose, and have agreed to comply with this Agreement, as named in the application; "Database" the KIDMS database containing clinical and demographic and health surveillance data on Data Subjects; "Data Subjects" the individuals who have contributed their data to the Database; "Data" the data within the Database; "Agreed Purpose" means the medical research purpose(s) approved by the Data Governance Committee in writing; "Publications" means, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.

Statement of agreement: I agree to the above conditions and limitations for sharing data as requested in this application:

Name:_____ Date:_____

Signature: _____

Appendix Bii. Application form/Data Transfer Agreement for external requests

1. REQUESTOR DETAILS					
Name					
Contact details: address, phone and email		**Phone**		**Email**	
2. STUDY DETAILS					
Title of Research Project			**Start & end dates**		
Ethical approval sought / planned (with dates)					
3. INVESTIGATORS					
Names of all investigators who will have access to data (begin with Principal Investigator)* include names of KWTRP collaborators where applicable.					
Name	**Role**				**Institution**
4. BRIEF DESCRIPTION TYPE OF DATA REQUIRED					
5. OBJECTIVES AND STUDY DETAILS INCLUDING TIME FRAME					
6. BRIEF DESCRIPTION OF ANALYSIS PLANNED WITHIN KIDMS DATA *specify if study specific data not KIDMS data					
7.POTENTIAL RISKS OF THE STUDY including risks to confidentiality of individuals or communities					
8.POTENTIAL BENEFITS OF THE STUDY including to participant communities, scientific capacity building or health policy					
9. PLANNED OUTPUTS OF STUDY					

Conditions and limitations for data sharing

20. You understand and acknowledge that custodianship of the Data is held jointly by the Programme and the Ministry of Health in Kilifi, and will be retained by the Programme and the Ministry of Health in Kilifi in case of any data transfer to a Recipient.
21. You understand and acknowledge that the Data is experimental in nature, and that access to the Data is provided without any representations or warranties of any kind in relation to the Database or the Data.
22. You will only access the Database and use the Data for the Agreed Purpose and shall not use the Data in such a way that damage or distress is or is reasonably likely to be caused to any Data Subjects.
23. The Data relates directly to individual Data Subjects and is strictly confidential. Data from subjects will be shared in a fully anonymised form without access to personal identifiers, including names and/or specialised roles. Geographic identifiers for subjects will routinely be aggregated to the level of the sub location or similarly de-identified. Consideration of requests for data with greater granularity will be informed by the local importance of the research question and the ability to protect the confidentiality of individuals and communities.
24. You shall only disclose the Data to your Data Users. You shall take all reasonable measures to ensure that your Data Users shall not make copies of the whole or any part of the Data without your consent, and shall keep a written record of any such copies sufficient to permit you to fulfil your obligations under clauses 3 and 7 of this Agreement. You shall not transfer or disclose any part of the Data to any other person or body.
25. You understand and acknowledge that the Data is protected by copyright and other intellectual property rights.
26. You agree at all times to keep strictly confidential, and ensure that the Data Users keep confidential the information and Data pertaining to Data Subjects. In particular, You undertake not to use, or attempt to use, or permit anyone other than the Data Users to use the Data on its own or in conjunction with other data, to seek to discover the identity of any Data Subjects, to compromise or otherwise infringe the confidentiality of information on Data Subjects and their right to privacy.
27. You accept that the Data is protected by and subject to national and international laws, and that You are responsible for ensuring compliance with any applicable laws.
28. You agree that you will submit a summary report and any other information reasonably requested to the KEMRI Wellcome Trust Research Programme for the purposes of monitoring data use on the understanding that such information, data, results, and conclusions contained within will be treated as confidential information belonging to the Recipient.
29. This agreement is not transferable and You may not purport to assign it (in whole or in part) without the written consent of the KEMRI Wellcome Trust Research Programme.
30. If You commit a material breach of this Agreement or for any persistent breach of this Agreement, the KEMRI Wellcome Trust may terminate this Agreement immediately by notice in writing, without prejudice to its accrued rights and remedies.
31. You accept that it may be necessary for the KEMRI Wellcome Trust Research Programme to alter the terms of this Agreement from time to time in order to address new concerns. In this event, the KEMRI Wellcome Trust Research Programme will contact You to inform You of any changes and You agree that Your continued use of the Data shall be dependent on the parties entering into a variation of the Agreement.
32. If requested to do so by the Data Governance Committee, the KEMRI Wellcome Trust Research Programme may terminate this Agreement at any time by giving one month's notice in writing to You.
33. Your duty to protect the confidentiality of the Data received under this agreement shall survive termination of this Agreement and shall continue in full force and effect indefinitely.
34. Upon termination of this Agreement you will permanently delete all copies of the Data from your computer systems and storage devices and will ensure that all Your Data Users shall also permanently delete such copies. You may retain aggregate information on the proviso that such aggregate information does not allow any individuals or groups of individuals who are the subject of the Data to be identified with reasonable effort.
35. You may publish Your results arising from the use of the Data for the Agreed Purpose providing the Data itself is not disclosed. Aggregate or generic information generated from the Data may be published on the provisos that: i) such aggregate or generic information does not allow Data Subjects or groups of Data Subjects to be identified with reasonable effort; ii) no damage or distress is or is reasonably likely to be caused to any Data Subjects or groups of Data Subjects; iii) the Data will not be used in any way that could reasonably be expected to lead to ethnic stigmatisation; and iv) no attempt will be made to identify the Data Subjects.
36. You agree to acknowledge the KEMRI Wellcome Trust Research Programme or appropriate Programme researchers (via authorship or an acknowledgment statement) in any work based in whole or part on the Data in the following way :*"This paper/publication has used data and/or biological samples provided by the KEMRI Wellcome Trust Research programme in accordance with the consent provided by participants and approved by the KEMRI Ethics Review Committee".*
37. You agree that if your application is approved, information about the proposed research use can be posted on the KEMRI Wellcome Trust Research Programme's public website. The information may include Your name and institution, the title of the project, and a non-technical summary of the research question.
38. You recognise that nothing in this Agreement shall operate to transfer to You any intellectual property rights relating to the Data. You have the right to develop intellectual property based on comparisons with Your own data.

Definitions in the agreement above:

"Recipient" means the principal researcher named above; "Recipient Institution" means the organisation named above at which the Recipient is employed, affiliated or enrolled; "Data Users" means those officers, employees and students of the Recipient Institution, who work directly with the Recipient and have a need to use the Data for the performance of their work with respect to the Agreed Purpose, and have agreed to comply with this Agreement, as named in the application; "Database" the KIDMS database containing clinical and demographic and health surveillance data on Data Subjects; "Data Subjects" the individuals who have contributed their data to the Database; "Data" the data within the Database; "Agreed Purpose" means the medical research purpose(s) approved by the Data Governance Committee in writing; "Publications" means, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.

Statement of agreement: I agree to the above conditions and limitations for sharing data as requested in this application:

Name:_____ Date:_____

Signature:_____

Signed on behalf of KEMRI-Wellcome Trust Research Programme:

……

Title:…Professor Philip Bejon……

Position:…Programme Executive Director…….

Signature: ……..

Date:……..