MEDICAL COLLEGE OF WISCONSIN CANCER CENTER **Cancer Center Clinical Trials Office**

STANDARD OPERATING PROCEDURE **STUDY SUBJECT UNBLINDING**	
SOP#: 5.7	**Original Approval Date: 12/5/14**
Version#: 4.0	**Current Revision Date: 3/16/20**

1.0 PURPOSE/BACKGROUND

Blinded research is an important tool in many fields of research. Clinical trials have a long history of using a Single Blind or Double Blind study design to prevent conscious and unconscious bias when comparing the safety and efficacy of two or more treatments. Unblinding is the process by which the allocation code is broken so that the investigator, clinical staff, and/or the trial statistician becomes aware of the intervention for a person participating in a trial. Unblinding must be undertaken by a pre-determined process to ensure that participating subjects are not unblinded unnecessarily and the study results are not compromised. Equally, unblinding should occur in a responsive manner when it is clinically indicated. The purpose of this SOP is to establish a quality standard for study subject unblinding for clinical trials managed by the Medical College of Wisconsin Cancer Center Clinical Trials Office (CCCTO).

2.0 SCOPE

This SOP applies to all blinded studies managed by the CCCTO.

3.0 RESPONSIBILITY

Individuals impacted by this SOP may include:

- Study Staff
- Investigational Drug Pharmacy
- Study Sponsors and their designees
- Others as required

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions.

Allocation Code: The code which identifies the intervention to which the subject is assigned.

Blinding: The procedure in which one or more parties in the study are kept unaware of the treatment assignment or allocation code (e.g., medication #1 vs. medication #2, investigational medication vs. placebo).

Double Blind: A blinded study design in which neither the study staff nor the study subjects know the treatment assignment or allocation code

Single Blind: A blinded study design in which members of the study staff know the treatment assignment or allocation code, but the study subjects do not know.

5.0 ROLES AND PROCEDURES

5.1 Blinding should be discussed with the potential study subjects during the initial consent conference and throughout their participation, as appropriate for each trial. For example, when appropriate, subjects should be made aware – and reminded – that they may likely never know to which treatment group they were assigned, even when going from active treatment into follow up.

5.2 Study staff must make every effort to ensure that the study blind is broken only in accordance with the study protocol. Written sponsor approval must be obtained prior to unblinding whenever possible. If the treating physician is not the Principal Investigator (PI), written approval from the PI should also be obtained.

5.3 The study sponsor may decide to unblind study subjects according to their own policies, practices, and SOPs. This SOP does not apply to subjects unblinded by the sponsor.

Non-Emergency Unblinding

5.4 With sponsor approval, it *may* be possible to unblind a subject when knowing the treatment assignment will directly impact the subject's next line of treatment.

5.5 Documented correspondence with the PI and study sponsor's approval to unblind must be obtained prior to unblinding.

Emergency Unblinding

5.6 Emergency unblinding is only appropriate during a medical emergency (as determined by the PI or treating physician) where knowledge of the treatment allocation code is likely to have a significant effect on the clinical management of the subject and would be instrumental in immediate treatment decisions (e.g., there is an antidote for the study drug for the serious adverse event that the subject is experiencing.)

5.7 In an emergency, it may not be feasible to obtain prior approval from the PI or sponsor. In this case, after the subject is successfully unblinded, there must be clear documentation explaining why unblinding was necessary. The PI, sponsor, IRB, and Research Manager should be notified as soon as possible.

Accidental Unblinding

5.8 If a subject is accidentally unblinded, clear documentation of events must be recorded, as well as communication with the sponsor, PI, and Research Manager. The treatment assignment must not be revealed to any other members of the study staff, pharmacy staff, or to the subject, unless written approval from the study sponsor is obtained. Every effort should be made to maintain what remains of the blind. In this case, a protocol deviation should be reported to the IRB of record.

6.0 REFERENCES

Guidance for Industry E6: Good Clinical Practice, section 4.7 *Randomization Procedures & Unblinding*.

7.0 APPENDICES

N/A

Authorized by: _____
James Thomas, Medical Director

_____
Betty Oleson, CTO Administrative Director

Revision dates:
12/5/14, v 1.0
2/14/17, v 2.0
2/20/18, v 3.0
3/16/20, v 4.0

Review dates:
3/2/15, 1/8/16, 2/14/17, 2/20/18, 3/16/20