LCTU Data Sharing Policy

Introduction and Aim:

This policy is to document the data access and data sharing policy of the CR-UK Liverpool Cancer Trial Unit, The Northwest Surgical Centre and the LCTU NIHR Division. The LCTU as a charity and publically funded organisation has a duty to share data to advance clinical research and benefit patients. External organisations and collaborators can apply for access to data generated by the LCTU. Data Sharing is encouraged to promote research and maximise patient benefits of these data, although a limited period defined in consultation with lead applicant/CI of exclusive use of data for primary research is necessary. The purpose of the policy is to define the LCTU procedures for data sharing to ensure the appropriate data sharing of LCTU data for purposes of scientific research, achievement of the LCTU strategy and to ensure the requirements of funding bodies and data protection regulations are adhered to.

Benefits of data sharing are as follows:

- Enabling new research questions to be answered in existing data
- Promoting collaboration between different research teams and diverse disciplines
- Sharing of knowledge about best methods for data collection, linkage and analysis
- Ensuring that collected data are cleaned, well documented, with value added
- Independently verifying established research findings
- Development and testing of new research methods
- Using to best effect the gift of data made by study participants

The LCTU will make data available for sharing for a minimum of five years following the end of a research grant.

Scope:

The policy covers all studies conducted across the divisions of the LCTU in the UK and worldwide regardless of the source of the funding. It also covers all types of data requests including but not limited to: Individual Patient Data from Clinical trials, Clinical trial metrics, metadata and translational data. External organisations and collaborators can apply for access to data generated by the LCTU operational activity. However there will be a limited period (defined in consultation with the lead applicant /CI) of exclusive use of the data for the primary research question.

LCTU Data access policy should:

- Provide an approach and framework to implement, maintain, monitor and improve data access and sharing in line with MRC, NIHR and CRUK guidance;
- Provide all LCTU and collaborators guidance on the sharing of LCTU data collections

Eligibility

Data sharing is the practice of making data used for research available to other investigators. The sharing of data needs to be regulated and controlled as a general principle personally identifiable data should not be used to undertake research unless there is consent to do and appropriate ethical approval. The LCTU has a responsibility to ensure that data is only shared with researchers with genuine project reaching high scientific integrity and within the terms and conditions of the material transfer agreement with the university.

The LCTU decisions regarding the sharing data are based on the following criteria:

- Data will be used in high quality research ideas that aligns with the LCTU over aching strategy and offers benefit to patients
- The data sharing does not contravene the participant consent and meets all ethical regulatory requirements
- The sharing is compliant with the data protection 1998 and human tissue act 2004
- Priority of the access (only applicable for limited resource i.e. Tissue Micro arrays)
- The research proposed has been peer reviewed
- Projects that transform or link pre-existing datasets
- The data requester agrees that CRUK and the LCTU are acknowledged were appropriate

Terminology

Data Set: Any dataset, including summary datasets, or set of human samples with associated data

Custodian: The person, organisation, body or committee with responsibility for a collection (typically this is the Chief Investigator or Chair of the Steering Committee)

Material transfer Agreement: Agreement covering data or material transfer

Requester: An individual/group of researchers seeking access to data and/or samples from a data set

Responsibilities

The **LCTU Operational Director** is responsible for developing and updating the Data Access Policy and will be decimated through the LCTU document management system. The Policy must also be ratified by the **LCTU Senior Management Team** prior to implementation and dissemination.

The **LCTU Senior Information Systems Developer** is responsible for the recording, processing and tracking of all data requests. In addition they will facilitate the transfer of data, track the custodianship and location of LCTU data collections and supply the contact details of the relevant custodian on request.

The **LCTU Trial Adoption Committee** as part of its remit will review, monitor and oversee data sharing requests and decide on requests where the study in question no longer has an active Custodian. For on-going studies with an active Chief Investigator (CI) or Trial Steering Committee they will be considered the active custodian and therefore review and approve access to the data in line with this Policy.

The LCTU adoption committee (5-10 members) is agreed by the LCTU senior management team and reviewed from time to time. The trial adoption committee meets at least 1 every two months. A minimum of 2 members of the SMT, in addition to the Senior IS developer, and a lay representative should be present to review requests . The meeting are convened and administered by the **LCTU Senior Administrator.**

Process for Data sharing

Potential Requesters are encouraged to approach the relevant study investigators informally in the first instance to discuss acceptability and feasibility. Requesters should be employees of a recognised academic institution, health service organisation or commercial research organisation with experience in medical research. Requesters should be able to demonstrate, through their peer reviewed publications in the area of interest, their ability to carry out the proposed study. Initial emails requests should come from a recognised email domain or on an appropriate letterhead.

After the initial scoping exercise if the data sharing is a possibility for consideration an outline of the proposed study (the Proposal) is to be submitted to the LCTU IS developer and the relevant CI for consideration. The Proposal should include a clear statement of the background to the study, the objectives, and details of the methodology proposed and relevant references. In addition a copy of the researcher CV and the projects ethics approval should be provided

The Senior IS developer will check the content of the proposal and liaise with the Requester as necessary for any further information. Proposals will then be forwarded as appropriate to the Custodian the LCTU SMT and the Trial Adoption Committee for review and decision making.

The Custodian (i.e. an active Steering Committee or CI) will decide whether or not to accept the Proposal. Agreed proposals will be reviewed at the next appropriate Trial Adoption Committee meeting as part of their monitoring of data sharing requests. Sharing requests that are refused will also be reviewed by the Committee and Requesters may appeal if they disagree with the Custodian's refusal. Proposals provisionally agreed between acting Custodian and the Requester are reviewed by the TAC either in person or by email and a decision made on approval or further actions. Applications may be sent for scientific review by independent peer reviewers if the Custodian or Committee feels external help is required.

Ethics Committee approval from the Requester's local ethics committee is the responsibility of the Requester. The Requester, in conjunction with any LCTU study investigators, may also need to obtain approval from the Research Ethics Committee responsible for the existing LCTU study. Local Research Governance approval and R&D approvals, if required, are the responsibility of the Requester.

The dataset MUST only be used for the purposes of medical research and within the constraints of the Consent under which the data were originally gathered. Where demand for material exceeds its availability, or availability of staffing resources to make the data available are exceeded, access will be prioritised on scientific merit (as judged by the Trial Adoption Committee).

Data or samples supplied from the dataset may only be transferred to Requesters named at the time of the original application or in subsequent applications and specified in the Access Agreement or later amendments. Data from the collection may not be transferred to individuals outside the Requester's research group.

Governance

Access to the LCTU Data, whether summary tables, individual participant information, or biological samples will only be permitted by application and will be done so under the terms and conditions of a Material Transfer Agreement (MTA). A template for this is available from the University Research Support Office on request. The MTA will include clauses to cover ownership, intellectual property, publications, exploitation and dissemination of results. It may specify a fee payable and include requirements that the user conform to Ethics and Governance terms, the terms of the participants' consent and the LCTU Data Access Policy. Data or samples supplied from the LCTU must only be used for the purpose stipulated by the Custodian and described in MTA agreement.

The LCTU IS team is trained in the principles of Data Protection and are responsible for the security and transmission of all shared data. The IS team will determine the best method and format for transfer. Metadata will be provided to describe the data and associated format. Data will be encrypted prior to any transmission

Identifying data will not be made available to research collaborators. All data provided to a Requester will be anonymised; the processes for anonymisation will be discussed as part of the request review and specified by the relevant custodian. The MTA will contain confidentiality undertakings to further safeguard participants' privacy. Commercial confidentiality will be maintained when publishing or sharing data.

Recipients must agree not to link the anonymised data provided with any other data set without the permission of the Custodian. Recipients must not attempt to identify any individual from the data provided. Should recipients believe that they have inadvertently identified any individual, they must not record this, share the identification with any other person or attempt to contact the individual. Applications for funding for research including data from CTSU research studies will be required to include a CTSU study investigator as a co-applicant. Requesters will be required to submit regular progress reports to the LCTU or Custodian

The recipient may be required to cover the costs of administering the data sharing (including legal fees if applicable), retrieving, processing and sending the data or samples. Estimated costs for a particular request will be provided after initial review of the application.

Research Results

The LCTU reserves the right to publish the title, the names(s) and affiliations(s) of the Chief Investigator(s), a lay summary and a scientific abstract of each piece of collaborative research for which access to the resource has been granted, before identification or publication of results. This summary will be made available on the LCTU public website. Requesters who do not wish details of their study to be openly available should state this in their application to the collection and give the reason.

In order to recognise the contribution made by past and current LCTU staff and collaborators (around the UK and internationally) to setting up and maintaining study data sets, it would be expected that a representative of the study would be offered co-authorship. It may also be appropriate to acknowledge individual members of the study staff who have contributed directly to the study in order that they may claim authorship as members of the study team. Each paper to be submitted for publication by collaborators must be forwarded to LCTU for consideration at least 28 days before submission.