

[REDACTED]

By email to [REDACTED]

Human Tissue Authority  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel 020 7269 1900  
Email enquiries@hta.gov.uk  
Web www.hta.gov.uk

Date 18 July 2019

Dear [REDACTED]

### Freedom of Information request

Thank you for your request for information under the Freedom of Information Act (FOIA), which was received by the Human Tissue Authority (HTA) on 3 July 2019. Your email outlined the following request:

Dear sir/madam

Please could you provide me with the documents submitted as part of King's Health Partners Cancer Biobank (London UK)'s application for a Human Tissue Authority licence, reference 12121?

Please reply to me by email [REDACTED] within 20 working days (i.e. by 31st July 2019).

### Response

Information within the scope of the request – which consists of the original licence application and an associated email trail - is provided in the attachment to this letter, comprising a single PDF document.

Some information has been redacted in accordance with relevant exemptions set out in the Freedom of Information Act 2000 (FOIA) and following the redaction guidance set out in the HTA's applicable corporate document.

The lawful exemption relied on in this response is section 40 of the FOIA.

Section 40 provides an exemption for information, which constitutes the personal data of a third party and disclosure would breach any of the data protection principles. In this case, we have withheld information, which relates to identifiable individuals and so constitutes personal data as defined in the General Data

Protection Regulation (GDPR), and disclosing it would be unlawful and unfair, therefore breaching the data protection principles contained in the GDPR. Where possible, we have simply redacted the names of individuals to disguise their identities. However, we have also needed to redact additional information, which could be used to identify those individuals.

### **Further information**

If you are unhappy with the way the HTA has handled your request for information in this case, you may in the first instance ask us for an internal review by writing to us at the above postal or email address.

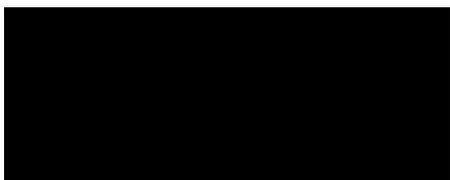
If you remain dissatisfied with the handling of your request or complaint, you have the right to appeal directly to the Information Commissioner for a decision, at the address below. There is no charge for making an appeal.

Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire SK9 5AF

Telephone: 08456 30 60 60 or 01625 54 57 45

Website: [www.ico.gov.uk](http://www.ico.gov.uk)

Yours sincerely

A large black rectangular redaction box covering the signature area.A black rectangular redaction box covering the signature area, with a smaller redaction box below it.

[REDACTED]

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**From:** [REDACTED]  
**Sent:** 30 May 2007 17:03  
**To:** [REDACTED]  
**Subject:** Re: HTA Licence application 12121  
**Importance:** High

Dear [REDACTED]

I have hopefully clarified the points you raised below;

C1 – In November 2006 the Guy's Breast Tissue Bank updated the consent form and patient information sheet to reflect changes introduced by the Human Tissue Act 2004 and take into account the HTA Code of Practice for consent. These changes and updates were approved by Guy's Research Ethics Committee.

C3 – The Guy's & St Thomas NHS Foundation Trust Policy for Consent to Examination or Treatment, stipulates which staff can obtain consent for these activities and the training they require. A record is kept by the Trusts Clinical Governance Department of those who have been trained to take consent. The Trusts Consent Policy is currently (May 2007) being re-drafted to include information on implications of the Human Tissue Act 2004. As an interim measure all staff within the Breast Unit at Guy's who are trained to take generic consent and those who wish to train have been supplied with information about the Human Tissue Act and HTA Code of Practice.

GQ4 – All records, (policies, procedures and forms) are defined and monitored within the document control system. This enables all documents to be tracked from conception to destruction and records all amendments during the lifetime of the document.

PFE1 – The most recent Health & Safety Audit, which included risk assessment was undertaken by the [REDACTED] on [REDACTED]

[REDACTED] Summary of inspection was;

"The health and safety standards and awareness seen within this department were very good, with minor housekeeping issues being noted. A great deal of effort has been put into health and safety by the department and it should be encouraged to maintain and indeed improve upon standards demonstrated".

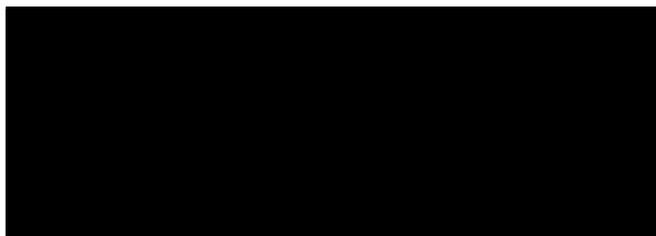
The laboratory is currently in the process of being formally transferred to King's College London (completion due October 2007) at that stage the [REDACTED] [REDACTED] will be invited to review the facilities.

There is ample space to carry out all procedures associated with the collection and storage of tissues.

If you require any further information please do not hesitate to get in touch with me.

31/05/2007

Best wishes,



Guy's Hospital,  
London SE1 9RT  
020 7188 0874

On 22/5/07 10:56 am, [redacted] wrote:

Dear [redacted]

I am in the process of evaluating your HTA licence application and require further information to support your application:

HTA Standard – Consent

C1 - Do consent forms meet the requirements of the Human Tissue Act 2004 and the HTA Code of Practice?

C3 - How do you ensure the persons responsible for seeking consent have attended training and are aware of the requirements of seeking consent in accordance with the Human Tissue Act and the HTA Code of Practice?

HTA Standard – Governance and Quality Systems

GQ4 - Do you have documented procedures for the creation, amendment, retention and destruction of records?

HTA Standard – Premises, Facilities and Equipment

PFE1 – Have risk assessments been performed on premises to ensure they are fit for purpose?

Do the premises have sufficient space for procedures to be carried out safely and efficiently?

I would be grateful if you could return reply in 10 working days to allow me to complete the evaluation process. If you have any queries please contact me on my direct line number detailed below

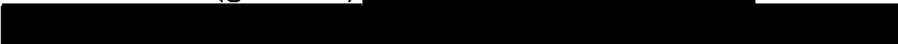
Kind Regards

  
**Human Tissue Authority**

Finlaison House

15-17 Furnival Street

London EC4A 1AB

**Tel** 020 7211 3400 (general) **Email** **Web** [www.hta.gov.uk](http://www.hta.gov.uk) <<http://www.hta.gov.uk/>>

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**Establishment Info,  
Licence Num: 12121**



Has your establishment already received an HTA licensing number?

If yes - please enter the licensing number

What is the range of body parts, tissues or cells that are collected or stored?

Surplus diagnostic material

Specific body parts, tissue or cells type(s)

If specific types, please identify tissue(s) collected

Breast Tissue & Sites of Metastatic Breast cancer

Do you store material obtained from the living and / or the deceased?

Living

Deceased

How are the body parts, tissues or cells stored?

Refrigerated

Frozen

Fixed and frozen

Fixed and stored at room temperature

Liquid nitrogen storage

other please describe

What types of procedures are carried out at the establishment?

Donor selection

Consent

Procurement

Storage

Distribution

Import / export

**Distribution**

Local

Regional

National

European Community

European Economic Area

Other international destination

Do you store samples on behalf of other organisations, and if so how many organisations are you storing on behalf of?

False

Approximately how many samples are collected each year?

1000

Approximately how many samples are distributed each year?

800

To assist the HTA, please provide a short synopsis describing your establishment

The GSTT/KCL Breast Tissue Bank has a collection of fixed paraffin-embedded tissue from 30,000 cases (5600 of which are primary breast cancers) accrued between 1975 to date. It also has a bank of frozen breast tissues collected since 1985 consisting of 4100 samples of which 1600 are primary breast cancers. Tissue is provided to individual researchers within the Bank, other university and Trust staff and external groups (national and international)

Please document how many adverse events have occurred in your establishment in the past 12 months None

### Information about inspection and accreditation

Do the premises where the licensable activity takes place have any form of accreditation?

If yes, give the date of the accreditation and some information about the activities covered by the accreditation / licence:

Accredited CPA  Date

Accredited ISO / 9000  Date

Accredited Investors in People  Date

GMP  Date

Further information: (e.g. explaining the activities covered by the accreditation, date of last inspection) N/A

Does the establishment have any other form of accreditation? If yes, please describe, explain the activities covered by the accreditation and date of last inspection

**Designated Individual,  
Licence Num: 12121**

**Application Summary:**

**Status** Returned to Manager

**Designated Individual** [REDACTED]

**If you have been known by another name, please give details**

**Date of Birth** [REDACTED]

**Job Title** [REDACTED]

**Employer** [REDACTED]

**Establishment's name** Guy's & St Thomas' Research Tissue Bank

**Activities to be licenced**  **The storage of relevant material which has come from a human body for a Scheduled Purpose**

**Have you applied to be a DI for another establishment?**

**Licensing number**

**Establishment name**

**Education or professional qualifications** [REDACTED]

**Membership of relevant professional bodies (please provide registration numbers where applicable)** [REDACTED]

**Details of any other relevant experience including managerial experience and training** [REDACTED]

**With regard to the organisational structure of the establishment, please indicate the lines of responsibility between the DI and any persons working under the licence** [REDACTED] supervision of all technical and clerical staff associated with the Breast Tissue Bank

**Please explain your involvement in ensuring that staff who will work under the licence are appropriately qualified and trained in techniques relevant to their work and that they are continuously updating their skills** [REDACTED] recruitment of staff to the tissue bank, ensuring that all new staff meet minimum educational requirements for the post. All technical staff have previous laboratory experience and are then trained in post. Throughout their training period they are closely supervised with regular review and feed-back sessions. All staff are actively encouraged to attend meetings and courses to keep up-to-date on developments in banking and tissue-associated techniques.

**Please explain your involvement in governance and quality management activities within the establishment** [REDACTED] on the Breast Tissue Bank Management Committee which reports directly to the Guy's & St Thomas NHS Trust Clinical Governance and Risk Management Committee. [REDACTED] Access Sub-Committee, being responsible for applicants obtaining study approval from different regulatory bodies.

Please explain your why you think you are suitable for the role of DI [REDACTED] working in the GSTT/ KCL Breast Tissue Bank as both a provider and user of the resource. [REDACTED] I have regular contact (daily) with them to ensure best practice is being met. I also have [REDACTED] with the [REDACTED] and the [REDACTED].

Names of person(s) who have consented to be designated on the licence (where establishment is applying for a

Address(es) of satellite site's premises and activities to be licensed

Names of person(s) who have consented to be designated on the licence at the

**Declaration by proposed DI**

- a. I will follow the guidance set out in the Codes of Practice produced by the HTA and as amended from time to time;  Yes  
 No
- b. The licensed activity will be carried out under my supervision  Yes  
 No
- c. I accept I am responsible for securing that the other persons to whom the licences apply are suitable persons to participate in the carrying out of the licensed activity;  Yes  
 No
- d. I accept that I am responsible for securing that suitable practises are used by the persons under my supervision in the course of carrying out the licensed activity;  Yes  
 No
- e. I accept I am responsible for compliance with the conditions of any licences granted;  Yes  
 No
- f. The information provided is true and accurate to the best of my knowledge;  Yes  
 No
- g. I consent to be the DI for the licence applications made by the proposed Licence Holder and where applicable consent to be the Licence Holder.  Yes  
 No

**Contact Methods**

Method	Value	Notes	Preferred
Email	<span style="background-color: black; color: black;">[REDACTED]</span>	soon to be stopped	
Fax	<span style="background-color: black; color: black;">[REDACTED]</span>		Preferred
Phone	<span style="background-color: black; color: black;">[REDACTED]</span>		Preferred
Email	<span style="background-color: black; color: black;">[REDACTED]</span>		Preferred
Phone	<span style="background-color: black; color: black;">[REDACTED]</span>		Preferred

**Corporate Licence Holder,  
Licence Num: 12121**



**Full name of body** Guy's and St Thomas' NHS Foundation Trust

**Trading name / business name if  
different from company name**

**Type of corporate body**

- Limited Company
- Sole Proprietor
- Public Limited Company
- Partnership
- Charity
- NHS Organisation
- Other Public Body

**If other Public Body, please describe**

- Higher Education Institution
- Other

**If other, please describe**

**If a Private / Public / Limited Company - Co. Registered No.**

**If a sole proprietor - name and address**

**If a charity - Charities Registered No.**

**If partnership - Names and addresses of partners**

**Other - Trading / Business Address**

**Name and registered office of parent  
company, if any**

**If the body has been known by another  
name in the past 5 years please detail**

**Year when established** 0

**Name of person completing application  
on behalf of the corporate body**

**Please explain why the corporate body is  
suitable for the role of Licence Holder**

**Declaration by the corporate applicant**

**a. The information provided is true and accurate**

Yes

No

**b. The DI has consented to this application**

Yes

No

c. I have been authorised to make this application on behalf of the applicant

Yes

No

**Contact Methods**

<b>Method</b>	<b>Value</b>	<b>Notes</b>	<b>Preferred</b>
Email	[REDACTED]		Preferred
Fax	[REDACTED]		Preferred
Phone	[REDACTED]		Preferred

**C1: Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 & as set out in the Code of Practice**

- Self-assessment rating
- 1 = Standard not met
  - 2 = Standard partially met
  - 3 = Standard almost met
  - 4 = Standard fully met or exceeded

Consent to bank tissue for generic research purposes has been sought from patients' attending Guy's Breast Unit since 1999 as an ethically approved activity (Guy's LREC 01/03/09). Completed consent forms are kept in the office of the [REDACTED] and information transferred to database to ensure only patients who have given consent are included in research activities.

**C2: Information about the consent process is provided and in a variety of formats**

- Self-assessment rating
- 1 = Standard not met
  - 2 = Standard partially met
  - 3 = Standard almost met
  - 4 = Standard fully met or exceeded

There is a SOP in place for requesting consent from patients to bank tissue surplus to diagnostic requirements. The procedure and information given to the patient has been approved by Guy's LREC. Information and a request to bank tissue surplus to diagnostic requirements is done during the first clinic visit. The surgeon provides the patient with an information sheet and discusses the consequence of allowing tissue to be collected for research. Consent to collect tissue is discussed with the patient by a breast surgeon as part of the overall discussion to obtain consent for a surgical procedure. Interpreters used to obtain surgical procedure consent are also available to provide information on banking. Surgeons may also be helped to convey information by relative/ friends of patients who have special communication needs.

**C3: Staff involved in seeking consent receive training & support in the implications and essential requirements of taking**

- Self-assessment rating
- 1 = Standard not met
  - 2 = Standard partially met
  - 3 = Standard almost met
  - 4 = Standard fully met or exceeded

There is a SOP in place for requesting consent from patients to bank tissue surplus to diagnostic requirements. Currently only surgeons ask patients to give consent to bank. They have already received some training in seeking consent as part of the surgical procedure requirement.

The new consent form which supercedes Guy's LREC 01/03/09, allows patients to provide feedback on documentation and activities involved in seeking consent.

**Time to complete** 35

**GQ1: All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process**

**Self-assessment rating**

- 1 = Standard not met
- 2 = Standard partially met
- 3 = Standard almost met
- 4 = Standard fully met or exceeded

**Self-assessment comment** There are SOPs and policies in place for all Bank activity, including identifying potential samples to bank, seeking consent, revoking consent, access and all technical activities.  
All SOPs and policies are reviewed by the [REDACTED] on an annual basis unless they've been amended within that time. There are regular management committee meetings which incorporate health and safety and risk management of the Breast Tissue Bank.  
A formal complaints system needs to be introduced

**GQ2: There is a documented system of quality management and audit**

**Self-assessment rating**

- 1 = Standard not met
- 2 = Standard partially met
- 3 = Standard almost met
- 4 = Standard fully met or exceeded

**Self-assessment comment** The document control system in place allows version numbers, document update, distribution and recall to be monitored. This is retained by the [REDACTED].  
There is an annual review of the accrual and distribution of tissue by the Management Committee which is forwarded to Trust Clinical Governance and Risk management committee.  
A policy of regular audit of tissue access procedures and Tissue Bank contents is in place.

**GQ3: Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills**

**Self-assessment rating**

- 1 = Standard not met
- 2 = Standard partially met
- 3 = Standard almost met
- 4 = Standard fully met or exceeded

**Self-assessment comment** Each member of staff has a personal file with documented evidence of qualifications and training records, held by the [REDACTED]. A record is also kept of meetings attended, appraisal and personal development plan, sickness and annual leave.

**GQ4: There is a systematic and planned approach to the management of records**

**Self-assessment rating**

- 1 = Standard not met
- 2 = Standard partially met
- 3 = Standard almost met
- 4 = Standard fully met or exceeded

**Self-assessment comment** All paper reports are entered onto a clinical or Tissue Bank database. Policies are in place which limit access, entry and interrogation of databases to specified members of the Breast Tissue Bank. Servers for both Tissue Bank and linked clinical data are housed within secure areas of the department. Both databases are audited at 6 monthly intervals, including random and consistency checks. Back-up of data occurs daily.

**GQ5: There are documented procedures for distribution body parts, tissues or cells****Self-assessment rating**

- 1 = Standard not met
- 2 = Standard partially met
- 3 = Standard almost met
- 4 = Standard fully met or exceeded

**Self-assessment comment** Applications are made to Breast Tissue Bank sub-committee, who review scientific value, resource requirement and financial support. No tissue is released without Access sub-committee and regulatory body approval (eg LREC or R&D). Applicants must also complete the material transfer agreement before tissues are released. This ensures their awareness and agreement to comply with requirements for health and safety and disposal policies.

**GQ6: A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a****Self-assessment rating**

- 1 = Standard not met
- 2 = Standard partially met
- 3 = Standard almost met
- 4 = Standard fully met or exceeded

**Self-assessment comment** Each sample is assigned a unique code which is used to identify the tissue for all subsequent approved tissue studies. For each sample there is linked data on consent, date sample acquired, pathology and patient clinical features. A log is also kept of what tissue has been provided for different studies. The Material Transfer Agreement dictates procedure for the disposal of unwanted material.

**GQ7: There are systems to ensure that all adverse events are investigated promptly****Self-assessment rating**

- 1 = Standard not met
- 2 = Standard partially met
- 3 = Standard almost met
- 4 = Standard fully met or exceeded

**Self-assessment comment** A log is kept of all adverse events which affect security, safety and processes of both staff and material. These are reviewed and where appropriate procedures are

modified to avoid repetition of an incident. Information is displayed of Department noticeboards.

**GQ8: Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately**

**Self-assessment rating**

- 1 = Standard not met
- 2 = Standard partially met
- 3 = Standard almost met
- 4 = Standard fully met or exceeded

**Self-assessment comment** Risk assessments have been made on all appropriate aspects of the banking process. Like SOPs these risk assessments are reviewed on an annual basis or earlier if they require updating.  
Risk assessments are available to all staff and visitors . A copy is located adjacent to equipment or near the location of banking activity. Discussion and comprehension of risk assessment is part of every individuals orientation programme, There is a procedure that ensures that all staff are made aware of updates.

**Time to complete** 120



**PFE1: The premises are fit for purpose**

- Self-assessment rating**
- 1 = Standard not met
  - 2 = Standard partially met
  - 3 = Standard almost met
  - 4 = Standard fully met or exceeded

The Breast Tissue Bank is located within a purpose-built pathology laboratory . There is a secure (swip card) entry system to the laboratory. Health and safety policies are in place with both general and local rules available to staff. All staff receive mandatory health and safety instruction as part of their induction programme.

There is a policy on reporting and investigating all incidents and accidents within the Tissue Bank to both host institutions, KCL and the NHS Trust.

There is a procedure in place to ensure that all staff are made aware of health and safety updates

**PFE2: Environmental controls are in place to avoid potential contamination**

- Self-assessment rating**
- 1 = Standard not met
  - 2 = Standard partially met
  - 3 = Standard almost met
  - 4 = Standard fully met or exceeded

There are SOPs in place for handling potentially hazardous tissues to protect staff and visitors. Likewise, SOPs are available for decontamination of equipment, instruments and work-surfaces. All staff are provided with personal protective equipment for differing levels of risk.

**PFE3: There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records**

- Self-assessment rating**
- 1 = Standard not met
  - 2 = Standard partially met
  - 3 = Standard almost met
  - 4 = Standard fully met or exceeded

Frozen tissue is kept in individual vials within a freezer racking system. Location of individual tissue pieces is recorded on the Tissue Bank database. Frozen tissue is kept in a locked freezer with a CO2 back-up and alarm system which notifies hospital security of a drop in temperature. Freezer temperature is recorded daily.

Paraffin blocks are stored sequentially in purpose made filing cabinets and housed in a dedicated archive store. This room is kept locked when not in use and is further protected by being in a non-public area.

Access to both frozen tissue and blocks is restricted to trained Tissue Bank staff only.

**PFE4: Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during**

- Self-assessment rating**
- 1 = Standard not met
  - 2 = Standard partially met
  - 3 = Standard almost met
  - 4 = Standard fully met or exceeded

There is a policy and SOP for transporting frozen tissue from the pathology laboratory where fresh specimen dissection takes place to the Breast Tissue Bank facility (approx 40m distance but in the same building) and also in the provision of tissue to researchers. Tissue can be transported personally, by Royal Mail Special Delivery or by Courier dependant upon tissue format, value and distance. SOP also outlines the precautions which need to be taken when transporting potentially biohazardous material. Records are kept of transport details and confirmation of receipt. No tissue is despatched without an authorised material transfer agreement in place.

**PFE5: Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored**

- Self-assessment rating**
- 1 = Standard not met
  - 2 = Standard partially met
  - 3 = Standard almost met
  - 4 = Standard fully met or exceeded

Equipment has regular, documented maintenance checks, the frequency of which depends upon complexity and use. Records are kept of all maintenance procedures and services. Operating manuals are kept in the vicinity of the equipment and there is a procedure for notifying either [REDACTED] or responsible member of staff if a fault develops. Spare capacity is always available in a reserve freezer to accommodate tissue should there be a major, irreparable freezer fault in one of the main Breast Tissue Bank freezers.

**Time to complete** 40

**D1: There is a clear and sensitive policy for disposing of human body parts and tissues**

- Self-assessment rating**
- 1 = Standard not met
  - 2 = Standard partially met
  - 3 = Standard almost met
  - 4 = Standard fully met or exceeded

Policies are in place for the safe and appropriate disposal of tissues by the Breast Tissue Bank and groups to whom tissues have been supplied. Material transfer agreements include provision for either return of unused samples or their disposal. Currently seeking input from patient groups on these policies to ensure they reflect public opinion.

**D2: The reasons for disposal and the methods used are carefully documented**

- Self-assessment rating**
- 1 = Standard not met
  - 2 = Standard partially met
  - 3 = Standard almost met
  - 4 = Standard fully met or exceeded

SOP's are in place for the segregation and safe disposal of frozen , fixed and paraffin blocks/ sections. A record is kept of any tissue disposed of from an approved study.

Patients who give consent for their tissues to be used can provide details on disposal by stipulating their wishes on the consent form. Our practice is to incinerate all tissue which needs to be disposed of, regardless of thie format.

**Time to complete** 15