MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE MANAGEMENT OF EXPANDED ACCESS & TREATMENT IND PROTOCOLS	
SOP#: 2.3	**Original Approval Date: 8/27/15**
Version#: 3.0	**Current revision Date: 3/10/25**

1.0 PURPOSE/BACKGROUND

Expanded Access and Treatment Use protocols (abbreviated to "Expanded Access protocols" in the remainder of this document) require substantial resource support to implement and maintain regulatory compliance. Often they require support for protocol submission to the IRB, acquisition of an IND, data collection and reporting of adverse events and drug utilization to the sponsor/IRB, and detailed discussions with patients regarding medical and financial risk. While the Cancer Center CTO and OCRICC have expertise relevant to these requirements, any resources devoted to maintaining Expanded Access protocols represents a trade-off against opening and accruing to meaningful clinical trials for the Cancer Center. Expanded Access protocols are not clinical research and therefore, do not contribute to the clinical trial accrual goals of the organization or publications for investigators.

Very careful consideration will be given to Expanded Access proposals submitted by clinicians to the Disease Oriented Teams (DOT). On rare occasions, consideration of an Expanded Access protocol is strategically valuable to the Cancer Center and the patients served. In these circumstances, it is important to have a rigorous process by which value of Expanded Access protocols can be fairly weighed against alternative clinical research opportunities that compete for the same resources. The purpose of this SOP is to outline the process for consideration and resource allocation of Expanded Access protocols in the Cancer Center.

2.0 SCOPE

This SOP affects all Expanded Access protocols proposed by an MCW Cancer Center clinician.

3.0 RESPONSIBILITY

Individuals impacted by this SOP include any regulatory staff, study coordinators, research managers, and physicians involved in the facilitation of all Expanded Access protocols. This will also impact the Cancer Center Disease Oriented Teams, Froedtert Pharmacy Staff, Froedtert clinic and/or inpatient staff, and the Office of Clinical Research and Innovative Care Compliance (OCRICC).

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions

Additional definitions:

Expanded Access Protocol: The use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition rather than to obtain the kind of information about the drug that is generally derived from clinical trials

Individual Patient Expanded Access IND: The use of an investigational drug (including a biologic) for use by a single patient submitted as a protocol under a new IND. The investigational product may or may not be under development.

Individual Patient Expanded Access Protocol: The use of an investigational drug (including a biologic) for use by a single patient submitted as a new protocol to an existing IND by the sponsor of the existing IND. Typically, several patients may follow the same protocol. The investigational product may or may not be under development.

5.0 ROLES AND PROCEDURES

5.1 Clinicians interested in an Expanded Access protocol must submit the *Expanded Access and Treatment IND Appendix* (Appendix I) to the corresponding DOT along with the Protocol Review - New Trial Submission Form. The submission must include a synopsis from the CCCTO and OCRICC summarizing resource requirements for the proposed protocol.

5.2 Once submitted to the DOT, the *Protocol Review – New Trial Submission Form*, the *Expanded Access and Treatment IND Supplement*, and protocol (if available) will be reviewed by the DOT Committee, the CCCTO Medical Director, and the CCCTO Administrative Director. If the CTO Medical and Administrative Directors require additional input, it will be escalated to the Associate Director of Clinical Research and/or Assistant Director. All reviewers should specifically consider the risk of withdrawing personnel from active or future research studies to conduct an expanded access or treatment IND protocol. This review should confirm there are no competing clinical research studies available to the program, and carefully consider its portfolio of active and pending studies and accrual as pertains to resource management. The sponsoring clinician may be expected to present and address questions.

5.3 If an Expanded Access protocol is approved by the DOT, CTO Medical Director, and CCCTO Administrative Director, and adequate funding is confirmed, the CCCTO will allocate resources to manage the protocol.

5.4 If an Expanded Access protocol is not approved by the DOT, CTO Medical Director, and CCCTO Administrative Director, the CCCTO will NOT allocate resources to manage the protocol in any way. Therefore, the sponsoring clinician will be responsible for the following:

- Completing sponsor and FDA documents, including requirements for ongoing FDA reporting.

- Completing application materials for the sponsor
- Reviewing, editing and submitting the application to the IRB and all relevant safety committees.
- Reviewing, editing and obtaining sponsor approval of the consent documents
- Contacting IDS pharmacy to facilitate drug procurement and ordering.
- Reviewing, editing and completing all Advance Beneficiary Notice of Noncoverage (ABN) and financial liability forms.
- Obtaining informed consent and ABN documentation for all potentially eligible patients.
- Collecting, reviewing, and submitting required data (including adverse events) to sponsor.
- Submitting amendments, continuing reviews, and reportable events to the IRB as required.

NOTE: The above list is not all encompassing. Many of the above bullet points are multi-step processes. Guidelines for the above will be provided to the clinician by CCCTO upon request.

6.0 REFERENCES

Expanded Access information, FDA website:
http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm

7.0 APPENDICES

Appendix I*: New Trial Submission Form: Expanded Access and Treatment IND Supplement*

8.0

Authorized by:	Signed Electronically by: Erin Lynch - eelynch@mcw.edu 21-Mar-2025 @ 12:55 PM CDT Reason: Approval CCCTO Administrative Director

Revision dates:
8/27/15, v 1.0
2/20/18, v 2.0
3/10/25 v 3.0

Review dates:
1/8/16, 2/14/17, 2/20/18, 3/16/20, 2/11/22, 3/10/25

Appendix I: New Trial Submission Form – *EXPANDED ACCESS AND TREATMENT IND SUPPLEMENT*

Note to submitting clinicians: Expanded Access protocols require substantial resource support to implement and maintain regulatory compliance. Often they require support for protocol submission to the IRB, acquisition of an IND, data collection, reporting of adverse events and drug utilization to the sponsor/IRB, and detailed discussions with patients regarding medical and financial risk of complications. While the Cancer Center CTO and OCRICC have expertise relevant to these requirements, any resources devoted to opening and maintaining Expanded Access protocols represents a trade-off against opening and accruing to meaningful clinical trials for the Cancer Center. Expanded Access protocols are not clinical research and therefore, do not contribute to the clinical trial accrual goals of the organization or publications for investigators.

Very careful consideration will be given to Expanded Access proposals submitted by clinicians to the Disease Oriented Teams. On rare occasions, consideration of an Expanded Access protocol is strategically valuable to the cancer center and the patients served.

Please complete the following form in addition to the New Trial Submission Form

Principal Investigator:	
Protocol Title & Synopsis:	
Type of Study	☐ Expanded Access ☐ Single Patient IND
Study Overview	
Drug indication:	*[NOTE: If this drug is FDA approved for any other indication, it would NOT be eligible for Treatment or Compassionate use.]*
Strategic value of the drug in the treatment portfolio of the indication; response rates:	
Treatment alternatives to the expanded access/treatment use drug:	
Would this Expanded Access protocol compete with any existing protocols?	

Anticipated duration of expanded access protocol, including FDA decision date, if known:	
Is this drug available via Expanded Access at any other regional medical centers?	
Please describe the anticipated value to the health system, if any. (i.e. Likelihood to attract new patients, establish relationship to new pharma company, etc.)	
Will this trial require an IND held by MCW?	
Describe sponsor/FDA reporting requirements:	
(a) List funding source(s) that will support this protocol **(b)** Confirm drug will be provided to patients for free. **(c)** Describe any other patient liability (i.e. infusion costs, hospitalizations, etc.)	
Estimation of resources required to manage protocol. (To be completed by CCCTO Research Manager, CCCTO Regulatory Manager, Froedtert Investigational Drug Pharmacy, OCRICC).	*[Most likely will be an attachment]*

Disease Oriented Team Recommendation:

☐ Disapprove
☐ Approve

DOT Chair Signature Date

☐ Disapprove
☐ Approve

CTO Medical Director Date

☐ Disapprove
☐ Approve

CCCTO Administrative Director Date

Return form to CTO Research Manager.