TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADMINISTRATIVE POLICY NO.: 490-33
DEPT. POLICY NO.: CR - 9

DATE: 8/30/86
REVIEWED: 04/27/94; 01/15/96; 6/15/97; 04/13/00; 03/11/01; 01/2/02; 01/13/03; 02/10/04; 10/22/09; 04/13
REVISED: 04/10/87; 12/98; 6/12/99; 02/10/04; 10/22/09; 04/10/11; 01/2014

I. SUBJECT:

ABSTRACTION OF TUMOR REGISTRY DATA Ref.: ACoS E-5;

II. POLICY:

1. Cancer cases are abstracted using the Kentucky Cancer Registry's Cancer Patient Data Management System's (CPDMS.net) established principles and data definition for abstracting.
2. Each year (calculated based upon a rolling 12-month calendar), 90% of all cases are abstracted within six (6) months of the date of first contact with the program, as required by the Kentucky Cancer Registry.

III. PURPOSE:

To outline steps to perform either paper or computerized abstracting.

IV. PROCEDURE:

1. Obtain a listing of medical record numbers for patients to be included in the Tumor Registry using the hospital database.

2. Retrieve the medical records from Healthcare Information Management permanent file area, or access to the electronic medical record. Terminal digit filing system is utilized.

3. Compare each record on the listing to assure that patient meets criteria for inclusion into the registry. One or more of the following items should be present.

   a. Patients with an active malignant neoplasm (cancer) either treated or untreated. Terms such as carcinoma, sarcoma, melanoma and hematopoietic disorders should be further identified by ICD-9-CM (International Classification of Diseases, Ninth Edition, Clinical Modification) codes;
   b. Clinically disease-free patients who are receiving prophylactic or adjuvant cancer directed therapy;

4. The most effective places in the medical record to identify positive reportable cancer diagnoses are: History and Physical Examination, Discharge Summary, Operative Report, Radiology Report, Pathology Report and Initial Nursing Assessment.

The following procedure is applicable for completion of computerized abstracting into CPDMS.net.

1. Enter cases into CPDMS.net (Cancer Patient Data Management System online program) using the definitions as defined in the Kentucky Cancer Registry CPDMS.net Abstractor's Manual.

2. Refer to the CPDMS.net Operator's Manual pp. 16-83.

REFERENCES REQUIRED FOR ABSTRACT COMPLETION:

ICD-O Third Edition;
Multiple Primary and Histologies Coding Manual
AJCC Manual for Staging of Cancer, Seventh Edition
Collaborative Staging Manual and Coding Instructions
CPDMS Abstractor's Manual
FORDS Manual

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY NO.: 490-25
DEPT. POLICY NO.: CR - 1

Date: 08/30/86
Reviewed: 04/27/94;01/15/96;06/15/97;04/13/00;03/11/01
10/20/09; 04/13
Revised: 04/10/87;12/98;06/12/99;02/10/04; 10/20/09; 04/12
08/15

I. SUBJECT:

AJCC (American Joint Committee on Cancer) TNM STAGING POLICY **Ref.: American College of Surgeons (ACoS), CoC Standard: Eligibility Requirement E5; CoC Standard 1.6**

II. POLICY:

The medical record for patients with newly diagnosed malignancy requires having documentation of clinical or working AJCC TNM information by the managing physician by utilizing the AJCC Staging Form or documentation by managing physician in the patient's medical record. A minimum of 90% of all TNM Staging Forms must be staged by the managing physician.

III. PURPOSE:

The Cancer Committee is responsible to approve the process to monitor physician(s) use of clinical and/or working AJCC or other appropriate staging information in treatment planning of all analytical cases for the purposes of:

1. Documentation of site specific prognostic indicator(s).
2. Consistent documentation of cancer staging utilizing evidence based on national treatment guidelines.
3. Review of complete physician stage recommended, but not required.
4. Presence of pathologic stage effective with January 1, 2015 cases.

IV. DEFINITIONS:

1. AJCC TNM Staging Form: American Joint Committee on Cancer, Tumor, Node, Metastasis Staging Form. The AJCC TNM Staging form is the nationally recognized standard for documenting how much cancer there is in the body and where it is located. The AJCC Staging Form provides a common language with which doctors can communicate about a patient's case.
2. Managing Physician: may be considered any of the following: the surgeon, medical oncologist, radiation oncologist, pathologist, radiologist or the patient's attending physician. Residents, medical students, physician assistants, cancer registrars, or other non-physicians do not meet Commission on Cancer requirements.
3. Accuracy Rate: Physician staging must be present in at least 90% of eligible cases. Presence of the AJCC Staging Form is encouraged, but not required if the correct TNM Staging is completed and documented by the managing physician in the patient's medical record.

4. Clinical Stage: Is based on evidence acquired before primary treatment. Clinical assessment uses information available prior to first treatment, including but not limited to physical examination, imaging, endoscopy, biopsy and surgical exploration. Clinical state is assigned prior to any cancer-directed treatment and is not changed on the basis of subsequent information. Clinical stage ends if a decision is made not to treat the patient. The clinical stage is essential to selecting and evaluating primary therapy.

V. PROCEDURE:

1. Appropriate AJCC Staging Form will be identified by the Pathologist or Cancer Registrar.

2. The Cancer Registrar assures all necessary data is present on the patient's medical record.

3. The Cancer Registrar will flag the AJCC TNM Staging Form with the managing physician's appropriate chart flag color, per HCIS Policy/Procedure #4.

4. The medical record will not be considered complete until the AJCC TNM Staging Form is completed and signed on applicable records.

5. Records will be reviewed by the Cancer Registrar for completeness.
   A. Incomplete forms will be returned to the physician.
   B. Staging issues, specifically lack of completeness and/or accuracy will be addressed by the Cancer Committee.

6. If the managing physician records the staging elements of T, N, and M on the staging form, but has not recorded a stage group, the Cancer Registrar may assign a stage group based on the staging elements and record this information in the Cancer Registry database.

7. AJCC Staging will be reviewed by the physician members of the Cancer Committee as a function of quality monitoring for continual improvement.

8. If/when a staging discrepancy is identified, either through the quality monitoring process or by the Cancer Registrar, the following steps shall be taken to resolve the discrepancy:

   a. The Cancer Registrar will either refer the record for QA physician to review, or return the staging form to the managing physician for clarification and/or correction. The Cancer Registry staff may provide the supporting information to the managing physician/QA physician.

9. Presence of staging information is encouraged, but not required when patients have been diagnosed at TRH and choose to go to another facility for treatment.

10. Clinical and/or working staging of patients diagnosed with cancer is required to be present for patients diagnosed and treated at TRH.

11. Physician members of the Cancer Committee (and other medical staff physicians who manage care of cancer patients) will retrospectively review a minimum of 10% of analytical cases annually at Taylor Regional Hospital. The attached QA form shall be completed and maintained in the Cancer Registry. See Attachment A.

12. AJCC Quality Assurance results will be reported to the Cancer Committee.

13. The final AJCC staging form will be scanned into the patient's permanent medical record behind the Pathology Report, in "Other Reports" section.

Administrative Policy/Procedure: 490-25
Cancer Registry P/P: CR-01

TAYLOR REGIONAL HOSPITAL

ACOS COC

Medical Record Chart Audit-Collaborative Stage QC

Chart	Accession#	Dx Site	Date 1st Contact	Date Abstracted	6 Mths Y or N	COC & Histology Y or N	AJCC TNM Y or N	CAP Compliance Y or N	CS Stage	Staging Info	Stages Match Y or N	Follow-up Correct Y or N	1st Course Rx

Standard 5.2 Abstracting Timeliness

#of charts reviewed: ______ #of charts abstracted within 6 months: ______ Compliance %: ______

Standard 2.1 CAP compliance

#CAP eligible charts reviewed: ______ # of charts CAP compliant: ______ Compliance %: ______

Standard 1.6 Quality Control of Registry Abstracted Data

Compliance Rate ______/______

(Number of cases with correct abstracted data/number of cases reviewed)

Review date: Physician Reviewer:

ADM. POLICY NO.: 490-35
CR POLICY NO.: 12

DATE: 8/30/86
REVIEWED: 4/27/94;1/15/96;6/15/97;4/13/00;3/11/01;
1/2/02;01/13/03;2/10/04; 04/06/ 04/09;
REVISED: 4/10/87;12/98;6/12/99;2/10/04; 04/12; 04/14

I. Subject:

CANCER COMMITTEE MEETING Reference: ACoS (American College of Surgeons) CoC (Commission on Cancer) Standard 1.4

II. Policy:

The Cancer Committee of Taylor Regional Hospital meets once each calendar quarter per Taylor Regional Hospital Medical Staff Bylaws. See Medical Staff Bylaws Article IX, Section 12 and Commission on Cancer Program Standards 2012.

III. Purpose:

To outline preparation and meeting procedures for the Cancer Committee.

IV. Procedure:

1. No less than one week in advance of the scheduled meeting, the Tumor Registrar will prepare a memorandum announcing the Cancer Committee meeting. This notation may be added to the monthly Tumor Conference notice. **(SEE ATTACHMENT A. Note: This Attachment will change annually as membership dictates)**

2. Each required member shall attend at least 50% of the Cancer Committee meetings held during any given calendar year. Substitute or delegate member attendance does not count toward the attendance target, per ACoS CoC standards.

3. The membership of the Cancer Committee is multidisciplinary, representing physicians from the diagnostic and treatment specialities and non-physicians from administrative and supportive services. The Cancer Committee Chair and the Cancer Liaison Physician may also fulfill the role of one (1) of the required physician specialities. Below is a listing of the required physician specialities as it applies to Taylor Regional Hospital:
    - Cancer Liaision Physician;
    - Pathologist;
    - Diagnostic Radiologist;
    - Surgeon (involved in general surgery and/or surgical specialist involved in cancer care);
    - Medical Oncologist;
    - Radiation Oncologist.

4. Listed below are the required non-physician members of the cancer committee:
    - Cancer Program Administrator (responsible for the administrative oversight or has budget authority for the cancer program);
    - Oncology Nurse;
    - Social Worker or Care Manager;
    - Certified Tumor Registrar;
    - Quality Improvement representative;
    - Staff responsible for Community Outreach functions within the hospital;

5. Listed below are additional members of the Cancer Committee:
    - Specialty physician(s) representing the major cancer experience at our facility;
    - American Cancer Society representative;
    - Registered Dietitian;
    - Rehabilitation representative;
    - Pharmacy representative.

6. Individual members of the Cancer Committee are appointed to coordinate important aspects of the Cancer Program. An individual cannot fulfill more than one (1) role. The Coordinators, appointed annually, are as follows:
    - Cancer Conference Coordinator;
    - Quality Improvement Coordinator;
    - Cancer Registry Quality Coordinator;
    - Community Outreach Coordinator;
    - Clinical Research Coordinator;
    - Psychosocial Services Coordinator.

7. Each year the Cancer Committee Chair is responsible for guiding the committee through the development and evaluation of annual goals. The Cancer Committee is to establish realistic goals appropriate to Taylor Regional Hospital's Cancer Program. At least one (1) clinical and one (1) programmatic goal are established each year and are evaluated at least twice per year. Examples of the topics addressed in the two (2) types of goals include, but are not limited to the following:
    - **Clinical:** Involving the diagnosis, treatment and care of TRH's cancer patients;
    - **Programmatic:** Directed towards the scope, coordination and processes of care for TRH's cancer patients.

8. The Cancer Committee shall establish the time frame for achieving each goal. Evaluation the goals are documented in the Cancer Committee minutes.

9. Copies of the notice shall be distributed to all Cancer Committee member via their hospital mailboxes and/or e-mail.

10. Prepare "Agenda" for Cancer Committee meeting. **(SEE ATTACHMENT B)** This is saved in Microsoft Word under the filename "ccagenda," followed by the appropriate month and year on the Tumor Registrar's computer. This notice must:

    A. Invite Cancer Committee members to submit items to the Tumor Registar;
    B. Include tumor Registrar's Report on all Agendas;
    C. Include Quality Control of Cancer Registry Data Coordinator's report on all Agendas;
    D. Include Quality Improvement Coordinator's report on all Agendas, but at least semi-annually;
    E. Include Community Outreach Coordinator's report when applicable, but at least annually;
    F. Include Clinical Research Coordinator's report, when applicable, but at least annually and,
    G. Include Psychosocial Services Coordinator's report, when applicable, but at least annually.

11. At least three (3) days prior to the scheduled Cancer Committee meeting send a copy of prepared Agenda, minutes from the previous meeting and handouts to all Cancer Committee members.

12. The Tumor Registrar shall serve as Coordinator for the Cancer Committee meeting and shall be responsible for taking minutes at each meeting.

13. File minutes on Tumor Registrar's computer under: "ccminutes" followed by the appropriate date, month and year.

14. Submit minutes to Cancer Committee Chairman for review.

15. Original minutes are maintained in Administration with a signed copy to be maintained in the Cancer Registry.

2014 Cancer Committee/Designated Alternate List

ADM. POLICY NO.: 490-35
CR POLICY NO.: 12
ATTACHMENT A

Required Physician Members	**Designated Alternate**
Robert Romines, M. D., Chairman (Surgeon)	**James Watkins, M. D.** (Surgeon)
Eugene Shively, M. D., Liaision (Surgeon)	
Zewdu Lissanu, M. D., Medical Oncologist	
James Dunnington, M. D. Pathologist	**Kathy Bruner, M. D.** Pathologist
Peter Hardin, M. D. Radiation Oncologist	**Linda Hathaway, M. D.** Radiation Oncologist
Cynthia Hart, M. D. Diagnostic Radiologist	**Richard Black, D. O.** Diagnostic Radiologist
Other Required Members	**Designated Alternate**
Lisa Dunnington, RHIT, Administrator, Cancer Quality Improvement Coordinator	
Jo Ann Smith, RHIT, CTR Cancer Conference Coordinator	
Sam Underwood, CTR, Cancer Registry Quality Coordinator	
Sherri Angel, RN, OCN, Medical Oncology Nurse, Clinical Research Coordinator	**Mary Tena Smith, RN, OCN** Medical Oncology Nurse
Sheila Thomas, MSW, Social Worker/Care Manager, Psychosocial Services Coordinator	**Lisa Haliday, RN,** Care Manager
Nichole Gwilliam, RN, Quality Management Director/Community Outreach Coordinator	**Gayle Bright, RN,** Educational Coordinator
Recommended Members	**Designated Alternate**
Lora Sztendera, M. D., Family Practice	**Jerome Dixon, D. O.,** Family Practice
Carrie Phillips, RD, Registered Dietitian	
Eric Sprowles, Pharm D., Pharmacy Director	**John Wilcher, Pharm D.** Pharmacist
Tomi Jo Moore, PT, Rehabilitation Director	**Nick Bobrowski, PT,** Rehabilitation Rep.
Additional Members	**Designated Alternate**
Sherri Howard, RT(R)M, Mammography Team Leader	**Debbie Carrico, RT,** Radiology Director
Cindy Rose, Public Relations/Hospitality Services	**Les Chadwick,** Grant Writer/Fundraiser
Susan Kelly, Medical Group Office Coordinator	**Abbey Fryrear,** Medical Group Office Coordinator
Ex-Officio Members	
Cathy Settle, Clinical Services Administrator	
Dana Garrett, RN, BSN Nursing Services Administrator	
Jane Wheatlely, FACHE, CEO	
Jim Murphy, Pastoral Representative	

2015 Cancer Committee/Designated Alternate List

ADM. POLICY NO.: 490-35
CR POLICY NO.: 12
ATTACHMENT A

Required Physician Members	**Designated Alternate**
Robert Romines, M. D., Chairman (Surgeon)	**James Watkins, M. D.** (Surgeon)
Eugene Shively, M. D., Liaision (Surgeon)	
Zewdu Lissanu, M. D., Medical Oncologist	
James Dunnington, M. D. Pathologist	**Kathy Bruner, M. D.** Pathologist
Peter Hardin, M. D. Radiation Oncologist	**Linda Hathaway, M. D.** Radiation Oncologist
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Sam Underwood, CTR, Cancer Registry Quality Coordinator	
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Sheila Thomas, MSW, Social Worker/Care Manager, Psychosocial Services Coordinator	**Lisa Haliday, RN,** Care Manager
Nichole Gwilliam, RN, Quality Management Director/Community Outreach Coordinator	**Gayle Bright, RN,** Educational Coordinator
Recommended Members	**Designated Alternate**
Lora Sztendera, M. D., Family Practice	**Jerome Dixon, D. O.,** Family Practice
Carrie Phillips, RD, Registered Dietitian	
Eric Sprowles, Pharm D., Pharmacy Director	**John Wilcher, Pharm D.** Pharmacist
Tomi Jo Moore, PT, Rehabilitation Director	**Nick Bobrowski, PT,** Rehabilitation Rep.
Additional Members	**Designated Alternate**
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Cindy Rose, Public Relations/Hospitality Services	
Susan Kelly, Medical Group Office Coordinator	**Abbey Fryrear,** Medical Group Office Coordinator
Ex-Officio Members	
Cathy Settle, Clinical Services Administrator	
Dana Garrett, RN, BSN Nursing Services Administrator	
Jane Wheatlely, FACHE, CEO	
Jim Murphy, Pastoral Representative	

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY NO.: 490-30
CR POLICY NO.: 06

DATE: 8/30/86
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1/2/02;01/13/03;2/10/04; 04/15
REVISED: 4/10/87;12/98;6/12/99;2/10/04; 12/8/09; 04/2012;

I. Subject

CANCER PROGRAM REPORTS

II. Policy

The Taylor Regional Hospital Cancer Program will generate reports required by the American College of Surgeons (ACoS), Kentucky Cancer Registry (KCR) and Taylor Regional Hospital internal reporting structure.

III. Purpose

To outline the policy and procedure for reporting to the Cancer Committee.

IV. Procedure

1. Taylor Regional Hospital shall submit data to the NCDB (National Cancer Data Base) as requested.
2. Procedures denoted in the NCDB Call for Data correspondence shall be followed and shall be submitted prior to the deadline imposed by the NCDB.
3. All required data included in any NCDB request is submitted to the NCDB electronically via a secure internet connection.
4. All reportable cancer cases shall be abstracted and reported to the Kentucky Cancer Registry.
5. Abstraction is performed by CTR(s) employed or contracted by Taylor Regional Hospital.
6. Please refer to pp. #114-171 of the CPDMS Operator's Manual for detailed instructions to run each report that can be generated by CPDMS (Cancer Patient Data Management System).
7. These reports shall include (at a minimum): Case Abstracting Timeliness, ~~PCE~~ Quality data collection status (if applicable) and follow-up rates.
8. Reporting to NCDB and the KCR reports shall be reported to the Cancer Committee at each meeting following submission of data.
9. Any other activities and progress of the Tumor Registry and/or Registrar shall be reported to the Cancer Committee.
10. At any time reports are requested by Hospital Administration, the Quality Assurance Committee, or any other entity entitled to review information, the data will be generated by the Tumor Registrar and forwarded via the Director of Care Management.

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY NO.: 490-28
CR POLICY NO.: 04

DATE: 8/30/86
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1/2/02;01/13/03;2/10/04; 04/06/ 04/09; 4/12; 02/2015
REVISED: 4/10/87;12/98;6/12/99;2/10/04; 04/11;

I. Subject:

CANCER REGISTRY FOLLOW-UP

II. Policy:

Annual follow-up is conducted throughout the lifetime of registry patients. Follow-up information is reported to the Kentucky Cancer Registry within 15 months from the last date of contact known Taylor Regional Hospital. Follow-up letters are sent to patients for documented contact after all other attempts for follow-up have been unsuccessful.

III. Purpose:

To outline the process for following up on Cancer Registry patients.

IV. Procedure:

1. Produce a listing from the Kentucky Cancer Registry's (KCR) CPDMS (Cancer Patient Data Management System) for 12 months prior to that day's date.

2. Compare follow-up listing to TRH's Meditech computer database for any contact dates more recent than the date recorded.

3. If there is documentation of a more recent contact date in the hospital database, go refer to the patient's abstract in CPDMS.net and update the abstract to reflect more current contact date.

4. The internet site, www.ancestory.com provides a database which can be searched for deceased patients who may be lost to follow-up. This should be queried.

5. If there is no information regarding the patient on the follow-up listing, generate a follow-up letter (SEE ATTACHMENT A). Forward the follow-up correspondence to the patient's attending physician.

6. If other physicians or facilities are known to be involved in the patient's care, generate follow-up correspondence (SEE ATTACHMENT A). Forward the follow-up correspondence with a stamped Business Reply envelope.

7. If none of the above is successful, forward a follow-up letter to the patient (SEE ATTACHMENT B). Enclose a Business Reply envelope.

8. Should there be no success in locating a patient to provide documentation for follow-up in CPDMS.net, attempt to locate the patient via telephone. Utilize the telephone number listed for patient and/or Emergency Contact on the patient's most recent documented encounter at Taylor Regional Hospital. This should occur only as a last resort to complete follow-up documentation.

9. During the telephone conversation with the patient/emergency contact, utilize the following guidelines:

10.

   A. Never contact the patient without the express permission of the patient's attending physician/practitioner.

   B. Always clearly identify yourself (who you are and what you do) and explain that you have spoken with the patient's physician/practitioner regarding this contact.

   C. Never mention cancer during the course of the conversation.

Taylor Regional Hospital
*1700 Old Lebanon Road * Campbellsville, KY 42718*
(270) 789-5853

Dear Dr.

Follow-up of cancer cases added to the Taylor Regional Hospital database is conducted by the Cancer Registry. This is an important part of our cancer program to assure that we operate under the guidelines of the American College of Surgeons Commission on Cancer. We ask that you complete this form with the most recent information you have regarding the patient named below. Thank you very much for your assistance.

Jo Ann Smith, CTR, RHIT
Cancer Registry

Patient Name: ______________________________

Date of Last Contact: Month ______ **Day** ______ **Year** ______

Is the patient disease free: __________ **Yes** __________ **No**

If not: ________ **Local recurrence** **Additional Treatment:**

________ **Residual disease** **Date:** ____________

________ **Metastatic disease** **Type:** ____________

________ **Remission**

________ **Unknown**

Death Information:

Date of death: ______________________________

Place of death: ______________________________

Cause of death: ______________________________

Comments and/or other resources for follow-up:

Taylor Regional Hospital
*1700 Old Lebanon Road * Campbellsville, KY 42718*
(270) 789-5853

Date:

Dear ______________________________

Because our hospital is interested in your health and well being as a former patient, we are collecting information about the status of your health since your last visit with us. We encourage and remind you to continue with regular medical check-ups as often as prescribed by your physician.

In addition to following your progress, Taylor Regional Hospital collects annual follow-up data and information for any special studies we may perform from time to time. This information we collect helps us to evaluate the quality of care given to all our patients.

Please aid us in our efforts to collect this information and help others by kindly sending us the information requested below. You may be reassured ~~that~~ we will maintain the highest level of confidentiality of your medical history and follow-up information.

A postage paid envelope is enclosed for your convenience. We look forward to hearing from you very soon. Thank you for your cooperation and assistance.

Sincerely,

Jo Ann Smith, CTR, RHIT, Tumor Registry

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY NO.: 490-28
CR POLICY NO.: 04
ATTACHMENT B

DATE: ______________________________

NAME: ______________________________

ADDRESS: ______________________________

WHAT IS YOUR PRESENT HEALTH STATUS? ______________________________

____

____.

PLEASE CIRCLEL THE MOST APPROPRIATE RESPONSE:

A. NORMAL ACTIVITY

B. UNABLE TO WORK

C. SEVERELY DISABLED

YOUR PRESENT DOCTOR'S NAME AND ADDRESS: (Please list any physician/practitioner who is currently caring for you)

____

____

____

If your name or address is not correct as listed above, please make corrections here:

____

____

Who, other than your spouse, will always know your address?

Name: ______________________________ **Relationship:** ____________________

Address: ____

Telephone Number: ____

WE SINCERELY THANK YOU FOR TAKING THE TIME TO PROVIDE US WITH THIS VALUABLE INFORMATION

TAYLOR REGIONAL HOSPITAL
ADM. POLICY NO.: 490-23
DEPT. POLICY NO.: CR - 10

DATE: 08/30/86
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01/2/02;01/13/03;02/10/04;10/20/09;
REVISED: 04/10/87;12/98;6/12/99;02/10/04;10/20/09; 04/04/12; 07/2013;
08/2015; 02/2016

SUBJECT:

CANCER REGISTRY QUALITY CONTROL PLAN Ref.: Eligibility Requirements ER5; CoC Standards 1.2, 1.6, 2.1 and 5.1

I. **Policy:** 1. The Cancer Committee establishes and implements a plan to evaluate the quality of Cancer registry data and activity. The plan includes procedures to monitor and evaluate each component. (Ref.: CoC Standard 1.6).

2. College of American Pathologist (CAP) protocols are followed to report the required data element elements on 90% of the eligible cancer pathology reports each year. (Ref.: CoC Standard 2.1).

3. Case abstracting is performed by a Certified Tumor Registrar (CTR). - There is a plan for CTR supervision of non-credentialed staff that performs case Abstracting in the Cancer Registry (Ref.: CoC Standard 5.1.)

II. **Purpose:** To ensure that high quality cancer registry data is accurately assessed. The Cancer Committee establishes and implements this plan to monitor multiple areas of the cancer registry and cancer program activity as well as the accuracy and completeness of abstracted and cancer program data.

The Taylor Regional Hospital Cancer Committee is responsible for registry supervision and quality control of registry data to ensure compliance with American College of Surgeons (ACoS), Commission on Cancer (CoC) Standards 1.6, 2.1 & 5.1:

AJCC TNM Staging accuracy rate should be at least 90%.

III. **Responsibilities:**

The **Cancer Registry Quality Coordinator**:

A. Is a member of the Cancer Committee.

B. The Quality Control of Cancer Registry Data Coordinator, or a representative of the coordinator, conducts the quality control activities and report the outcomes at least annually, or as denoted in this policy during Cancer Committee meetings.

C. Recommends corrective action if any area falls below the annual goals set by the Cancer Committee, the Commission on Cancer of the American College of Surgeons or the measures specified in the plan. (Ref.: CoC Standard 1.6).

D. Assures that results and recommendations are documented in the Cancer Committee minutes or other sources. (Ref.: CoC Standard 1.6).

E. Coordinates and assures that all non-CTR abstracting and collaborative staging is reviewed by a CTR. (Ref.: CoC Standard 5.1.

The **Cancer Committee** will be responsible for:

A. Designating a Cancer Registry Quality Coordinator is designated annually. (Ref.: CoC Standard 1.2).

B. Establishing and evaluating the plan for the required areas of the cancer registry activity (Ref.: CoC Standard 1.6).

C. Annually, assess if the plan was completed, and implement any corrective actions that do not meet the standards of the Commission on Cancer of the American College of Surgeons.

D. Documents the plan and evaluation activity in the Cancer Committee minutes. (Ref.: CoC Standard 1.6).

E. Physician(s) will be responsible for completing the quality review of cancer registry abstracting and AJCC TNM Staging. (Ref.: CoC Standard 1.6).

F. CTR (Certified Tumor Registrar) will review quality review of information coded as unknown (usually coded as 9 or a string of 9's). (Ref.: CoC Standard 1.6).

G. CTR (Certified Tumor Registrar) will perform quality review of cancer registry case finding. (Ref.: CoC Standard 1.6).

H. Physician(s) will conduct quality control of compliance with pathology CAP (College of American Pathologists) protocol reporting. (Ref. CoC Standard 2.1).

IV. PROCEDURE FOR REGISTRY QUALITY CONTROL ACTIVITY:

1. Coordinator or designee will report to the Cancer Committee at least annually:
   A. Outcome of quality review activity;
   B. NCDB (National Cancer Data Base) Call for Data:
      a) Data submission;
      b) Correction of data errors;
      c) Resubmission of corrected data;
      d) Data submitted meet the established quality criteria included in the NCDB Call for Data.

2. Coordinator or designee will assure the following quality audits are completed Quarterly/Annually:
   A. Quality review of Cancer Registry abstracting and AJCC TNM Staging: Annually; (Ref.: CoC Standard 1.6);
   B. Quality review of Cancer Registry information coded as unknown: Annually (Ref.: CoC Standard 1.6);
   C. Any non-CTR (Certified Tumor Registrar) review of abstracting accuracy and AJCC TNM Staging: At least annually. (Ref.: CoC Standard 5.1);
      a) Audit performed by contracted or employed CTR. Kentucky Cancer Registry's quality review of selected cases during monthly visits will be accepted. (Ref.: CoC Standard 5.1)
   D. Quality review of the Cancer Registry case finding: Annually. (Ref.: CoC Standard 1.6). External sources may be used to fulfill this case finding. These external sources may include state or central registry case finding audits, to be reported to the Cancer Committee following completion of any audit.
   E. Quality Review of Pathology Report CAP (College of American Pathologists) Protocol Audit: Annually (Ref.: CoC Standard 2.1).
   F. Quality review of Cancer Registry cases for abstracting timeliness: Annually. (Ref.: CoC Standard 1.6)

3. Coordinator will recommend corrective action if any area(s) fall below the annual goals set by the Cancer Committee or the Commission on Cancer (CoC) of the American College of Surgeons (ACoS).

4. Coordinator will submit a summary to the Cancer Committee of review for all quality activity.

5. Coordinator will maintain all documentation from quality review activity and provide documentation during CoC (Commission on Cancer) survey, if requested.

V. Procedure for Physician Quality Review of Cancer Registry Abstracting and AJCC TNM Staging (Ref.: CoC Standard 1.6)

1. The Cancer Registry staff is responsible for organizing this review.

2. Within each current abstracting year, a random review of a minimum 10% of the CURRENT analytic cases accessioned the previous year.

3. To arrive at a total number of cases in the sample review, multiply the total number of analytic cases accessioned during the previous year by 10%.

4. This random of Abstracting and AJCC TNM Staging must be accomplished by the end of the calendar year. Only currently abstracting analytic cases diagnosed and/or treated at TRH will be eligible for review by the physician.

5. Currently abstracted medical records will be made available to the reviewing physician. Pathology and other reports may be viewed in the Electronic Medical Record (EMR). The corresponding abstract will be printed.

6. The Coordinator will access the patient's record electronically and the following areas will be highlighted on the Abstract:
   A. Class of Case
   B. Primary Site
   C. Histology
   D. AJCC (American Joint Commission on Cancer) TNM Stage, both clinical and pathologic stage, or other appropriate staging system
   E. First Course of Treatment
   F. Follow-up Information, to include:
      a) Date of first recurrence
      b) Type of first recurrence
      c) Cancer status
   G. Abstracting timeliness

7. After completing the review, compile the highlighted areas. Document the date of the audit and name of physician completing the audit. **(See Attachment A).**

8. A quality review summary will be completed and presented to the next Cancer Committee meeting. The summary is to address all performance rates that fall below the established recommended rates.

VI. PROCEDURE FOR PHYSICIAN QUALITY REVIEW OF INFORMATION CODED AS UNKNOWN (Ref.: CoC Standard 1.6):

1. The Cancer Registry staff will be responsible for organizing this review.

2. Annually, prior to this review, the Cancer Registry staff shall perform a review of specific areas of the "NCDB Data Completeness and Default Overuse Report" for a high percentage of unknown coding.

3. The outcome of the quality review shall be presented to the Cancer Committee annually, by the end of each given calendar year.

4. The Cancer Committee will take action to correct the abstracting quality.

5. In Datalink's go to "NCDB Data Submission Report" for ___(the year being reviewed).

6. The following are to be accessed and reviewed:

A. Select "Taylor Regional Hospital, Campbellsville KY"
B. Select "All items"
C. Copy and paste the report into a Word document for review and printing. The review process will be performed as follows:
  a) Select the item(s) with the highest percentage of "unknown" coding and review/correct all cases.
  b) Enter/re-enter these items into the Cancer Registry database.
  c) If it is not possible to reconcile the highest percentage of "unknowns", move to the second highest percentage of "unknown" coding and follow the same procedure for entering/re-entering correction into the Cancer Registry database.

7. Quality review summary should be presented during the next Cancer Committee meeting following completion of the review. All performance rates that fall below the established recommended rates shall be addressed and an action plan for correction shall be agreed upon by the Cancer Committee.

VII. PROCEDURE FOR QUALITY REVIEW OF NON-CERTIFIED CANCER REGISTRAR (CTR) ABSTRACTING AND AJCC TNM STAGING (Ref.: CoC Standard 5.1):

1. The Cancer Registry staff will perform a quality review of non-CTR Abstracting and Collaborative staging.

2. Any non-CTR Abstracting and AJCC TNM Staging should document at least overall 90% accuracy of abstracting.

3. If the non-CTR accuracy of abstracting and/or AJCC TNM Staging falls below 90%, the Cancer Committee will put in place an Action Plan.

4. If review is not completed on-site, the CTR will access currently abstracted charts on Meditech and perform a review of the following:
   A. Class of Case
   B. Primary Site
   C. Histology
   D. AJCC (American Joint Committee on Cancer) TNM Stage, both clinical and pathologic stage, or other appropriate staging system
   E. First course of treatment
   F. Follow-up information, including:
      a) Date of first recurrence;
      b) Type of first recurrence;
      c) Cancer status;
   G. Abstract timeliness.

5. A summary of the results of the quality review of any non-CTR Abstraction/AJCC TNM Staging will be presented at least annually.
   A. If abstract corrective action is required, the Cancer Registry database will be updated with the correct coding.

6. Upon review/evaluation of the audits, if there is a need to address performance rates that fall below established rates, the Cancer Committee will make suggestions and recommendations as to who is to address these.
   A. If abstract corrective action is required, the Cancer Registry database will be updated with the correct coding.

VIII. PROCEDURE FOR PHYSICIAN QUALITY REVIEW OF CANCER REGISTRY CASEFINDING (Ref.: CoC Standard 1.6)

1. Case Finding is a daily function performed in the Cancer Registry. The daily process for Case Finding is addressed in Administrative Policy/Procedure #490-32; CR-08.

2. The scope of the case finding audit shall be:
   A. A random review of patients within at least a three (3) month sample size from case finding sources that ensures a minimum of 10% of the CURRENT analytic cases accessioned.

3. **ALL** patients, including the case finding sources are eligible for review in the case finding audit. This quality review includes analytic and non-analytic cases, if applicable.

4. After selecting the patient name, medical record ID number from the case finding sources, compare the patient names with the cancer registry patient master list.

5. If a patient is not identified on the master patient list, check the patient name on the listing of patients not included or not reportable to the Cancer Registry.

6. If the case was identified on the Cancer Registry Master Patient Listing or identified on the "Not Reportable" list, this case has passed the case finding quality review. If a patient was NOT identified on the Cancer Registry Master Patient list or the not reportable list, this case did not pass the case finding audit. **SEE ATTACHMENT A.**

7. Results are to be reported to the Cancer Committee at least annually.

8. Upon review/evaluation of the audits, if there is a need to address performance rates that fall below established rates, the Cancer committee will develop an Action Plan to be implemented in the Cancer Registry.

VIX. PROCEDURE FOR PHYSICIAN REVIEW OF PATHOLOGY CAP (COLLEGE OF AMERICAN PATHOLOGY) PROTOCOL REPORTS (Ref.: CoC Standard 2.1)

NOTE: Patient management and treatment guidelines promote an organized approach to providing quality care. The Commission on Cancer (CoC) requires that 90% of pathology reports that include a cancer diagnosis will contain the scientifically validated data elements outlined on the surgical case summary checklist of the American College of Pathologists (CAP) publications, *Reporting on Cancer Specimens.*

1. The Cancer Committee will monitor and report compliance with patient management and treatment guidelines currently required by the Commission on Cancer (CoC).

2. Annually, a physician will conduct the quality control activities and report the outcomes to the Cancer committee.

3. Pathology reports will be selected for review by the Cancer Registry staff. A random sample of 10% of the total pathology reports eligible for CAP Protocol of the total analytic cases must be reviewed annually.

4. The following cases are excluded from review:
   A. Biopsy specimens;
   B. Cytology specimens;
   C. Special studies
   D. Reports of in situ tumors (except ductal carcinoma in situ (DCIS) histologic features).

5. The CAP (College of Pathology) audit form shall be completed and the outcome information during the next Cancer Committee meeting after the audit is performed. **SEE ATTACHMENT A.**

6. The Cancer Committee shall develop an Action Plan for any recommendations and address performance rates that fall below the established rates.

7. Upon review/evaluation of the audits, if there is a need to address performance rates that fall below established rates, the Cancer Committee will develop an Action Plan to be implemented by the Department of Pathology.

X. RESOLUTION OF CONFLICTS IN REVIEW OF QUALITY CONTROL

1. There may be instances when there are conflicting opinions regarding findings performed within the Quality Control Plan. If conflicting opinions are documented, then any or all of the following steps may occur in an attempt to resolve the conflict:
   A. The Cancer Registry staff as a group may review the conflicting opinions.
   B. The Department Director/Cancer Program Administrator responsible for the Cancer Registry may review the data and conflict.
   C. The Chairman of the Cancer Committee may review the data and conflict.

2. If the conflict is resolved, a summary of the conflict and the action taken/information learned that resolved the conflict should be presented in summary form to the Cancer committee at its next meeting following resolution of the conflict.

3. If the conflict is not resolved, a summary of the conflict and all relevant information shall be presented to the Cancer committee and the chairman will appoint a group of qualified individuals to perform a review and resolve the conflict. The results of the review and resolution will be presented to the Cancer Committee at its next Committee meeting following completion of the review.

4. If conflict in quality control findings is identified regarding any function performed by the Kentucky Cancer Registry, the Cancer Registrar responsible for that function within the Quality Control Plan shall work with the Kentucky Cancer Registry and its policies and practices to resolve the conflict.

5. Once the conflict is resolved, a summary of the identified conflict and its resolution shall be presented to the Cancer Committee at its next regular meeting.

[illegible] Policy/Procedure: 110-05
Dept. Policy/Procedure: CR-10
Attachment A

TAYLOR REGIONAL HOSPITAL

ACOS COC

Medical Record Chart Audit-Collaborative Stage QC

Chart	Accession#	Dx Site	Date 1st Contact	Date Abstracted	6 Mths Y or N	COC & Histology Y or N	AJCC TNM Y or N	CAP Compliance Y or N	CS Stage	Staging Info	Stages Match Y or N	Follow-up Correct Y or N	1st Course Rx

Standard 1.6 Abstracting Timeliness

#of charts reviewed: ______ #of charts abstracted within 6 months: ______ Compliance %: ______

Standard 2.1 CAP compliance

#CAP eligible charts reviewed: ______ # of charts CAP compliant: ______ Compliance %: ______

Standard 1.6 Quality Control of Registry Abstracted Data

Compliance Rate ______/______

(Number of cases with correct abstracted data/number of cases reviewed)

Review date: ______ Physician Reviewer: ______

Taylor Regional Hospital
Administrative P/P: 490-23
Dept. P/P: 10
Attachment B

TAYLOR REGIONAL HOSPITAL CANCER REGISTRY CASEFINDING QUALITY REVIEW – STANDARD 1.6

DATE REVIEWED: ______________________ REVIEW COMPLETED BY: ______________________

DATE REPORTED TO CANCER COMMITTEE: ____________

MEDICAL RECORD NUMBER	**SOURCE OF CASEFINDING:** KEY: 1. Master Pt. Listing; 2. Path/Autopsy Rept. 3. Medical Oncology 4. Radiation Oncology 5. Death Index 6. Radiology Report 7. Phys. Office Record	Patient was <u>FOUND</u> on the Master Patient Listing – or – <u>FOUND</u> On the list of patients NOT included/not reportable in the Cancer Registry	Patient <u>MISSED during casefinding</u> and was <u>NOT FOUND</u> on the master patient list or any other source listed as reportable to the Cancer Registry	**Comments and/or Action for Error Resolution**

Number of Patients Included in Casefinding Audit	**Number of Missed Patients Identified in Audit**	**Percent Compliant**

____

Reviewer Date

[Type text]

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM POLICY NO.: 490-32
CR POLICY NO.: 08

DATE: 8/30/86
REVIEWED: 4/27/94;1/15/96;6/15/97;4/13/00;3/11/01;
1/2/02;01/13/03;2/10/04; 3/2006; 4/2009; 04/2014
REVISED: 4/10/87;12/98;6/12/99;2/10/04;4/2011;

I. Subject

CASEFINDING

II. Policy

Casefinding is a constant, ongoing process that occurs to determine cases that are to be included in the Taylor Regional Hospital Cancer Registry.

III. Purpose

To outline the casefinding process for the Patient Diagnosis Index.

IV. Procedure

1. Utilize the ICD-9-CM Casefinding Codes for ICD-O-3 Reportable Diseases listing provided at the www.training.seer.cancer.gov website.

2. Print monthly copy of Patient Diagnosis Index from the hospital computer system which includes all patients (inpatient and outpatient) from the ICD-9-CM Casefinding codes for ICD-O-3 Reportable Disease listing.

3. Print monthly listing of all patients coded with a discharge code of 20 (expired).

4. Refer to the daily pathology, cytology, and radiology maintained in the Suspense File
   NOTE: Words such as carcinoma, neoplasm, adenocarcinoma, sarcoma, melanoma, leukemia or lymphoma are indicative of cancer and should be included in any casefinding documentation.

5. Obtain patient listing files from the Medical Oncology Department.

6. Consult with Pathology staff within the Laboratory and request any reports that are positive for cancer diagnosis.

7. Compare cases identified to the CPDMS.net to determine whether patient has previously been included in the Registry.

8. If so, determine whether the recently identified diagnosis is linked to the previous disease.

9. If so, update CPDMS.net to reflect current status of disease by updating any treatment and/or follow-up information.

10. If not, communicate with the attending physician to clarify whether this is a new primary. If so, follow CPDMS.net guidelines for inclusion into the Registry.

11. Abstract all reportable cases.

12. Quality Control of Case Finding will be performed and results reported to the Cancer Committee at least annually. See TRH Cancer Registry Quality Control Plan.

TAYLOR REGIONAL HOSPITAL

DATE: September 20, 2012

ADM. POLICY NO.: 490-41
DEPT. POLICY NO.: CR-17

EFFECTIVE: November 1, 2012
REVIEWED: August, 2015

I. Subject:

Clinical Trial Patient Information – E9

II. Policy: Any patient who is considered by their oncologist to be appropriate for or any patient who requests clinical trial information will receive educational information regarding clinical trials. Any patient may be referred to a center for clinical trial appropriate for his/her diagnosis. Taylor Regional Hospital does not perform or participate in clinical trials.

III. Purpose: Clinical research advances science and ensures that patient care approaches the highest possible level of quality. Patient who participate in clinical trials have the opportunity to advance evidence based medicine. **Ref. ACoS CoC Standard 1.9**

IV. Procedure:

1. At the time of initial presentation to the oncology clinic, each patient is screened regarding appropriateness and probable eligibility in a clinical trial.

2. Referral to a clinical trial may involve either therapeutic or non-therapeutic clinical trial. **Ref.: ACoS CoC Standard 1.9 (2012)**

3. Resources that may be utilized during the screening process are, as follows but are not limited to:

   A. NCI Physician Data Query;
   B. American Cancer Society clinical trials matching service;
   C. Patient diagnosis and/or treatment plan;
   D. Patient and support caregiver(s) ability to travel to the clinical trial site;
   E. Patient initiative and ability to participate in clinical trial.

4. Patients who voice interest or whom the medical oncologist/nursing staff considers a candidate for any clinical trial will be provided educational information to allow the patient and support caregiver(s) to make an informed decision prior to referral. Other resources that may initiate a patients referral to a clinical trial center is not limited to, but may be:

   A. Based upon cancer diagnosis and/or treatment within TRH Oncology;
   B. Based upon diagnosis and/or treatment through the office of a staff physician;
   C. Based upon diagnosis and/or treatment and referred to TRH Oncology from another program.
   D. An informational booklet (from the American Cancer Society) explaining clinical trials are given in <u>each</u> teaching session for whom chemotherapy has been ordered. **(See Attachment B)**

   E. The American Cancer Society Informational Booklet addressing clinical trials is also given to any patient who chooses, or is referred to another facility/physician for a second opinion if he/she does not receive chemotherapy at Taylor Regional Cancer Center.

5. Educational information is attached to this policy/procedure. Specific resources provided initially are:

   A. Taylor Regional Medical Oncology and Hematology Cancer Clinical Trials Fact Sheet. **See Attachment A.**
   B. "Is Cancer Treatment Clinical Trial the Right Choice for Me? published by the American Cancer Society. **See Attachment B.**

6. Patient referral to a clinical trial group will be based upon patient desire as well as ability to travel and availability of a clinical trial that meets the patients wishes and needs. Treatment related clinical trial groups that are considered, but are not limited to the following:

   A. NCI-sponsored cooperative cancer clinical trial groups;
   B. Pharmaceutical company sponsored research;
   C. Approved university research settings.

7. Referrals to clinical trials will be documented in the patient's medical record and a report presented to the Cancer Committee annually. The report will include, at a minimum, the following: **Ref.: ACoS CoC Standard 1.9 (2012)**

   A. Patient identifier;
   B. Reason for referral to clinical trial (i.e., diagnosis of referral);
   C. Location of referral;
   D. Acceptance into trial.
   E. Type of trial (Phase 1, etc.)

8. The Cancer Registry will maintain the number of patients (percentage) based on the category and the number of analytic accessions. This report will be annualized. **Reference: ACoS CoC Standard: 1.9 (2012)**

Sanctions: Failure to comply with this policy could result in disciplinary action up to and including termination.

Taylor Regional Hospital

Jewish Hospital Health Network

Taylor Regional Medical Oncology and Hematology

Adm. Policy: 490-41
Dept. Policy: CR - 17
ATTACHMENT A

Cancer Clinical Trials Fact Sheet

Key Points

- Clinical trials are research studies that involve people and test new ways to prevent, detect, diagnose, or treat cancer and other diseases.
- Every clinical trial has a protocol that describes what will be done in the trial, how the trial will be conducted, and why each part of the trial is necessary.
- National and international regulations and policies have been developed to protect the rights, safety, and well-being of people who take part in clinical trials and to ensure that trials are conducted according to strict scientific and ethical principles.
- Informed consent is a process through which people learn the important facts about a clinical trial to help them decide whether or not to take part in it, or whether to continue participating in it.
- Many states require that insurance companies cover the costs of routine care for people taking part in a clinical trial. In other states, voluntary agreements between the states and insurance companies include such a provision. However, coverage varies by state, by health insurance plan, and by type of clinical trial.

1. What are clinical trials, and why are they important?

Clinical trials are research studies that involve people and test new ways to prevent, detect, diagnose, or treat diseases.

2. Are there different types of cancer clinical trials?

Yes. Cancer clinical trials differ according to their primary purpose. They include the following types:

Treatment. These trials test the effectiveness of new treatments or new ways of using current treatments in people who have cancer. Combinations of different treatment types may also be tested in these trials.

Prevention. These trials test new interventions that may lower the risk of developing certain types of cancer. These may involve healthy people who have not had cancer or include people who have a higher than average risk of developing a specific type of cancer. Some cancer prevention trials involve people who have had cancer in the past and test interventions that may help prevent the return (recurrence) of the original cancer or reduce the chance of developing a new type of cancer.

Screening. These trials test new ways of finding cancer early.

Diagnostic. These trials study new tests or procedures that may help identify, or diagnose, cancer more accurately.

Quality of life or supportive care. These trials focus on the comfort and quality of life of cancer patients and cancer survivors.

3. Who sponsors clinical trials?
Government agencies, such as NCI and other parts of the National Institutes of Health (NIH), the Department of Defense, and the Department of Veterans Affairs, sponsor and conduct clinical trials. In addition, organizations or individuals, including physicians, academic medical centers, foundations, volunteer groups, and biotechnology and pharmaceutical companies, also sponsor cancer clinical trials.

4. Where do cancer clinical trials take place?
Cancer clinical trials take place in cities and towns across the United States and in other countries. They take place in doctors'offices, cancer centers and other medical centers, community hospitals and clinics, and veterans'and military hospitals.

5. Who manages clinical trials?
Each clinical trial is managed by a research team that can include doctors, nurses, research assistants, data analysts, and other specialists who may work closely with other health professionals, such as other doctors and nurses, laboratory technicians, pharmacists, dietitians, and social workers.

6. What are eligibility criteria, and why are they important?
Every clinical trial has a protocol, or action plan, that describes what will be done in the trial, how the trial will be conducted, and why each part of the trial is necessary. The protocol also includes guidelines for who can and cannot participate in the trial. Enrolling people who have similar characteristics helps ensure that the outcome of a trial is due to the intervention being tested and not to other factors. In this way, eligibility criteria help researchers obtain the most accurate and meaningful results possible.

7. How is the safety of clinical trial participants protected?
National and international regulations and policies have been developed to help ensure that research involving people is conducted according to strict scientific and ethical principles.
Clinical trials that are conducted or supported by agencies of the U.S. federal government or that evaluate new drugs or medical devices that are subject to regulation by the U.S. Food and Drug Administration (FDA) must be reviewed and approved by an Institutional Review Board (IRB).

8. What is informed consent?
Informed consent is a process through which people 1) learn the important facts about a clinical trial to help them decide whether or not to take part in it, and 2) continue to learn new information about the trial that helps them decide whether or not to continue participating in it. Potential trial participants are given a form, called an informed consent form, that provides information about the trial in writing. People who agree to take part in the trial are asked to sign the form. However, signing this form does not mean that a person must remain in the trial. Anyone can choose to leave a trial at any time—

either before it starts or at any time during the trial or during the follow-up period. It is important for people who decide to leave a trial to get information from the research team about how to leave the trial safely.

The informed consent process continues throughout a trial. If new benefits, risks, or side effects are discovered during the course of a trial, the researchers must inform the participants so they can decide whether or not they want to continue to take part in the trial. In some cases, participants who want to continue to take part in a trial may be asked to sign a new informed consent form.

9. What does a trial's "phase" mean?

New interventions are often studied in a stepwise fashion, with each step representing a different "phase" in the clinical research process. The following phases are used for cancer treatment trials:

Phase 0. These trials represent the earliest step in testing new treatments in humans. In a phase 0 trial, a very small dose of a chemical or biologic agent is given to a small number of people to gather preliminary information about how the agent is processed by the body and how the agent affects the body. The people who take part in these trials usually have advanced disease, and no known, effective treatment options are available to them.

Phase I (also called phase 1). These trials are conducted mainly to evaluate the safety of chemical or biologic agents or other types of interventions. They help determine the maximum dose that can be given safely. Phase I trials enroll small numbers of people who have advanced cancer that cannot be treated effectively with standard (usual) treatments or for which no standard treatment exists.

Phase II (also called phase 2). These trials test the effectiveness of interventions in people who have a specific type of cancer or related cancers and continue to look at the safety of interventions. The people who participate in phase II trials may or may not have been treated previously with standard therapy for their type of cancer.

Phase III (also called phase 3). These trials compare the effectiveness of a new intervention, or new use of an existing intervention, with the current standard of care (usual treatment) for a particular type of cancer and also examine how the side effects of the new intervention compare with those of the usual treatment. If the new intervention is more effective than the usual treatment and/or is easier to tolerate, it may become the new standard of care.

Phase IV (also called phase 4). These trials further evaluate the effectiveness and long-term safety of drugs or other interventions. They usually take place after a drug or intervention has been approved by the FDA for standard use.

10. Are placebos used in cancer treatment clinical trials?

The use of placebos as comparison or "control" interventions in cancer treatment trials is rare although placebos may be given along with a standard treatment. For example a trial might compare the effects of a standard treatment plus a new treatment with the effects of the same standard treatment plus a placebo.

11. What are some of the possible benefits of taking part in a clinical trial?

The benefits of participating in a clinical trial include the following:

Trial participants have access to promising new interventions that are generally not available outside of a clinical trial.
The intervention being studied may be more effective than standard therapy. If it is more effective, trial participants may be the first to benefit from it.
Trial participants receive regular and careful medical attention from a research team that includes doctors, nurses, and other health professionals.
The results of the trial may help other people who need cancer treatment in the future.
Trial participants are helping scientists learn more about cancer (e.g., how it grows, how it acts, and what influences its growth and spread).

12. What are some of the potential harms associated with taking part in a clinical trial?

The potential harms of participating in a clinical trial include the following:
The new intervention being studied may not be better than standard therapy, or it may have harmful side effects that doctors do not expect or that are worse than those associated with standard therapy.
Trial participants may be required to make more visits to the doctor than they would if they were not in a clinical trial and/or may need to travel farther for those visits.
Health insurance may not cover all patient care costs in a trial.

13. What are correlative research studies, and how are they related to clinical trials?

In addition to answering questions about the effectiveness of new interventions, clinical trials provide the opportunity for additional research. These additional research studies, called correlative or ancillary studies, may use blood, tumor, or other tissue specimens obtained from trial participants before, during, or after treatment. For example, the molecular characteristics of tumor specimens collected during a trial might be analyzed to see if there is a relationship between the presence of a certain gene mutation or the amount of a specific protein and how trial participants responded to the treatment they received. Information obtained from these types of studies could lead to more accurate predictions about how individual patients will respond to certain cancer treatments, improved ways of finding cancer earlier, new methods of identifying people who have an increased risk of cancer, and new approaches to try to prevent cancer.
Clinical trial participants must give their permission before biospecimens obtained from them can be used for research purposes.

14. Who is responsible for the costs of care for people taking part in a clinical trial?

The costs of care for people participating in a clinical trial fall into two general categories: 1) routine care costs and 2) research costs. Routine care costs are costs associated with treating a person's cancer whether or not they are in a trial. These costs are usually covered by health insurance, but requirements vary by state and type of health plan. Research costs are costs associated with conducting a clinical trial; these costs may include the costs of extra doctor visits, extra tests, and procedures that are required for the trial but would not be part of routine care. Research costs are usually covered by the organization that sponsors the trial.

It is important to investigate how the costs of care will be covered before joining a clinical trial. Anyone thinking about taking part in a clinical trial should discuss cost coverage issues with representatives of their health plan.

15. What happens when a clinical trial is over?

After a clinical trial is completed, the researchers look carefully at the data collected during the trial to understand the meaning of the findings and to plan further research. After a phase I or phase II trial, the researchers decide whether or not to move on to the next phase or stop testing the intervention because it was not safe or effective. When a phase III trial is completed, the researchers analyze the data to determine whether the results have medical importance and, if so, whether the tested intervention could become the new standard of care.

The results of clinical trials are often published in peer-reviewed scientific journals. Peer review is a process by which cancer research experts, not associated with a trial, review the study report before it is published to make sure that the data are sound, the data analysis was performed correctly, and the conclusions are appropriate. Once a new intervention has proven safe and effective in a clinical trial, it may become a new standard of care.

The FDA Amendments Act of 2007 requires that researchers report the "basic" results of clinical trials that tested FDA-regulated and FDA-approved chemical or biologic agents or medical devices in ClinicalTrials.gov, a publicly accessible database maintained by the U.S. National Library of Medicine (NLM). Basic trial results must be submitted whether or not the results are published in a peer-reviewed scientific journal and include the following items:

Demographic and baseline information about the participants

The progress of the participants through each stage of the trial (e.g., the number of participants who left the trial and at which stage)

Results for the primary and secondary outcomes (also called endpoints) measured in the trial (e.g., tumor response, disease-free survival, overall survival, quality of life, etc.)

A point of contact for the trial (to obtain additional information about the trial and its results)

More information is available on the About the ClinicalTrials.gov Results Database page. NLM's website also has an FAQ that lists other ways to find clinical trial results.

16. Where can people find more information about clinical trials?

People interested in taking part in a clinical trial should talk with their health care provider.

Information about cancer clinical trials is also available from NCI's Cancer Information Service (CIS). CIS information specialists use NCI's website to identify and provide detailed information about clinical trials that are currently accepting patients. NCI's website contains updated information about NCI-sponsored clinical trials and many other clinical trials conducted by independent investigators at hospitals and medical centers in the United States and around the world, as well as trials sponsored by pharmaceutical companies.

People also have the option of searching for clinical trials on their own by visiting the clinical trials search form. Another resource is NLM's ClinicalTrials.gov, which lists clinical trials for a wide range of diseases and conditions, including cancer.

NCI's website further contains educational materials about clinical trials, articles about recent clinical trial results, and information for research teams about conducting clinical trials. These resources can be accessed by visiting the Clinical Trials home page.

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY NO.: 490-29
CR POLICY NO.: 05

DATE: 8/30/86
REVIEWED: 4/27/94;1/15/96;6/15/97;4/13/00;3/11/01;
1/2/02;01/13/03;2/10/04;10/20/09; 04/12; 04/2015
REVISED: 4/10/87;12/98;6/12/99;2/10/04; 10/20/09; 04/11

I. Subject

CODING

II. Policy

Topography and histology codes are assigned using the ICD-0-3 (Third Edition of the International Classification of Diseases for Oncology). General staging codes are assigned using Collaborative Staging Manual and Coding Instructions, and Multiple Primaries and Histologies Coding Rules.

III. Purpose

To assure consistent coding of cancer cases in order to abstract into Taylor Regional Hospital Cancer Registry and to assure that Commission on Cancer data standards and coding instructions set using the FORDS (Facility Oncology Registry Data Standards) manual are used to describe all reportable cases diagnosed January 1, 2003 and after.

IV. Procedure

1. Select the most specific code to identify the topography and histology of the disease to be coded.
2. As necessary, refer to the Third Edition of the International Classification of Diseases for Oncology for a complete listing of codes.
3. As necessary, refer to the Collaborative Staging Manual and Coding Instructions.
4. As necessary, refer to the Multiple Primaries and Histologies Coding Rules.

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY NO.: 490-38
CR POLICY NO.: 18

DATE: 04/03/2010
REVIEWED: 04/2015
REVISED: 08/2012

I. **Subject:**

COMPLETION AND SUBMISSION OF COMMISSION ON CANCER (CoC) SURVEY APPLICATION RECORD (SAR)

II. **Policy:**

The Taylor Regional Hospital Cancer Registry shall complete the Commission on Cancer (CoC) Survey Application Record (SAR) in a timely manner and in compliance with all ACoS (American College of Surgeons) CoC Standards.

III. **Purpose:**

To assure that Taylor Regional Hospital consistently, without fail, is in compliance with all ACoS CoC standards and that all team members work together as requested to complete the Survey Application Record (SAR).

IV. **Procedure:**

1. The Cancer Registrar is responsible for continuously updating the SAR in accordance with Commission on Cancer guidelines.
2. All contact information is to be input and maintained in the SAR via CoC Datalinks.
3. When the SAR is made available to TRH staff, it shall be utilized as the method to document Taylor Regional Hospital's compliance with Commission on Cancer standards since the previous survey.
4. It is acceptable to utilize the most recent SAR available as a reference for completion of a new SAR. NOTE: Contents from an old SAR will not be copied over to a new SAR.
5. All members of the Cancer Committee and others within the TRH hierarchy, as requested, shall provide data, reports and information as requested by the Tumor Registry to assist in completion of the SAR.
6. Several tools and resources to prepare for survey are available through both the CoC Online Education Portal and the Best Practices Repository accessible from the CoC website. Use of these references is encouraged, both during completion of the SAR as well as for any process question that arises to the Cancer Program.
7. If there is any reason the SAR is not completed and submitted per CoC guidelines, the Director of the Care Management (Cancer Program Admnistrator), The Cancer Committee Chairman, the Cancer Liaison Physician and the Administrator responsible for the Tumor Registry are to be notified immediately.
8. Survey extensions or postponements are discourages; however, if it is necessary to requests either of these conditions, the Survey Extension Policy on the Commission on Cancer website is to be referenced and any request for extension or postponement is to be made only upon dire hospital necessity.

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY NO.: 490-26
DEPT. POLICY NO.: CR - 2

Date: 08/30/86
Reviewed: 04/27/94; 01/15/96; 06/15/97; 04/13/00;
03/11/01; 02/2006; 03/2008; 04/2009; 04/12; 08/2015
Revised: 4/10/87; 12/98; 6/12/99; 2/10/04; 04/13;

I. Subject:

CONFIDENTIALITY, SECURITY AND RELEASE OF INFORMATION FROM TAYLOR REGIONAL HOSPITAL CANCER PROGRAM

II. Policy:

Participants in the Cancer Program and with the Cancer Registry of Taylor Regional Hospital will assure that all data and information is maintained in a confidential and secure manner and in compliance with HIPAA laws. HIPAA allows for the reporting of identifiable cancer data to public health entities. Because the Kentucky Cancer Registry falls under the definition of a public health entity, HIPAA allows our facility to continue to report data in compliance with state law. Written informed consent from each cancer patient to public health entities is not required under HIPAA; rather hospitals must document that reporting has occurred. REFER TO: Administrative Policy/Procedure #460-19, HCIS Policy/Procedure # No.: HCIS-24 Accounting of Disclosures of Protected Health Information shall be followed.

III. Purpose:

To ensure patient's rights to confidentiality are secured and that Taylor Regional Hospital's information security and release of information policies are followed.

IV. Procedure:

A. The Director of Care Management shall be consulted prior to release of any patient information that identifies a patient by name.

B. Information may be released to other Tumor Registries, but there must be verification that the requester is affiliated with a recognized Tumor Registry.

C. Patient information/data is to be treated in a confidential manner at all times. All team members must sign a HIPAA compliant confidentiality statement. See Administrative P/P: 600-19 (See ATTACHMENT A).

D. Any information maintained in the Cancer Registry computer is to be treated in a secure manner per Administrative Policy/Procedure #600-22 (Computer System Access/Change of Job Responsibilities/Resignation/Termination of Access Privileges to Hospital Based Computer System. (See ATTACHMENT B).

Adm. P/P: 490-26
CE: 02
Attachment A.

Taylor Regional Hospital

Management Staff Computer and Information Usage Agreement

TRH considers maintaining the security and confidentiality of protected health information a matter of its highest priority. All those granted access to this information must agree to the standards set forth in this computer and information usage agreement. All those who cannot agree to these terms will be denied access to protected health information entrusted by our patients to this information and must recognize the responsibilities entrusted in preserving the security and confidentiality of this information. The following conditions apply to all those having access to protected health information.

As a team member of TRH and as a condition of my employment, I agree to the following:

1. I understand that I am responsible for complying with the TRH policies based on the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that are available to me for review.
2. I will treat all information received in the course of my employment with TRH, including but not limited to the patients of TRH, as confidential and privileged information.
3. Upon cessation of my employment with TRH, I agree to continue to maintain the confidentiality of any information I learned while a team member and agree to turn over the keys, access cards, or any other device that would provide access to TRH or its information.
4. I will respect the privacy and rules governing the use of any information accessible through the computer system/network only access and/or utilize protected health information that I have a need to know in order to perform my job.
5. I will respect the confidentiality of any reports or documents printed from any information system containing patient/member information and handle, store and dispose of material appropriately.
6. I will not disclose information regarding the patients of TRH to any person or entity other that as necessary to perform my job and as permitted under the organization's policies. I understand that the information accessed through all TRH information technology contain sensitive and confidential patient care, business, financial and hospital team member information, which should only be disclosed to those, authorized to receive it.
7. I will not use or disclose any information that identifies a patient except that which is allowed by TRH policies based on HIPAA regulations.
8. I will prevent unauthorized use or viewing of any information in files maintained, stored or processed by TRH.
9. I will not remove any worksheet, record, report or copy of such from the area or office where it is kept except in the performance of my duties. I will report any violation of this code.
10. I will not seek personal benefit or permit others to benefit personally from any confidential information or use of equipment available through my work assignment.
11. I will not log on to any TRH computer systems that currently exist or may exist in the future using a password other than my own.
12. I will safeguard my computer password and will not post it in a public place, e.g., the computer monitor, or a place where it will be easily lost, e.g., on my nametag.
13. I will not allow anyone, including other team members, to use my password and/or authentication device to log on to the computer or alter information under my identity.
14. I will not utilize anyone else's password and/or authentication device in order to access any TRH system.

15. I will log off the computer as soon as I have finished using it.

16. I will not attempt to establish electronic communication to the TRH network except by approved methods.

17. I will use an approved cover sheet for all faxes containing protected health information.

18. I will not use E-mail to transmit a patient's protected health information.

19. I will comply with TRH Internet and Electronic mail usage policies and in particular will not use these business tools for non-TRH commercial or personal use.

20. I will ensure all electronic storage media (CD, DVD, floppy diskette, computer hard drive, etc.) containing protected health information is destroyed according to TRH policy.

21. I will respect the ownership of proprietary software. I will not make unauthorized copies of such software even when the software is not physically protected against copying.

22. I will respect the procedures established to manage the use of all systems.

23. I understand that all access to the system will be monitored.

24. As a manager, I will ensure team members resignations and terminations are communicated in the timeframe established by TRH policy to ensure the appropriate updates to information system access.

25. As a manager, I will ensure team member changes in job role or responsibility that affect system access requirements are communicated in the timeframe established by TRH policy.

I understand that my access to protected health information maintained by TRH is a privilege and not a right afforded to me. By signing this agreement, I agree to protect the security of this information and maintain all protected health information in a manner consistent with the requirements outlined under the federal privacy regulations. Any breach of the terms outlined in this agreement will subject me to penalties, including disciplinary action, under TRH policies as well as any applicable State and Federal law. By signing this agreement, I agree that I have read, understand and will comply with all the conditions outlined in this agreement.

Signature	Title
Print Name	Department
Date	

Administrative P/P: 49
CR: 02
Attachment B

External Computer and Information Usage Agreement

Taylor Regional Hospital considers maintaining the security and confidentiality of protected health information a matter of its highest priority. All those granted access to this information must agree to the standards set forth in this Computer and Information Usage Agreement. All those who cannot agree to these terms will be denied access to protected health information entrusted by our patients to this organization. Each person accessing TRH data and resources holds a position of trust relative to this information and must recognize the responsibilities entrusted in preserving the security and confidentiality of this information. The following conditions apply to all those having access to protected health information.

As a team member of ____, I agree to the following:

1. I understand that I am responsible for complying with the TRH policies based on the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that are available to me for review.

2. I will treat all information received in the course of my interactions with TRH, including but not limited to the patients of TRH, as confidential and privileged information.

3. Upon cessation of my employment with the above for mentioned , I agree to continue to maintain the confidentiality of any information I learned while a team member and agree to turn over the keys, access cards, or any other device that would provide access to TRH or its information.

4. I will respect the privacy and rules governing the use of any information accessible through the computer system/network and only access and/or utilize protected health information that I have a need to know in order to perform my job.

5. I will respect the confidentiality of any reports or documents printed from any information system containing patient/member information and handle, store and dispose of material appropriately.

6. I will not disclose information regarding the patients of TRH to any person or entity other than as necessary to perform my job and as permitted under the organization's policies. I understand that the information accessed through all TRH information systems contains sensitive and confidential patients care, business, and financial information which should only be disclosed to those authorized to receive it.

7. I will not use or disclose any information that identifies a patient except that which is allowed by TRH policies based on HIPAA regulations.

8. I will prevent unauthorized use or viewing of any information in files maintained, stored or processed by TRH.

9. I will not remove any worksheet, record, report or copy of such from the area of office where it is kept except in the performance of my duties. I will report any violation of this code.

10. I will not seek personal benefit or permit others to benefit personally from any confidential information or use of equipment available through my work assignment.

11. I will not log on to any TRH computer systems that currently exist or may exist in the future using a password other than my own.

12. I will safeguard my computer password and will not post it in a public place, e.g., the computer monitor, or a place where it will be easily lost, e.g., on my nametag.

13. I will not allow anyone, including other team members, to use my password and/or authentication device to log on the computer or alter information under my identity.

14. I will log off of the applicable program or computer as soon as I have finished using it.

15. I will not attempt to establish electronic communication to the TRH network except by approved methods.

17. I will use an approved cover sheet for all faxes containing protected health information.

18. I will not use E-mail to transmit a patient's protected health information unless instructed to do so by my Departmental Management.

20. I will ensure all electronic storage media (CD, DVD, floppy diskette, computer hard drive, etc.) containing protected health information is destroyed.

21. I will respect the ownership of proprietary software. I will not make unauthorized copies of such software even when the software is not physically protected against copying.

22. I will respect the procedures established to manage the use of all systems.

23. I understand that all access to the system will be monitored.

I understand that my access to protected health information maintained by TRH is a privilege and not a right afforded to me. By signing this agreement, I agree to protect the security of this information and maintain all protected health information in a manner consistent with the requirements outlined under the federal privacy regulations. Any breach of the terms outlined in this agreement will subject me to penalties, as well as any applicable State and Federal law. By signing this agreement, I agree that I have read, understand and will comply with all the conditions outlined in this agreement.

Signature ______________________ Title ______________________

Print Name ______________________ Department ______________________

Date ______________________

ADM. POLICY NO.: 800-34
DEPT. POLICY NO.: 490-39
CR POLICY NO.: 16

DATE: 8/30/86
REVIEWED: 4/27/94;1/15/96;6/15/97;4/13/00;3/11/01; 1/2/02;01/13/03;2/10/04; 04/06/; 04/12
REVISED: 4/10/87;12/98;6/12/99;2/10/04; 04/09; 04/11; 01/15

I. Subject:

CONTINUING MEDICAL EDUCATION CREDIT FOR TUMOR CONFERENCE

II. Policy:

It shall be the Policy of Taylor Regional Hospital to maintain an agreement with an entity approved to provide CME (Continuing Medical Education) credit (Category I) for physicians/mid-level practitioners who attend Tumor Conference.

III. Purpose:

To allow attending medical staff to remain current regarding treatment of patients diagnosed with malignancies.

STATEMENT OF AGREEMENT: As of March 2009, the University of Louisville Continuing Health Sciences Education has agreed to assure that those physicians who attend Tumor Conferences at Taylor Regional Hospital will receive Continuing Medical Education Credit (Category I). CME Credits will be issued based on the length of the monthly Tumor Conference meeting (i.e., two (2) hour meeting = 2 CME credits).

IV. Procedure:

1. An attendance roster for physicians will be prepared prior to each monthly Tumor Conference.

2. Continuing Medical Education units via the University of Louisville will be automatically assigned via each physician/mid-level practitioner electronically signing into the designated telephone number with an assigned CME credit ID# to be assigned for Taylor Regional Hospital Tumor Conference. This number will be provided to each physician/mid-level practitioner member in attendance.

3. Those in attendance must sign-in on the roster to receive CME credit. EXCEPTION: Any physician participating in Tumor Conference via teleconference may be signed in by a designee.

4. An evaluation must be completed by those physicians in attendance, either personally or via teleconference, who are seeking CME credit. One (1) evaluation must be completed for each Tumor Conference.

5. A copy of the Agenda, Sign-In sheet, Evaluations, the Report Form, Flyer, as well as Disclosure Forms will be e-mailed to the appropriate designee' at the University of Louisville (______@louisville.edu) by the Public Relations Director at TRH.

6. Each physician/mid-level practitioner in attendance will be responsible for accessing and printing his/her own transcript of attendance.

7. Bi-Annually, a summary of CME credits for physicians will be requested and forwarded to the Medical Staff office at TRH to allow maintenance of Medical Staff Credential files.

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY NO.: 490-34
CR POLICY NO.: 19

DATE: 8/30/86
REVIEWED: 4/27/94;1/15/96;6/15/97;4/13/00;3/11/01; 1/2/02;01/13/03;2/10/04; 04/06/ 04/09; 4/13
REVISED: 4/10/87;12/98;6/12/99;2/10/04; 04/12; 04/2015

I. Subject:

DISASTER RECOVERY OF KENTUCKY CANCER REGISTRY (KCR) CANCER PATIENT DATA MANAGEMENT SYSTEM (CPDMS) & COMPUTERIZED REGISTRY FILING

II. Policy:

The Cancer Registry maintains computerized files on all cases accessioned into the registry's reference date of 1987. This system is maintained per the Kentucky Cancer Registry's instruction, back-up, security and disaster recovery protocols.

III. Purpose:

To describe the Cancer Registry's computerized filing systems and to denote the Kentucky Cancer Registry & Taylor Regional Hospital's computer Disaster Recovery Protocols.

IV. Procedure:

A. Reporting:

1. Generate computerized reports according to the procedures outlined in the Kentucky Cancer Registry's (KCR) Cancer Patient Data Management System (CPDMS).

2. Refer to pages 114 – 171 of the KCR CPDMS Operator's Manual for a complete listing of computerized registry reports.

B. Back-up of Kentucky Cancer Registry data followed by the Kentucky Cancer Registry:

1. All Kentucky hospital/clinic data is backed up every eight (8) hours.

2. Each night the main server is copied to a back-up server, located at a different site.

3. Once each week all data on the back-up server is copied to a tape back-up system.

4. Once each month, the back-up tapes are taken to a 3rd (third) off-site secured facility.

5. Each change made to the database tables is recorded in a "History table." These history tables are backed up and once per month, are taken to the off-site secured facility.

C. Taylor Regional Hospital will utilize the TRH Disaster Recovery Plan for back-up of all computer related files. It is the Registrar's responsibility to assure there is internal back-up of all locally housed data.

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY NO.: 490-27
CR POLICY NO.: 03

DATE: 8/30/86
REVIEWED: 4/27/94;1/15/96;6/15/97;4/13/00;3/11/01; 1/2/02;01/13/03;2/10/04; 04/06/ 04/09; 04/12
REVISED: 4/10/87;12/98;6/12/99;2/10/04; 04/11; 06/15

I. Subject:

OBJECTIVES AND PURPOSE OF TAYLOR REGIONAL HOSPITAL TUMOR REGISTRY

II. Policy:

The Tumor Registry will serve as a system to monitor all types of reportable cases diagnosed and treated at Taylor Regional Hospital. This system shall comply with KCR (Kentucky Cancer Registry) and ACoS (American College of Surgeons) guidelines. The registry will provide information for programmic and administrative planning and for monitoring patient outcomes.

III. Purpose:

To outline objectives and the purpose of Taylor Regional Hospital's Tumor Registry.

IV. Procedure:

1. Establish procedures for identifying all cases of malignant diseases. Kentucky Cancer Registry (KCR) and American College of Surgeons (ACoS) guidelines are followed.
2. Obtain core information from patients' medical records.
3. Follow all living patients to obtain definitive outcomes.
4. The Tumor Registry shall obtain and maintain ACoS certification.
5. Remain current in all processes utilized by the Registry and its staff.
6. Coordinate monthly Tumor Conferences.
7. Coordinate quarterly Cancer Committee Meetings.
8. When requested, assist clinicians on cancer-related studies and research activities.
9. Assist the Cancer Committee in developing indicators, yearly goals and setting standards.
10. Perform data collection for quality improvement studies approved by the Cancer Committee and report information as requested.
11. Assist and perform Quality Control functions within the Cancer Registry as denoted in the Quality Control Plan.
12. If approved and recommended by the Cancer Committee and Administration prepare and provide Taylor Regional Hospital's Annual Cancer Report annually for distribution in the hospital, local and surrounding physician's offices and other cancer registries.

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY NO.: 490-36
CR POLICY NO.: 15

DATE: 8/30/86
REVIEWED: 4/27/94;1/15/96;6/15/97;4/13/00;3/11/01;
1/2/02;01/13/03;2/10/04; 04/06/ 04/09; 04/15
REVISED: 4/10/87;12/98;6/12/99;2/10/04; 04/12

I. Subject:

QUALITY MANAGEMENT AND IMPROVEMENT (REFERENCE: ACoS (American College of Surgeons) CoC (Commission on Cancer) Standards 4.5 – 4.8

II. Policy:

The Quality Management and Improvement system utilized by the Cancer Program at Taylor Regional Hospital (TRH) is conducted per ACoS CoC standards and is performed in accordance with the process and standards of the TRH Quality Improvement process and procedures.

III. Purpose:

To provide, in one (1) location, the process for documentation of all cancer-related quality studies, performance improvement initiatives and oversight of all those projects at TRH.

IV. QUALITY MANAGEMENT/IMPROVEMENT PRIORITIES:

1. To work toward the goal of increased desirable outcomes for all patients.
2. Assure appropriate, accurate and complete documentation of the clinical care processes.
3. Focus on providing appropriate and timely consultation, diagnosis, follow-up of findings and tests and timely referrals to assure continuity of care.
4. Provide for concise compilation of information that will be of value to other organizations, including reference databases.
5. Provide for established criteria that allow for setting of priorities for improvement activities. Such priorities will be based upon assessment of opportunities for improvement.
6. Assure that effort is made to provide care that is sufficient to assure patient cooperation and satisfaction.
7. Assure compliance with all federal, state and accrediting agencies in regard to quality management and improvement activities.

IV. Procedure:

1. Each year, the Cancer Committee will monitor the high quality of patient care by utilizing the CoC quality reporting tools appropriate to the patients who are treated by the staff of Taylor Regional Hospital. These may include tools such as CP3R, but this alone shall not meet the criteria for a Quality Management Study.

2. Annually, the Quality Improvement Coordinator shall, at the direction of the Cancer Committee, develop, analyze and document a minimum of two (2) studies per the ACoS CoC standards. One (1) of these studies shall be based upon the results of a completed study that measures cancer patient care quality of care and outcomes. One (1) improvement can be identified from another source that is directed for assuring that cancer care for patients at Taylor Regional Hospital is improved.

3. Each study shall include the goal of measuring the quality of care and working toward improvement of positive outcomes for patients with cancer who are treated at Taylor Regional Hospital.

4. Sources for improvement include, but are not limited to the following:
    - Actions based on analysis of a study of quality;
    - Actions to address undesirable performance;
    - Actions to improve unacceptable performance.

5. Quality Management studies (and their response) shall require active involvement by physicians, supporting members of the cancer committee and others as requested by the Cancer Committee. Studies shall focus on areas with potentially problematic quality-related issues relevant to the program and local cancer patient population.

6. Whenever possible, the entire continuum of care encompassed by the care/service to be studied shall be incorporated into the study and reporting of its results.

7. The Cancer Committee shall discuss all of the quality outcome results, concentrating on opportunities for improvement. The discussion should focus on processes that could improve patient outcome, that could improve performance and on areas that will assure continued patient satisfaction with care and services.

8. When clinically based Quality Management studies are recommended by the Cancer Committee, there shall be accepted sources for evidence-based care included as part of the study to be performed. Acceptable sources for evidence-based care may include, but is not limited to:
    - National Quality Forum (NQF);
    - NCCN (National Comprehensive Cancer Network) Guidelines;
    - Medical Specialty Recommendations (i.e., ASCO, ACoS, AGA, AOA, ASCP, etc.)
    - American Cancer Society Guidelines;
    - Other reputable article sources.

9. Each year, a physician member of the Cancer Committee shall perform a study to focus on the evaluation and treatment of patients, assuring compliance with national guidelines. Study results shall be presented to the Cancer Committee and will be documented in Cancer Committee minutes.

10. A formal report shall be submitted to the Cancer Committee explaining the results of any Quality Management study performed. The Quality Improvement Coordinator, and/or the physician member of the committee who performs the study (as appropriate) shall be responsible for sharing the results with the Cancer Committee.

11. The Cancer Committee shall have the responsibility of recommending corrective action to any entity whose area falls below acceptable norms or when undesirable performance is identified. Any recommendations shall follow the procedures for reporting denoted in the Taylor Regional Hospital Medical Staff Bylaws, Rules & Recommendations. Specifically, clinical recommendations are made to the Quality Assurance Committee and from the Quality Assurance Committee to the Medical Executive Committee for approval, with reporting made to the entire Medical Staff. Non-clinical recommendations shall follow the TRH chain-of-command, as a member of Administration shall be a member of the Cancer Committee, this will serve as notification of recommendation(s).

12. A prepared summary shall be presented to the Cancer Committee and shall be made an attachment to the minutes of the Committee meeting.

13. Annually, the Cancer Committee shall evaluate the effectiveness of its Quality Management system and recommendations for revision(s) to the program shall be implemented.

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY NO.: 490-31
CR POLICY NO.: 07

DATE: 8/30/86
REVIEWED: 4/27/94; 1/15/96; 6/15/97;4/13/00;3/11/01; 1/2/02; 01/13/03; 2/10/04; 04/06; 04/12; 04/15
REVISED: 4/10/87; 12/98; 6/12/99;2/10/04; 04/2009; 04/11

I. Subject:

SUSPENSE FILING

II. Policy:

A suspense file is maintained on all cases for inclusion in the Registry.

III. Purpose:

To describe the maintenance and use of the suspense file.

IV. Procedure:

1. Acquire daily Pathology records and maintain in current months file, in alphabetical order.
2. Monthly, review the Patient Diagnosis listing of applicable codes. The listing must include all ICD-9-CM codes (inpatient and outpatient) from the Reportable Codes Listing provided by the SEER (Surveillance Epidemiology and End Results) Cancer Staging Guide.
3. Review one (1) copy of all PET/CT Reports Place suspicious and documented malignant diagnoses in current months file, in alphabetical order.
4. The total Radiology PET/CT and Pathology diagnosis index listing are to be maintained in a file in the Tumor Registrar's office.
5. Maintain a file of all potentially malignant or suspicious cases identified either from the sources listed above, or a copy of any other source in alphabetical order in the Tumor Registrar's office.
6. Abstract cases between four (4) and six (6) months from date of first contact.
7. After abstraction is complete, copies of Radiology, Pathology and Diagnosis Index are to be shredded clinical reports and other documents within the suspense file that contain protected health information are to be shredded per Hospital Policy.

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network
ADM. POLICY: 490-24
DEPT. POLICY NO.: CR - 13

DATE:	8/30/86
REVIEWED:	04/27/94; 01/15/96; 06/15/97; 04/13/00; 3/11/01; 01/2/02; 01/13/03; 02/10/04; 10/20/09; 04/14
REVISED:	04/10/87; 12/98; 06/12/99; 02/10/04; 10/20/09; 04/15/12; 11/16/2016

I. SUBJECT:

TUMOR CONFERENCE: ACoS CoC Eligibility Requirement E-3; Standard 1.7

II. POLICY:

The Taylor Regional Hospital Tumor Conference will be held monthly. The Conference will be directed by the medical staff with participation by other allied and support staff as appropriate. The Tumor Conference will comply with expectations of the American College of Surgeons (ACoS) Commission on Cancer (CoC) Cancer Program Requirements.

III. PURPOSE:

A forum to ensure the highest possible quality clinical management of the cancer patient. The Tumor Conference is an essential opportunity for routine multidisciplinary collaboration between physician, clinicians, allied health and support professionals for the purpose of providing comprehensive management of oncology patients. The Conference is also an on-going educational opportunity for those who attend.

IV. DEFINITIONS:

1. Multidisciplinary: Includes major disciplines involved in the management of cancer care. Specifically, at a minimum surgery, medical oncology, pathology, radiation oncology & diagnostic imaging.

2. Prospective case presentation: Cancer cases that include, but are not limited to:
    - A. Newly diagnosed and treatment not yet initiated;
    - B. Newly diagnosed and treatment initiated, but discussion of additional treatment is needed;
    - C. Previously diagnosed, initial treatment completed, but discussion of adjuvant treatment or treatment for recurrence or progression is needed;
    - D. Previously diagnosed and discussion of supportive or palliative care is needed;

3. Analytic caseload: Cancer cases required by the Commission on Cancer to be abstracted by the TRH Tumor Registry because of our program's primary responsibility in management of the cancer.

IV. PROCEDURE:

1. A listing of patients to be presented at each monthly Tumor Conference is compiled by contacting physicians and their office staff as well as by working with the Pathologist to obtain a listing of all cases diagnosed by histologic confirmation between monthly Tumor Conferences. The Tumor Registry will communicate with physician offices to determine the cases each physician wishes to be placed on the presentation listing for Tumor Conference. The listing will include all patients diagnosed and presentation cases will be highlighted in yellow. Diagnostic Radiology reports of ultrasounds, CT Scans, Mammograms, MRI's are reviewed monthly. PET scans from Alliant Imaging are also reviewed monthly. PET Scan verbal interpretation will be available with remote connection to the interpreting Radiologist. Inpatient and outpatient cases (diagnosed in hospital owned physician practice offices) are also obtained. The following shall occur to assure that all cases are captured for presentation at Tumor Conference:

    a. Medical Staff are reminded frequently to notify Cancer Registrar of any diagnosed malignancy(ies)/reportable cases.
    b. One week prior to the Conference, prepare a memorandum and forward to all staff physicians, physicians in surrounding communities, allied health practitioners either by e-mail, FAX or paper memorandum, dependent upon the practitioner's preference. The memorandum should include notification of Tumor Conference with a request to provide a listing of any cases for presentation. ***(SEE ATTACHMENT A)*** This memorandum is stored in Microsoft Word as "tbnotice". The notice is also forwarded to Nutritional Services and to the Education/Quality Department.
    c. A listing of all cases scheduled to be presented is compiled four (4) working days prior to Tumor Conference. This listing is forwarded to the Radiology Tumor Conference representative and to the Pathology representative and Medical Oncology.
    d. The listing shall include patient identification information; medical record number; date of birth; site of cancer; and name of physician to present the case.

2. Although any clinical & allied health discipline, as well as any support service who provide services for cancer patients are invited, attendance at Tumor Conference is required to be, at a minimum:
    A. Surgery;
    B. Medical oncology;
    C. Pathology
    D. Radiation oncology;
    E. Diagnostic imaging;
    F. Oncology Nursing;
    G. Tumor Registry

    Any deficit in attendance of the required disciplines will be reported to the Cancer Committee for discussion and action as warranted.

3. An attendance requirement for each discipline is 75% annually.

4. The Pathologist and Diagnostic Radiology representative/Radiologist shall be responsible for preparing visual aids for histology and radiological presentations at Tumor Conference.

5. Case presentations will be made by the practitioner with the most complete knowledge of the patient's clinical diagnosis. Presentations are to include, at a minimum, the following discussion:

    A. Review of the clinical evaluation (i.e., pertinent history, presentation, diagnostic imaging studies and pathology);

B. Case management presentation and extent of patient's disease, patient's performance status, prognostic indicators and co-morbid conditions;
C. Treatment performed to this point or, treatment plans;
D. Accurate AJCC stage, AUA (American Urological Association), Best Practice Guidelines or other appropriate stage;
E. National Comprehensive Cancer Center Network (NCCN) treatment guidelines or other treatment guidelines developed by nationally recognized associations, such as the American Society of Clinical Oncology (ASCO), should be considered when discussing treatment options, where appropriate;
F. Options for clinical trial participation;
G. Referrals to appropriate tertiary disciplines, if indicated;
    Other considerations that may be discussed are:
    a. Genetic testing and/or counseling;
    b. Palliative care, if indicated;
    c. Psychosocial care, if indicated;
    d. Rehabilitative services, if indicated.

6. Any diagnosed cancer case may be placed on the Tumor Conference Agenda. A minimum requirement of 80% of all prospective cases and a minimum of 15% of the analytic case load (annually) must be included on the Agenda for discussion. It will be the Tumor Conference Coordinator's responsibility to assure this standard is maintained.

    A. The Cancer Conference Coordinator will be responsible for recording minutes of each Tumor Conference. The following, at a minimum, must be recorded at the time each case is presented: (***See Attachment B***)
    B. Attendance at Conference;
    C. Summary of each case presentation, including:
        a. Name of presenter(s);
        b. Whether the case is prospective or retrospective;
        c. Stage, including prognostic indicators;
        d. Treatment planning (use of evidence based guidelines [i.e., NCCN]);
        e. Options for clinical trials;
        f. Inclusion of other disciplines in planning (i.e., palliative, rehabilitative);
    D. Notations of any educational discussions held.

7. Following Tumor Conference, medical records from Tumor Conference will be placed in shredding receptacle. Completed Staging Forms and any adjunct medical records will be forwarded to Healthcare Information Management for inclusion in the patient's medical record.

8. Original record of Tumor Conference presentations are maintained in the Tumor Registrar's office.

TAYLOR REGIONAL HOSPITAL
Jewish Hospital Health Network

ADM. POLICY: 490-38
DEPT. POLICY NO.: CR – 13
ATTACHMENT A

TAYLOR REGIONAL HOSPITAL

1700 Old Lebanon Road
Campbellsville, KY
42718
(270) 465-3561

Memorandum

DATE:

TO: All Staff Physicians
Tumor Conference Members

FROM: Jo Ann Smith, RHIT/CTR, Coordinator

THRU: Robert B. Romines, M.D., Chairman

SUBJECT: **Taylor Regional Hospital (fill in month) Tumor Conference**

Tumor Conference will be held on **Tuesday, (fill in date)** ***at noon in the hospital Meeting Room.*** Lunch will be served.

Tumor Conference has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the University of Louisville and Taylor Regional Hospital. The University of Louisville is accredited by the ACCME to provide continuing medical education for physicians.

The University of Louisville designates this educational activity for a maximum of 3 credits of *AMA PRA Category 1 Credit(s)*™. **Physicians should only claim credit commensurate with the extent of their participation in the activity.**

Upon completion of this course, participants will be able to:

- ➢ Review selected cases of patients with cancer and outline their prospective treatment
- ➢ Assure that cancer patients are receiving appropriate treatment options
- ➢ Discuss indications for various modalities of treatment for cancer patients including radiation, medical oncology and surgery

Please notify Jo Ann Smith at extension 5853 or 2329 of any cases you wish to discuss by no later than Friday, (fill in date). Thank you for your continued support and attendance.

ATTACHMENT B

TRH Cancer Conference Minutes Grid
Date
Standard 1.7

MR #	Site	Discussion of Stage (c or p)	Evidence Based Treatment Guidelines: NCCN and Best Practice Guidelines (AUA)	Prognostic Indicator	Prospective Case	Options for Clinical Trials	Genetic Testing/ Counseling	Palliative Care	Psycho-social Care	Rehab Service

Total Number of Cases Presented: ____________
Total Number Cases Eligible for Staging: ________
Treatment Guidelines Discussed: _____________

Total Number and % Prospective: ___________
Total Number and % Stage Assigned: ________

DATE: August 1986
REVIEWED: April 1994, January 1996, June 1997, April 2000, March 2001, January 2002, January 2003, February 2004, October 2009, April 2012
REVISED; April 1987, December 1998, June 1999, February 2004, October 2009, April 2011

ADM. POLICY NO.: 490-29
DEPT. POLICY NO.: CR-05

I. SUBJECT: Coding

II. POLICY: Topography and histology codes are assigned using the ICD-0-3 (Third Edition of the International Classification of Diseases for Oncology). General staging codes are assigned using Collaborative Staging Manual and Coding Instructions, and Multiple Primaries and Histologies Coding Rules.

III. PURPOSE: To assure consistent coding of cancer cases in order to abstract into Taylor Regional Hospital Cancer Registry and to assure that Commission on Cancer data standards and coding instructions set using the FORDS (Facility Oncology Registry Data Standards) manual are used to describe all reportable cases diagnosed January 1, 2003 and after.

IV. PROCEDURE:

1. Select the most specific code to identify the topography and histology of the disease to be coded.

2. As necessary, refer to the Third Edition of the International Classification of Diseases for Oncology for a complete listing of codes.

3. As necessary, refer to the Collaborative Staging Manual and Coding Instructions.

4. As necessary, refer to the Multiple Primaries and Histologies Coding Rules.