24 November, 2008

Dr. CHEUNG, Suk-yee, Polly
Principal Surgeon,
Breast and Endocrine Surgery Centre

Dear Dr CHEUNG,

KWC-CREC Reference: KW/EX/08-090

Breast Cancer Registry in Hong Kong (Protocol No. : 22102008)

The Kowloon West Cluster Clinical Research Ethics Committee (KWC-CREC) is authorized by the Cluster Chief Executive to review and monitor clinical research. It serves to ensure that research complies with the Declaration of Helsinki, ICH GCP Guidelines, local regulations and HA policy. It has the authority to approve, require modifications in (to secure approval), or disapprove research. This Committee has power to terminate / suspend a research at any time if there is evidence to indicate that the above principles and requirements have been violated.

KWC-CREC has approved your research application on 15 November, 2008 by expedited review process, and reached the following decision on the documents submitted as shown below. You are required to adhere to the attached conditions.

Study site(s)	**Princess Margaret Hospital**
Document(s) approved	I. Clinical Research Ethics Review Application Form (revised on 27 October, 2008) II. Research Protocol (version 22102008) III. Appendix 1 – Consent Form IV. Appendix 2 – Questionnaire (Chinese version, revised on 25 July, 2008) V. Appendix 3 – Questionnaire (Chinese version, revised on 25 July, 2008) VI. Appendix 4 – Hong Kong Breast Cancer Registry Data Sheet (English version, revised on 25 July, 2008)
Document(s) reviewed	I. CV of Principal Investigator
Conditions	1. Do not deviate from, or make changes to the study protocol without prior written REC approval, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues. 2. Apply a clinical trial certificate from Department of Health if indicated. 3. Report the followings to KWC-CREC* : (i) study protocol or consent document changes, (ii) serious adverse event, (iii) study progress (iv) new information that may be relevant to a subject's willingness to continue participation in the study. 4. Report first study progress to KWC-CREC at **12-monthly intervals** until study closure. [*Forms are available from KWC-CREC intranet webpage]

Please quote the CREC Reference **(KW/EX/08-090)** in all your future correspondence with the KWC-CREC, including submission of progress reports and requesting for amendments to the research protocol.

If you have any inquiry, please feel free to contact Ms Catherine CHENG, Secretary of the KWC-CREC, at 2990 3749. Thank you for your attention.

Yours sincerely,

(Dr TSAO Yen-chow)
Chairperson
Clinical Research Ethics Committee
Kowloon West Cluster

c.c. COS(Oncology), PMH

醫院管理局
HOSPITAL AUTHORITY

群策群力爲病人・優質醫護滿杏林
Quality Patient - Centred Care Through Teamwork

Research Ethics Committee
(Kowloon Central / Kowloon East)

c/o Queen Elizabeth Hospital
30 Gascoigne Road Kowloon

Dr CHEUNG Suk Yee Polly

Principal Surgeon
Breast and Endocrine Surgery Centre
Hong Kong Breast Cancer Foundation
Room 903, Yip Fung Building,
2 – 18 D' Aguilar Street, Central, HK

10 March 2009

Ref: KC/KE-09-0013/ER-3

Dear Dr CHEUNG,

The REC(KC/KE) is authorized by the Cluster Chief Executives to review and monitor clinical research. It serves to ensure that research complies with the Declaration of Helsinki, ICH GCP Guidelines, local regulations and HA policy. It has the authority to approve, require modifications in (to secure approval), or disapprove research. This committee has power to terminate/suspend a research at any time if there is evidence to indicate that the above principles and requirements have been violated.

The Committee has reviewed and approved your research application on 10 March 2009 by an expedited process. The approval decision was based on the documents submitted. You are required to adhere to the attached conditions:

Title of Study	Breast Cancer Registry in Hong Kong
Principal Investigator	Dr CHEUNG Suk Yee Polly, Principal Surgeon, Breast and Endocrine Surgery Centre
Co-investigator	Dr Sharon CHAN, Associate Consultant, Dept of Surgery, UCH
Protocol title and version	Research Protocol [Dated 22 October 2008]
Informed Consent Form version	Informed Consent Form [Chinese version] [Revised version submitted 2 March 2009]
Certificate of indemnity/insurance	N/A
Other Documents	- Expedited Review Form Template for Multi-center Trial [REC SOP001F3b] - 香港乳癌資料庫 - 第 1 部分 [Revised version submitted 2 March 2009] - 香港乳癌資料庫 - 第 3 部分 [Revised version submitted 2 March 2009]

Other Documents (Cont'd)	- Hong Kong Breast Cancer Registry Data Sheet – Part 2 [Revised version submitted 2 March 2009] - BCR Study Log Sheet [Submitted 27 February 2009] - Stamp Chop Sample [Submitted 2 March 2009] - Corresponding emails 11 February and 2 March 2009
Study site approved	United Christian Hospital
Conditions	1. Do not deviate from, or make changes to the study protocol without prior written REC approval, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues. 2. Report the followings to REC(KC/KE): (i) study protocol or consent document change (use KCKE SOP001F7)* (ii) serious adverse event (use KCKE SOP001F8)* (iii) study progress (use KCKE SOP001F9)* (iv) new information that may be relevant to a subject's willingness to continue participation in the study. 3. Report the first study progress to REC by March 2010 and thereafter at 12 monthly intervals until study closure.

** Download forms from the KCC/KEC intra-net for use*

Encl. KCKE SOP001F7
KCKE SOP001F8
KCKE SOP001F9a
KCKE SOP001F9b

Dr Derrick AU
for Chairman of REC(KC/KE)

cc. Chief of Service, Dept of Surgery, UCH – w/o
Dr Sharon CHAN, Associate Consultant, Dept of Surgery, UCH – w/o
Human Resource Division, KEC – w/o

Protocol Amendment Application Form

(Download updated electronic form from the cluster intra-net for use)

Background information

Study title	

REC/IRB no.	
Protocol no.	
Principal investigator	

Study start date	
Anticipated end date	
Sponsor	

Proposed Amendments (Append new document with changes)

Current condition *(indicate source document & location)*	**Amendment**	**Proposed by**	**Reason for change**	**Will change increase risk to participants?**

Reported by

Name	Signature	Date

Serious Adverse Event (SAE) Report Form

(Download updated form from the cluster intra-net for use & submit supporting documents if applicable)

1. Basic Information

Study title	
REC/IRB no.	
Protocol no.	
Study start date	
Anticipated end date	
Number of subjects recruited	

2. Study Site(s) Involved

☐ Overseas site(s) (Submit report(s) from sponsor and omit section 1-5)

☐ Local site(s) Name of study site:

3. Subject Outcome at Time of Report

☐ Complete recovery ☐ Recovery with sequelae ☐ Events not yet resolved

☐ Unknown ☐ Death; cause:

4. Serious Adverse Events

Subject reference: Code Initials Age Sex

Relevant medical history & current treatments:

Nature of SAE: *(Describe temporal relationship with intervention & other concomitant therapies)*

SAE start date SAE stop date /not resolved*

Type of SAE ☐ Initial ☐ follow up

Frequency ☐ One episode ☐ Intermittent ☐ Continuous

Intensity ☐ Mild ☐ Moderate ☐ Severe ☐ Not applicable

Seriousness ☐ Life threatening ☐ Significant disability/incapacity

☐ Required hospitalisation ☐ Persistent disability/incapacity

☐ Prolonged hospitalisation ☐ Congenital anomaly/birth defect

☐ None of the above ☐ Other medically important condition

5. Suspected relationship to Study

☐ Definite ☐ Probable ☐ Possible ☐ Not related ☐ Not assessable

養和醫院
HONG KONG SANATORIUM & HOSPITAL
www.hksh.com
香港跑馬地山村道2號 2 Village Road, Happy Valley, Hong Kong Tel : (852) 2572 0211 Fax : (852) 2835 8008

Dr. Kwan Wing Hong
Associate Director of Comprehensive Clinical Oncology
Hong Kong Sanatorium & Hospital

29 November, 2012

Dear Dr. Kwan,

RE: Research Study Application

I am pleased to inform you that the Hospital Research Committee has given approval to the following research protocol amendment.

Hong Kong Breast Cancer Registry in Hong Kong

The following documents were reviewed and approved:

1. Cover letter from Amy Chan dated 24th September 2012
2. Research Study Application Form dated 19th October 2012
3. Research Protocol dated 19th April 2010
4. Ethics Approval (Ref. no.:KW/EX/08-090) dated 24th November 2008
5. Appendix 1 – Consent form
6. Appendix 2 – Questionnaire (Chinese and English, revised on 9 December 2011)
7. Appendix 3 – Questionnaire (Chinese and English, revised on 9 December 2011)
8. Appendix 4 – Hong Kong Breast Cancer Registry Datasheet (English, revised on 9 December 2011)
9. CV of Dr. Polly Cheung

Please forward to the Research Committee a copy of an interim report at 6 months, or a final report of the project whichever comes sooner.

If the study will be published, please also provide information on its publication.

Yours Sincerely,

Dr. Tsao Yen Chow
Chairman, Hospital Research Committee

香港中文大學醫學院
Faculty Of Medicine
The Chinese University Of Hong Kong

醫院管理局
新界東醫院聯網
Hospital Authority
New Territories East Cluster

Joint Chinese University of Hong Kong-New Territories East Cluster
Clinical Research Ethics Committee
香港中文大學-新界東醫院聯網 臨床研究倫理 聯席委員會

Flat 3C, Block B, Staff Quarters, Prince of Wales Hospital, Shatin, HK
Tel : (852) 2632 3935 / 2144 5926 Fax : (852) 2646 6653 Website : http://www.crec.cuhk.edu.hk

To: Dr. Joyce Joy See SUEN (Principal Investigator)
Dept. of Clinical Oncology
Prince of Wales Hospital

29 JUL '10

Ethics Approval of Research Protocol

CREC Ref. No.:	**CRE-2009.037**
Date of Renewal (Ethics Approval):	**14 June 2010***
Date of #Amendment(s) Approval:	**23 July 2010**
Study Title:	**Breast Cancer Registry in Hong Kong**
Investigator(s): #	**Joyce Joy See SUEN and Polly Suk Yee CHEUNG**

I write to inform you that ethics approval has been given for you to conduct the captioned study in accordance with the following document(s) submitted:

- Research Protocol (version: 22102008)
- Appendix 1 - Informed Consent Form, Chinese Version, revised on 04 March 2009
- Appendix 2 – Questionnaire, Chinese Version, revised on 25 July 2008
- Appendix 3 – Questionnaire, Chinese Version, revised on 25 July 2008
- Appendix 4 – Hong Kong Breast Cancer Registry Data Sheet, English Version, revised on 25 July 2008
  #**Amendment(s) dated 14 June 2010**
- Changed the Principal Investigator from Dr. Wing Hong KWAN to Dr. Joyce Joy See SUEN

This ethics approval* will be valid for 12 months. Application for further renewal can be made by submitting the Ethics Renewal and Research Progress Report Form to the CREC (Download the electronic form template from the http://www.crec.cuhk.edu.hk or http://ntec.home/Research%20Ethics/main.asp). You are kindly requested to report to the Committee upon completion of the project.

The Joint CUHK-NTEC Clinical Research Ethics Committee is organized and operates according to ICH-GCP and the applicable laws and regulations.

Miss Winkie Lui
CREC Officer
Joint CUHK-NTEC
Clinical Research Ethics Committee

Encl.
WL/ci

香港大學
University of Hong Kong

香港大學及醫管局港島西醫院聯網研究倫理委員會

醫院管理局
HOSPITAL AUTHORITY

Institutional Review Board of the University of Hong Kong/
Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB)

Address: Rm 901, Administration Block, QMH Tel 2855 3923 ~~2855~~ 4086 [2255] Fax 2855 4735

Dr. Janice Tsang
Clinical Oncology
Queen Mary Hospital

30-Sep-09

Dear Dr. Tsang,

IRB Reference Number: **UW 09-378**

The HKU/HA HKW IRB is authorized by a joint agreement of the University of Hong Kong and Hospital Authority Hong Kong West Cluster to review and monitor clinical research. It serves to ensure that research complies with the Declaration of Helsinki and acts in accordance to ICH GCP guidelines, local regulations and Hospital Authority and the University policies.

I write to inform that your research application/submission has been approved by an expedited process with details shown below. You are also requested to adhere to the conditions listed.

Protocol title	:	Breast Cancer Registry in Hong Kong
Study site(s)	:	Queen Mary Hospital
IRB reviewer	:	Dr. Godfrey Chan, Deputy Chairman of the HKU/HA HKW IRB
Document(s) approved	:	01. Clinical Research Ethics Review Application Form for Expedited Review for Multi-center Trial approved by another Cluster REC
	:	02. Kowloon West Cluster Clinical Research Ethics Committee Clinical Research Ethics Review Application Form
	:	03. Research Protocol (Date: 9 July 2009)
	:	04. Research Protocol (Date: 22 October 2008)
	:	05. BCR Consent form - English and Chinese
	:	06. 香港乳癌資料庫 – 第1部份 (Revised on 8 May 2009) - Chinese
	:	07. 香港乳癌資料庫 – 第3部份 (Revised on 20 Feb 2009) - Chinese
	:	08. Hong Kong Breast Cancer Registry Data Sheet - Part 2 (Revised 8 May 2009) - English
Document(s) reviewed	:	09. Approval letter from Clinical Research Ethics Committee, Kowloon West Cluster dated 24 November, 2008 (KWC-CREC Reference: KW/EX/08-090)
	:	10. Short CV of principal investigator (May, 2009)

(Conditions :
1. Do not deviate from, or make changes to the study protocol without prior written IRB approval, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues.
2. Report the following to HKU/HA HKW IRB: (i) study protocol or consent document change (use 'HKU/HA HKW IRB RE001F7'), (ii) serious adverse event (use 'HKU/HA HKW IRB RE001F8'). (iii) study progress (use 'HKU/HA HKW IRB RE001F9a') (iv) new information that may be relevant to a subject's willingness to continue participation in the study.
3. Report study progress to HKU/HA HKW IRB at a 12-monthly interval until study closure.)

Yours sincerely,

W. H. Lee
HKU/HA HKW IRB Secretary

新界西·醫院聯網
New Territories West Cluster
屯門醫院 TUEN MUN HOSPITAL
青山醫院 Castle Peak Hospital
Pok Oi Hospital
聯網辦事處 Cluster Office
屯門醫院 Tuen Mun Hospital
23 Tsing Chung Koon Road, Tuen Mun, New Territories, Hong Kong. Tel: (852) 2468 5111 Fax: (852) 2455 1911
新界屯門青松觀路23號 電話：(852) 2468 5111 傳真：(852) 2455 1911

NTW Cluster Clinical & Research Ethics Committee
新界西醫院聯網臨床及研究倫理委員會

Confidential

Our Ref.: (20) in NTWC/CREC/866/10

11 December 2013

Dr NG Ting-ying
Associate Consultant
Department of Clinical Oncology
Tuen Mun Hospital

Dear Dr NG

Application for Ethics Approval for
Protocol Amendment for Clinical Research Study

Study Title: Breast Cancer Registry in Hong Kong

Principal Investigator: Dr NG Ting-ying, AC (ONC), TMH

Study Site(s) Approved: Tuen Mun Hospital, Pok Oi Hosiptal

I am pleased to inform you that the following submissions for Protocol Amendment regarding the above study have been reviewed by an expedited process and ethics approval has been given by the NTW Cluster Clinical & Research Ethics Committee on 16 November 2013.

1.	Protocol Amendment Application Form dated 3 Sep 2013; - To include POH as an additional study site, - To include Dr YUEN Ho-yan of POH as an additional Co-investigator.
2.	CV of Dr YUEN Ho-yan.

Please note that you are required to adhere to the following conditions:

1. Do not deviate from, or make changes to the study protocol without prior written approval of the NTWC-C&REC, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues.

Secretary of NTW Cluster Clinical & Research Ethics Committee
5/F, Rehabilitation Block, Tuen Mun Hospital, Tuen Mun, N.T. Tel. No.: 3767 7144

聯網辦事處 Cluster Office
屯門醫院 Tuen Mun Hospital
23 Tsing Chung Koon Road, Tuen Mun, New Territories, Hong Kong. Tel: (852) 2468 5111 Fax: (852) 2455 1911
新界屯門青松觀路23號 電話：(852) 2468 5111 傳真：(852) 2455 1911

2. Report the followings to NTWC-C&REC: (i) study protocol or consent document change (use 'NTWC CREC001F7'), (ii) serious adverse event (use 'NTWC CREC001F8'), (iii) new information that may be relevant to a subject's willingness to continue participation in the research.

3. Report research progress [use "NTWC CREC001F9a"] to NTWC C&REC at 12-monthly intervals until study closure. Submit a final report [use "NTWC CREC001F9b"] to the NTWC C&REC upon research completion.

(Forms down-loadable from http://ntwc.home/ccrec/*)*

The NTW Cluster Clinical & Research Ethics Committee serves to ensure that research complies with the Declaration of Helsinki, ICH GCP Guidelines, local regulations and HA policies.

Yours sincerely

(Sonnia WONG)
Secretary
NTW Cluster
Clinical & Research Ethics Committee

Secretary of NTW Cluster Clinical & Research Ethics Committee
5/F, Rehabilitation Block, Tuen Mun Hospital, Tuen Mun, N.T. Tel. No.: 3767 7144

HONG KONG EAST CLUSTER
港 島 東 醫 院 聯 網

Ethics Committee, HKEC
3 Lok Man Road
Chai Wan
Hong Kong

Dr. YAU Tsz Kok
c/o Dept. of Clinical Oncology
PYNEH

23 August 2013

Ref: HKEC-2010-004

Dear Dr. YAU,

The Ethics Committee (EC) of HKEC is authorized by the Cluster Chief Executive to review and monitor clinical research. It serves to ensure that research complies with the Declaration of Helsinki, ICH GCP Guidelines, local regulations and HA policy. It has the authority to approve, require modifications in (to secure approval), or disapprove research. This Committee has power to terminate/suspend a research at any time if there is evidence to indicate that the above principles and requirements have been violated.

The Committee has reviewed your protocol amendment application on 23 August 2013 by an expedited process, and reached the following decision basing on the documents submitted.

The Committee approves your application and the following documents, and requires you to adhere to the attached conditions:

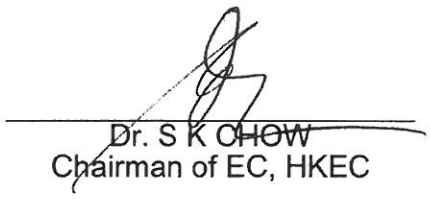
Title of Study	Breast Cancer Registry in Hong Kong
List of investigators	1. Dr. CHEUNG Foon Yiu, Consultant, Dept. of Clinical Oncology, PYNEH 2. Dr. Polly CHEUNG Suk Yee, Hong Kong Breast Cancer Foundation
Protocol title and version	N.A.
Consent Form versions	N.A.
Information sheet title and versions	N.A.
Certificate of indemnity/insurance	N.A.
Other Documents	1. Protocol Amendment Application Form dated 5 August 2013. 2. Curriculum Vitae of Dr. CHEUNG Foon Yiu.

3 Lok Man Road, Chai Wan, Hong Kong 香港柴灣樂民道三號 Tel 電話 : +852 2595 6111 Fax 傳真 : +852 2515 0794

Conditions	1. The Principal Investigator is responsible and accountable for the confidentiality of the personal data of the study subjects they hold. The Principal Investigator must also ensure that there is appropriate arrangement to protect the security of personal data when it is stored, sent or received. 2. Do not deviate from, or make changes to the study protocol without prior written EC approval, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues. 3. Report the following to EC/IRB: (i) study protocol or consent document change (use 'HKECRE001F7')*, (ii) serious adverse event (use 'HKECRE001F8')*, (iii) study progress (use 'HKECRE001F9')* (iv) new information that may be relevant to a subject's willingness to continue participation in the study. 4. Report first study progress to EC/IRB **as soon as possible** and thereafter at 12 monthly intervals until study closure. 5. Submit Research Final Report Form (use 'HKECRE001F9b')* to EC/IRB upon completion of study.

** Download forms from the HKEC intranet for use*

Yours sincerely,



Dr. S K CHOW
Chairman of EC, HKEC

cc. COS(ONC), PYNEH
Dr. F Y CHEUNG, Cons(ONC), PYNEH

新界西・醫院聯網
New Territories West Cluster

聯網辦事處 Cluster Office
屯門醫院 Tuen Mun Hospital
Tsing Chung Koon Road, Tuen Mun, New Territories, Hong Kong. Tel: (852) 2468 5111 Fax: (852) 2455 1911
新界屯門青松觀路 電話：(852) 2468 5111 傳真：(852) 2455 1911

NTW Cluster Clinical & Research Ethics Committee
新界西醫院聯網臨床及研究倫理委員會

Confidential

Our Ref.: (8) in NTWC/CREC/866/10

3 August 2010

Dr NG Ting-ying
Associate Consultant
Department of Clinical Oncology
Tuen Mun Hospital

Dear Dr NG

Application for Ethics Approval for
Clinical Research Study

Study Title: Breast Cancer Registry in Hong Kong

Principal Investigator: Dr NG Ting-ying, AC (ONC), TMH

Study Site(s) Approved: Tuen Mun Hospital

I am pleased to inform you that the following submissions regarding the above Study have been reviewed by an expedited process and ethics approval was given by the NTW Cluster Clinical & Research Ethics Committee on 26 July 2010:

1	Expedited Review Form for Multi-center Trial Approved by Another Cluster REC;
2	Copy of Approval Letter from KWC-CREC dated 24 November 2008;
3	Research Protocol dated 19 April 2010;
4	Appendix 1 - BCR Consent Form: 4.1 English Version; 4.2 Chinese Version;
5	Appendix 2 – 香港乳癌資料庫(Part 1), Chinese Version dated 8 May 2009;
6	Appendix 3 – 香港乳癌資料庫 (Part 3), Chinese Version dated 20 February 2009;
7	Appendix 4 – Hong Kong Breast Cancer Registry Data Sheet – Part 2, English Version dated 8 May 2009;

新界西・醫院聯網
New Territories West Cluster

聯網辦事處 Cluster Office
屯門醫院 Tuen Mun Hospital
Tsing Chung Koon Road, Tuen Mun, New Territories, Hong Kong. Tel: (852) 2468 5111 Fax: (852) 2455 1911
新界屯門青松觀路 電話：(852) 2468 5111 傳真：(852) 2455 1911

8	Investigator's Conflict of Interest Declaration Form: 8.1 Dr NG Ting-ying, Principal Investigator; 8.2 Dr CHEUNG Suk-yee Polly, Co-investigator;
9	CV of Investigators.

Please note that you are required to adhere to the following conditions:

1. Do not deviate from, or make changes to the study protocol without prior written approval of the NTWC-C&REC, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues.
2. Report the followings to NTWC-C&REC: (i) study protocol or consent document change (use 'NTWC CREC001F7'), (ii) serious adverse event (use 'NTWC CREC001F8'), (iii) new information that may be relevant to a subject's willingness to continue participation in the research.
3. Report research progress [use "NTWC CREC001F9a"] to NTWC C&REC at 12-monthly intervals until study closure. Submit a final report [use "NTWC CREC001F9b"] to the NTWC C&REC upon research completion.

(Forms down-loadable from http://ntwc.home/ccrec/*)*

The NTW Cluster Clinical & Research Ethics Committee serves to ensure that research complies with the Declaration of Helsinki, ICH GCP Guidelines, local regulations and HA policies.

Yours sincerely

(Karen LAM)
Secretary
NTW Cluster
Clinical & Research Ethics Committee

cc Dr TUNG Yuk, COS (ONC), TMH

22 February 2011

Dr. CHEUNG, Suk-yee, Polly
Principal Surgeon
Breast and Endocrine Surgery Centre

Dear Dr. CHEUNG,

KWC-CREC Reference: KW/EX/08-090(2)
Title: Breast Cancer Registry in Hong Kong (Protocol No. : 22102008)

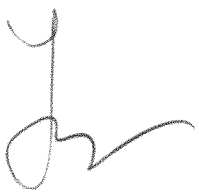
Thank you for submitting the protocol amendment application to the Research Ethics Committee of the Kowloon West Cluster (KWC-REC). I am pleased to inform you that the following amendment item and documents have been reviewed and approved by the KWC-REC through an expedited process on 14 Feb 2011.

No.	Document / Amendment Type
1	Protocol Amendment Application Form dated 15 December 2010
2	Declaration by Investigators and Endorsement by COS dated 21 December 2010
3	Investigator's Conflict of Interest Declaration Form dated 20 December 2010
4	CV of Co-investigator (Dr. Leung Siu Lan)
5	Research Protocol version 22102008 with amendment highlighted dated 22 October 2008

Please note that all conditions pertaining to the previous approval of your research study as stated in my letter of 24 November 2008 are still in force. If you have any enquiry, please feel free to contact Ms Catherine CHENG, Secretary of the KWC-REC, at 2990 3749.

Thank you for your attention.

Yours sincerely,



(Dr YU Wai-cho)
Chairperson
Research Ethics Committee
Kowloon West Cluster

Secretariat of Research Ethics Committee, Kowloon West Cluster
Room 136, 1/F, Block J, Princess Margaret Hospital, Lai Chi Kok, Kowloon, Hong Kong Tel (852) 2990 3749 Fax (852) 2990 1059

醫院管理局
HOSPITAL AUTHORITY

30 June, 2011

Dr. CHEUNG, Suk-yee, Polly
Principal Surgeon
Breast and Endocrine Surgery Centre

Dear Dr. CHEUNG,

KWC-REC Reference: KW/EX/08-090(3)
Title: Breast Cancer Registry in Hong Kong (Protocol No. : 22102008)

Thank you for submitting the protocol amendment application to the Research Ethics Committee of the Kowloon West Cluster (KWC-REC). I am pleased to inform you that the following amendment item and documents have been reviewed and approved by the KWC-REC through an expedited process on 27 June 2011.

No.	Document / Amendment Type
1	Protocol Amendment Application Form dated 11 April 2011 – (Co-Investigator: Dr. YING Wai Leung, Marcus added)
2	Declaration by Investigators and Endorsement by COS dated 3 June 2011
3	Investigator's Conflict of Interest Declaration Form dated 3 June 2011
4	CV of Co-investigator - Dr. YING Wai Leung, Marcus
5	Research Protocol version 22102008 dated 22 October 2008 (amendment highlighted in pink)

Please note that all conditions pertaining to the previous approval of your research study as stated in my letter of 24 November 2008 are still in force. If you have any enquiry, please feel free to contact Ms Catherine CHENG, Secretary of the KWC-REC, at 2990 3749.

Thank you for your attention.

Yours sincerely,

(Dr YU Wai-cho)
Chairperson
Research Ethics Committee
Kowloon West Cluster

Secretariat of Research Ethics Committee, Kowloon West Cluster
Room 133, Block J, Princess Margaret Hospital, Lai Chi Kok, Kowloon, Hong Kong Tel (852) 2990 3749 Fax (852) 2990 1059

HONG KONG EAST CLUSTER
港 島 東 醫 院 聯 網

Ethics Committee, HKEC
3 Lok Man Road
Chai Wan
Hong Kong

5 September 2011

Dr. Yvonne TSANG Yee Yan
Associate Consultant

Dept. of Surgery
PYNEH

Ref: HKEC-2011-061

Dear Dr. TSANG,

The Ethics Committee (EC) of HKEC is authorized by the Cluster Chief Executive to review and monitor clinical research. It serves to ensure that research complies with the Declaration of Helsinki, ICH GCP Guidelines, local regulations and HA policy. It has the authority to approve, require modifications in (to secure approval), or disapprove research. This Committee has power to terminate/suspend a research at any time if there is evidence to indicate that the above principles and requirements have been violated.

The Committee has reviewed your research application on 2 September 2011 by an expedited process, and reached the following decision basing on the documents submitted.

The Committee approves your application and the following documents, and requires you to adhere to the attached conditions:

Title of Study	Breast Cancer Registry in Hong Kong
List of investigators	1. Dr. Yvonne TSANG Yee Yan, AC(Surgery), PYNEH 2. Dr. Polly CHEUNG Suk Yee, HK Breast Cancer Foundation
Protocol title and version	Research Protocol (Version dated 19 April 2010)
Consent Form versions	Informed Consent Form, English & Chinese version (Appendix 1)
Information sheet title and versions	N.A.
Certificate of indemnity/insurance	N.A.

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Other Documents	1. 香港乳癌資料庫 – 第 1 部份, Revised 8 May 2009, Chinese version (Appendix 2). 2. 香港乳癌資料庫 – 第 3 部份, Revised 20 Feb 2009, Chinese version (Appendix 3). 3. Hong Kong Breast Cancer Registry Data Sheet – Part 2, Revised 8 May 2009, English version (Appendix 4). 4. Approval letter dated 24 Nov 2008 from CREC, KWC, to Dr. Polly CHEUNG, Breast and Endocrine Surgery Centre.
Conditions	1. The Principal Investigator is responsible and accountable for the confidentiality of the personal data of the study subjects they hold. The Principal Investigator must also ensure that there is appropriate arrangement to protect the security of personal data when it is stored, sent or received. 2. Apply a clinical trial certificate from department of health if applicable. 3. Do not deviate from, or make changes to the study protocol without prior written EC approval, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues. 4. Report the following to EC: (i) study protocol or consent document change (use 'HKECRE001F7')*, (ii) serious adverse event (use 'HKECRE001F8')*, (iii) study progress (use 'HKECRE001F9')* (iv) new information that may be relevant to a subject's willingness to continue participation in the study, (v) final report upon completion of study (use 'HKEC001F9b')*. 5. Report first study progress to EC by 4 September 2012 and thereafter at 12 monthly intervals until study closure. 6. Submit Research Final Report Form (use 'HKECRE001F9b')* to EC upon completion of study.

* *Download forms from the HKEC intranet for use*

Please report the progress of the study according to the time schedule stipulated in Clause 5 of Conditions shown above for the Cluster REC to consider whether the approval status can be maintained. Upon completion of the study, kindly furnish the EC with a final report using the form mentioned in Clause 6 of Conditions.

Yours sincerely,

Dr. Loletta SO
for Chairman of EC, HKEC

cc. COS(Surg), PYNEH