University at Buffalo The State University of New York

BUFFALO Clinical and Translational RESEARCH CENTER

Clinical Research Office

Clinical Trials Coverage Analysis Checklist

Purpose: Pursuant to the University at Buffalo Clinical Research Coverage Analysis Policy, the Principal Investigator (PI) shall complete and submit this checklist to the Clinical Research Office (CRO) to provide guidance for the accurate billing of research study clinical services, items and tests.

Instructions: Include this completed Analysis Checklist along with a copy of the Protocol, Budget, consent form and Contract. Note: Both the PI and Clinical Research Office representative must sign at Step IV before the study will be approved.

I. STUDY INFORMATION

Today's Date			
Principal Investigator's Name			
Study Long Title			
Study Short Title			
Sponsor(s)			
Sponsor Protocol #		**IRB #**	

1. Is this study investigator initiated? ☐ **Yes** ☐ **No**

2. What is the 8 digit ClinicalTrials.gov registration number for this study? (if applicable)

Effective January 1, 2014 this information is required on all claims:

Note: As of September, 2007, the FDA/NIH require registration of all clinical trials by the study sponsor at ClinicalTrials.gov. In investigator initiated clinical research, the Principal Investigator is responsible for compliance with this registration requirement. See http://clinicaltrials.gov/ct2/info/understand for further information.

3 a. At which site(s) of practice will study participants receive clinical services, items or tests?

Check all that apply

☐ **Women and Children's Hospital of Buffalo**
☐ **Gates Vascular Institute**
☐ **Buffalo General Medical Center**
☐ **Millard Fillmore Suburban**
☐ **ECMC**
☐ **DeGraff Memorial**
☐ **Other** (CRC, Practice Plan, Diagnostic testing site etc.) **_____CRC, Practice Plan_____**

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3 b. ☐ **100% OF STUDY PAID BY SPONSOR**

☐ **STUDY HAS SOME BILLABLE SERVICES**

FOR CRO USE ONLY: ☐ **Not QUAL** ☐ **QUAL** ☐ **IDE B** ☐ **IDE A**

4. What is the focus of this clinical research study? *Please check one:*

a. ☐ **Investigational device**
For investigational devices, please proceed to Sections II and IV ONLY

b. ☐ **Investigational drug or biologic**
For investigational drugs or biologics, please proceed to Sections III and IV ONLY

c. ☐ **Other (please describe): Post Approval Study**
For all "other" studies (non device, drug, or biologic), please proceed to Section IV ONLY

5. Do you consider the device, drug, biologic, or other that is the focus of the study to be:
☐ **Therapeutic** ☐ **Diagnostic** ☐ **Both** ☐ **Neither** *(Please check one)*

6. If considered a diagnostic or diagnostic *and* therapeutic study, will the study enroll any "healthy, control group volunteers"? ☐ **Yes** ☐ **No** ☐ **N/A** *(not a diagnostic study)*

II. INVESTIGATIONAL DEVICES

For investigational drugs, biologics or other studies, skip this section and proceed to Section III.

1. What is the FDA category of the device under investigation:
☐**Category A** ☐**Category B** ☐**Humanitarian Use** ☐**Post Approval** ☐**Other**

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2. Does the device have an Investigational Device Exemption (IDE) from the FDA? ☐ **Yes** ☒ **No**
If yes, please attach a copy of the FDA IDE assignment letter from study sponsor or FDA

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3. Who holds the IDE? ☐ **Sponsor** ☐ **Investigator** ☐ **Not Applicable**

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4. What is the IDE or Pre-Market Approval number assigned? **P050006/S060**
This information is Mandatory and required on all claims.

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5. Who will pay for the study device(s)?

☐ **Sponsor will provide device(s) free of charge**

☐ **Hospital will purchase device(s) and bill study participants and/or their insurance.**

☐ **Other, please describe:**

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6. Medicare and other third party payors may provide coverage for certain research-related clinical services, items, or tests provided to device study participants for studies that meet certain conditions and after pre-authorization is obtained from the local Medicare contractor or the appropriate CMS office.[1]

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[1] Effective January 1, 2015, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies, will have a centralized point of contact for submission, review and determination of Medicare coverage IDE study requests. 78 Fed. Reg. 74230, 74432. To seek coverage, submit requests via email to clinicalstudynotification@cms.hhs.gov or via hard copy to the following address: Centers for Medicare and Medicaid Services; Center for Clinical Standards and Quality; Director, Coverage and Analysis Group; ATTN: Clinical Study Certification; Mail Stop S3-02-01; 7500 Security Blvd.; Baltimore, MD 21244.

To qualify for coverage, the investigational device must:

- Appear on the listing of devices eligible for coverage/payment on CMS' master file of IDE devices, and the device or services associated with the use of a device must be provided to the beneficiary within the start and end dates contained in the master file;
- Be reasonable and necessary for the individual patient;
- Not be the subject of a national coverage policy prohibiting coverage

For pre-authorized Category A and Category B investigational devices, CMS typically covers "Routine Costs" including:

- "Standard of care": medically reasonable items or services which would be provided absent a patient's participation in a research study. Also called "usual care" and "conventional care." (examples include office visits, tests and procedures to evaluate, manage and treat patients.)

- "Expanded care": services "incident" or "related to" provision of the device, including items or services provided :
  - in preparation of use of the device or arising from the provision of the device, including for the prevention, diagnosis or treatment of complications;
  - contemporaneous with the device and necessary to use the device, such as the provision of the investigational item or service;
  - as necessary aftercare that is incident to recovery from use of the device, including the clinically appropriate monitoring of the effects of device.

- "Investigational": the investigational device itself if not provided free of charge by the sponsor and otherwise covered outside of the study. **Note: *CMS, Medicare/Medicaid, and other third party payors do not provide coverage of the device itself for Category A devices.***

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7. Does the PI intend to apply to the local Medicare contractor (National Government Services) or the appropriate CMS office to request clinical trial coverage? ☐ Yes ☐ No
(Please provide a copy of the approval letter when available)

III. INVESTIGATIONAL DRUGS, BIOLOGICS, AND OTHER

For investigational devices, skip this section and complete Section II.

1. Is the drug or biologic under investigation under an Investigational New Drug application (IND) or exempt from IND application under 21 CFR 312.2(b)(1)? (Meaning the study A. is not intended to be reported to the FDA in support of a new indication or a labeling change, B. is not intended to support a significant change in advertising, or C. does not involve a change in administration or dosage that significantly increases the risk associated with the product?)
☐ IND ☐ IND Exempt ☐ N/A

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2. If not exempt, who holds the IND? ☐ Sponsor ☐ Investigator ☐ N/A

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3. Does the study investigate an off-label use of a drug or biologic? ☐ Yes ☐ No ☐ N/A

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4. The study is a… ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Other _____

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5. If study involves neither an investigational drug nor biologic, please briefly describe study objective(s), goal(s), and/or aim(s): _____

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6. For all non-device clinical research studies, please evaluate whether the study is "Deemed Qualified" for coverage under Medicare's Clinical Trials Policy National Coverage Decision (NCD 310.1) by indicating whether this study meets the following criteria: Check all that apply.

	Yes	No
A. The purpose of the clinical research study is the evaluation of an item or service that falls within a Medicare benefit category, e.g. inpatient hospital care, physician services, durable medical equipment, diagnostic tests, etc. (For more information, see http://www.cms.hhs.gov/manuals/Downloads/bp102c16.pdf or http://www.medicare.gov/Coverage/home.asp).	☐	☐
B. The clinical research study has therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology.	☐	☐
C. The clinical research study design does not exclude enrollment of Medicare beneficiaries and if evaluating a therapeutic intervention, would enroll Medicare beneficiaries with diagnosed disease only, rather than healthy volunteers. If evaluating a diagnostic intervention, the trial may enroll healthy subjects as a control group.	☐	☐
D. The clinical research study is funded by one or more of the following (indicate funding source[s]): ☐ National Institute of Health (NIH), ☐ Centers for Disease Control (CDC), ☐ Agency for Healthcare Research and Quality (AHRQ), ☐ Centers for Medicare and Medicaid (CMS), ☐ Department of Defense (DOD), ☐ Veterans Affairs (VA), ☐ Supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, or VA.	☐	☐
E. The study will be conducted under an IND application or is exempt from needing an IND application (see #1 above).	☐	☐

If you checked 6A, 6B and 6C and at least one of 6D or 6E as Yes, the clinical research study is "Deemed Qualified" for Medicare coverage under NCD 310.1. Is this study deemed Qualified?

☐ **Yes** ☐ **No**

If "No," please STOP here and sign in Section IV. NOTE: Only "Routine Costs" care may be billed to study participants' Medicare or other third party payor. Such care will be denoted as "SOC" in the protocol billing grid.

"If Yes," please CONTINUE

7. Is the objective of this clinical research study to treat cancer or its complications?

☐ **Yes** ☐ **No**

If "No," please STOP here and sign in Section IV. NOTE: Only "Routine Costs" may be billed to study participants' Medicare or other third party payor.

If "Yes," please CONTINUE below.

8. Medicare/Medicaid and other third party payors may cover the following categories of care for deemed Qualified cancer treatment studies. Please check all care types for which the study intends to seek Medicare and/or third party coverage:

☐ "Standard of Care" (SOC):

- Medically reasonable items or services which would be provided absent a patient's participation in a research study. Also called “conventional care.” Examples include office visits, tests and procedures to evaluate, manage and treat patients.

☐ “Routine costs” such as items or services required for: -

- the provision of the investigational item or service (e.g. infusions or injections of a chemo-therapeutic agent);
- clinically appropriate monitoring of the effects of device, such as additional lab tests or radiological scans;
- medically reasonable and necessary care arising from the provision of the device, including the prevention, diagnosis or treatment of complications.

☐ The investigational item or service itself, if otherwise covered outside of the clinical trial and if not provided free of charge by sponsor

NOTE: The following non-covered, “Research only” items and services are always excluded from coverage and must be billed to the study grant, sponsor or department:

- Research only items and services provided *solely* to satisfy data collection and analysis needs and that are *not* used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan).
- Items and services customarily provided by the research sponsor free of charge for any enrollee in the trial.
- Other items and services paid for by the research sponsor or any other funding source.

NOTE: All other CMS coverage and billing rules apply.

Thank you. ***The Clinical Research Office will work with the study team to accurately identify each clinical item or service in the protocol and on the Protocol Billing Grid as one of the following: Standard of Care (SOC) – including any routine costs billable under Medicare’s NCD 310.1 or the investigational item or service itself if applicable – or non-covered Research-only (STUDY), billable only to the study.***

Please CONTINUE and sign in Section IV.

IV. INVESTIGATOR AND DEPARTMENT ATTESTATION

In signing this form, I confirm that all information contained herein is true and correct to the best of my knowledge. I also understand that changes made to the study protocol, informed consent, clinical trial agreement, budget, IRB application or other supporting documentation can affect the outcome of the Clinical Trials Policy Coverage Analysis and National Coverage Determination. I will communicate all changes promptly to the University at Buffalo Clinical Research Office for review and/or revision.

_____, Principal Investigator _____
(Signature) (Date)

_____, CRO Representative _____
(Signature) (Date)