PREPARATORY TO RESEARCH FORM

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PREPARATORY TO RESEARCH FORM - Required if LIFESPAN records will be reviewed without authorization from research participant (i.e., Screen Prior to Consent (and collect identifiable data); or, Review for Chart/Specimen/Image Review, etc.)

This form must be completed by any researcher seeking access to or review of **protected health information (PHI)** ***from LIFESPAN records, specimens, images, etc.,*** *in preparation for research or recruitment/screening purposes or for chart/specimen/image review studies.*
When data is reviewed by someone other than a Lifespan employee, e.g., foundation affiliated physician/employee, Brown student/employee (not registered as a volunteer), this is a considered a disclosure All disclosures require an accounting of disclosures be maintained.

Go to: http://www.lifespan.org/doc/Page.asp?PageID=DOC022108 for accounting information

Describe the ***protected health information (PHI)*** *you would like to review and the location of these data.*
For chart reviews please indicate range of dates of records you want to review, (e.g., want to review charts from 1/2000 thru 1/2010).
Chart Reviews must remain retrospective so the end point must precede the date of request. Chart reviews also require a Waiver of Authorization.
PHI collected using Prep to Research may NOT leave Lifespan premises, see below page 2 and 3.

☐ Screening subjects records for eligibility prior to obtaining consent ☑ Chart review; image review; specimen review
☐ Other – explain

Types of **LIFESPAN** Records to be reviewed:

We will be reviewing the medical records of patients who have undergone operations for gastric and esophageal cancer surgery, between the dates of 1/1/1999 to 12/31/2015, in order to attain demographics of patient outcomes (regarding symptom management, operative staging, peri-operative complications, adjuvant therapy and overall symptom free and progression free survival).

Dates of Records to be reviewed if applicable for chart/image/specimen review: From: 1/1/1999 To: 12-31-2015
N/A –will review current records for eligibility screening

Location of LIFESPAN Records to be reviewed:

The records are stored in the University Surgical Associates medical Office - MOC470. All data will be depersonalized and entered into an electronic spreadsheet form controlled by TM and lock up in APC435

1. Identifiers (or links) to private information MUST be destroyed at the earliest possible time. Please describe your plans and specify when this will occur.

ll data will be immediately depersonalized and entered into an electronic spreadsheet form and controlled by TM. Data will be stored on removable media which is password protected and kept in possession of TM at all times throughout the course of the study when in use. When not in use any data will be locked in APC435

2. Do you anticipate that information obtained in this study would require notification of pertinent information to participants? Yes ☐ No ☑
If Yes, explain how participants would be contacted, or reference where this information can be found in the research plan.

SPECIFIC REQUIRMENTS THAT MUST BE ADHERED TO UNDER PREPARATORY TO RESEARCH USE

1. The use or disclosure requested will be limited to the preparation of a research protocol or for similar purposes preparatory to research, i.e., chart review, screening subjects for eligibility to research study.
2. **No protected health information (PHI) will be removed from the covered entity by the researcher in the course of the review. Chart review information must not be saved to hard drive of a laptop, must NOT be removed from the Lifespan premises unless de-identified (remember there are 18 identifiers that must be removed to de-identify data.).**
3. The requested information constitutes the minimum necessary data to accomplish the goals of the research and is necessary for my review.
4. I seek access to the above PHI solely to prepare a research protocol or for similar purposes preparatory to research, e.g. screening potential participants.
5. I understand that if I record any PHI in a way that may directly or indirectly be used to identify particular individuals (*e.g.*, addresses, telephone numbers, etc.), **I will use such information only when I am on hospital premises**
6. If viewing PHI to determine enough data exists to proceed with a study, I understand that I may not continue to use and disclose the PHI described above without further permission from the IRB once the Principal Investigator has determined to go forward with the study.
7. **I will abide by all accounting of disclosures as described in the information provided at: http://www.lifespan.org/doc/Page.asp?PageID=DOC022108**

As the PI for this study electronically signing the IRBNet package certifies all of the above are true and that this Request for Reviews Preparatory to Research complies with the hospital's policy *Use and Disclosure of PHI for Research Purposes*.

See HRPP P&P Manual HIPAA Section 16 http://www.lifespan.org/doc/Page.asp?PageID=DOC022670

(All Preps to Research Require a Full Waiver of Consent whether you are conducting a chart review OR are screening patients records for eligibility AND recording identifiable data during this process). **Complete Appendix 2 Section B below)**

B. WAIVER OF CONSENT PROCESS ***You are requesting a waiver of informed consent, 45CFR46.116(d), please complete questions below***

1. Provide the following justification to waive informed consent: a) Does this research present greater than minimal risk to the subjects? Yes ☐ No ☑

b) Will the waiver adversely affect the rights and welfare of the subjects and could research be carried out without the waiver? Yes ☐ No ☑
If yes explain (*Researcher inconvenience is not a justification*)..

c) Will subjects be provided with additional pertinent information after participation when appropriate? Yes ☐ No ☑ If No, explain.

Study is retrospective and any results or knowledge gained will only serve patients in the future.

HIPAA LAW STATES: Preparatory to Research data collection does not permit researcher to remove identifiable PHI from the covered entity premises. (Lifespan in this case is the covered entity).

- **Data Collected using a Preparatory for Research MUST not leave the Lifespan premises if it is identifiable**
- **Do NOT save identifiable data to a laptop (Lifespan issued or personal) and take that laptop home or off Lifespan premises.**
- **If you save data to a USB flash drive, including the Lifespan issued USB drives that USB must remain on the premises.**
- **To de-identify data all 18 HIPAA identifiers must be deleted.**

Data being collected	Can be emailed encrypted outside Lifespan	Can laptop/data/USB leave the institution?	Can be viewed remotely from outside Lifespan
Data has one or more of the 18 HIPAA identifiers	NO	NO	NO
Identifiable Data will be collected and saved to the Laptop hard drive (Lifespan issued or Personal)	NO	NO	NO
Identifiable data will be saved to Lifespan issued USB flash drive	NO	NO	NO
Data Will be de-identified by removing all 18 identifiers	YES	YES	YES

EXAMPLE OF IDENTIFIABLE DATA THAT MAY NOT LEAVE LIFESPAN PREMISES

IDENTIFIABLE	IDENTIFIABLE	IDENTIFIABLE		IDENTIFIABLE			IDENTIFIABLE			IDENTIFIABLE
Name of Patient	MRN of Patient	DOB	AGE	Date of lab results	Lab results	medication patient prescribed	x-ray image with MRN/name	X-Ray image w/o identifiers	HOSPITAL LENGTH OF STAY	any of the 18 HIPAA identifiers, see below.

EXAMPLE OF DE- IDENTIFIED DATA THAT MAY LEAVE LIFESPAN PREMISES

			AGE		Lab results	medication patient prescribed		X-Ray image w/o identifiers	HOSPITAL LENGTH OF STAY	

IDENTIFIABLE COLUMNS HAVE BEEN DELETED NOT HIDDEN

18 identifiers as per HIPAA: Name, address (except state), phone/fax numbers, email address, member/account #, MRN (biometric ID), Dates of any kind (DOB, DOD, dates of procedures, etc), SSN, Health Care/Beneficiary #, voice/finger prints, certificate/license #, IP address, Vehicle/device ID #, URLs, full face photo, any other unique ID (patient one of two with specific disease – naming disease could identify the patient).

☑ I have read and understand the above and agree to the terms of collecting data under a Preparatory to Research

RPO use only

Research involves reviewing/collecting identifiers prior to consenting subjects or reviewing records without obtaining consent/authorization.
Chart Review or Screening for eligibility involves no more than minimal risk; and, waiver of consent will not adversely rights/welfare of subjects; and, whenever appropriate; subjects will be provided additional pertinent information after participation; Subjects will always be consented if study is subject to FDA regulation.

Grant full waiver of consent Yes ☑ No ☐ **Signature HIPAA Privacy Officer/IRB Chair Designee**: S. Candace Frater Date: 2/22/2016

Digitally signed by S. Candace Frater
DN: cn=S. Candace Frater, o=Lifespan, ou=RPO Manager, email=sfrater@lifespan.org, c=US
Date: 2016.02.22 10:35:20 -05'00'