Participation in the
ToxIC Qualified Clinical Data Registry

You (or your group) have expressed a willingness to participate in the American College of Medical Toxicology's ToxIC Qualified Clinical Data Registry (TQCDR). The TQCDR is one part of the ACMT ToxIC Registry. If you wish to participate in the TQCDR, it is required that you review, date and sign a Participation Agreement which details the obligations of the TQCDR and any obligations as it relates to the operations of the TQCDR.

AMERICAN COLLEGE OF MEDICAL TOXICOLOGY
TOXIC QCDR (TQCDR) PARTICIPANT AGREEMENT
BY AND BETWEEN THE AMERICAN COLLEGE OF MEDICAL TOXICOLOGY AND

_____

This Agreement is made on _____ [date], between the American College of Medical Toxicology (ACMT) and _____ [Site Lead "Participant"]. ACMT and Participant shall be referred to herein collectively as the "Parties" and individually as a "Party."

ACMT has developed the ACMT ToxIC QCDR (TQCDR), to collect and report on standardized national data related to medical toxicology information with the purpose of improving the quality of patient care.

The TQCDR permits comparisons of Participant data with national summary data to aid Participants in their efforts to improve patient care and to contribute to ACMT's research efforts to enhance quality improvement in medical toxicology.

Participant desires to participate in the TQCDR to contribute to the overall quality of patient care through quality assurance and improved peer review.

At the discretion of the participant, ACMT will provide the participant data to Centers for Medicare and Medicaid Services (CMS) as part of the CMS Merit-based Incentive Payment System (MIPS) program on an annual basis. Such reporting to CMS is a service provided by ACMT but is not mandatory and participation in the TQCDR does not require the participant report to CMS.

The Parties agree as follows:

1) Participant hereby agrees to participate in the TQCDR and ACMT hereby agrees to permit Participant to participate in the registry as provided herein.

2) Participant Responsibilities

a. Participant agrees to furnish clinical data for a twelve (12) month period following execution of this Agreement. Participant shall provide data for all eligible patients to ACMT for purposes of the TQCDR by securely transmitting the data as prescribed by the ToxIC Registry. These data will be entered into the TQCDR.

TQCDR measures database: Participant will submit one record containing de-identified data elements for each patient that is eligible for a TQCDR measure. Available measures and data element definitions for these measures are updated annually by the CMS and ACMT. TQCDR will update its list of measures and data elements annually following CMS announcements.

b. For those participants who wish to report to CMS, in Q1 2019 participants will attest that they are a Medicare provider and bill Medicare Part B services during the registration process for the submission of data for MIPS. Each will be asked to provide his/her name, NPI and TIN under which he/she bills Medicare, and contact information and confirm that the information is correct prior to submission of the data to CMS.

c. For those participants who wish to report to CMS, according to CMS requirements participants must report results on at least 60% of eligible cases for at least 6 quality measures.

c. Upon request by ACMT, Participant will furnish to ACMT independent corroboration, in a form satisfactory to ACMT in its sole, reasonable discretion, that all eligible patients' de-identified data has been submitted, based upon case volume counts.

d. Participant's data submission will be performed per specifications posted on the ToxIC Registry website.

e. Participant will designate a Site Contact who will serve as the primary point of contact for participation in the TRQCDR and will supervise the data collection, confirm the accuracy of the data, receive the confidential reports and act as direct liaison with ACMT.

f. In accordance with CMS requirements the participant agrees that its submitted data may be audited for accuracy and completeness by or on behalf of ACMT. If ACMT requests an audit, Participant agrees to provide corroborating evidence of the accuracy of submitted data in the form of additional supporting documentation. Participant agrees that if an audit process or the application of threshold criteria finds the data do not conform to ACMT standards, as a condition of continued participation in the TQCDR, Participant shall submit within forty-five (45) days of notice of the audit an action plan, in a form acceptable to ACMT, to correct such data issues. Furthermore, the non-conforming data submitted by the Participant will be withheld from the TRQCDR database for national reporting purposes, until such data are brought up to standard and resubmitted to ACMT by Participant. Moreover, during any such correction period, while Participant may receive information comparing its data to general data from the registry, ACMT makes no representation or warranty concerning the reliability of any such comparison or the conclusions Participant may draw from it.

f. Participant will promptly inform ACMT to deactivate the TRQCDR account of any staff member who is no longer employed by the participant or any staff member whose responsibilities no longer require access to the TRQCDR. Participant is responsible for the actions of any former staff member or current staff member who accesses the TRQCDR account without proper authority.

3) ACMT Responsibilities

a. ACMT agrees to accept Participant's clinical data, subject to review by ACMT, except where the submitted data do not conform to this Agreement including without limitation the data quality standards established by the TRQCDR as updated from time to time by ACMT. In such

cases, ACMT reserves the right to either reject the data submission in its entirety, or to limit the use of such data, if it does not meet ACMT's required standards, both with respect to new data and as set forth in Section 2e.

b. Prior to submission to CMS on behalf of each provider who wishes to report to CMS, ACMT will ask each provider to review and attest that all data and results are accurate and complete and authorize ACMT to share his or her email address for feedback report distribution.

ACMT will also confirm which measures should be submitted to CMS on the eligible participants' behalf, whether each has met the minimum number of measures within the performance period, whether the data is on all patients and not just Medicare, and any other data completeness requirements (e.g., at least 60% of patients seen regardless of payer that meet each measure's denominator criteria). The participant will be able to review and correct data prior to submission to CMS.

c. ACMT agrees to generate institutional reports for the registry based on Participant's submitted data and make reports available to Participant through the ACMT ToxIC Registry website. Reports include aggregated demographic, general procedural information and patient outcomes as appropriate in a form made available by ACMT to Participant and as updated by ACMT from time to time. Data Quality Reports will be made available as needed. National reports will be made available on a quarterly basis.

d. ACMT agrees to produce and periodically revise the data elements, definitions and formats used by the registry. Participant will be notified of any such revisions.

e. ACMT will provide a self-training document to guide Participant's data collection activities. ACMT will analyze the Participant's submitted data records by means of electronic data checks, consistency checks and range checks to review data accuracy and completeness. All reasonable efforts will be made by ACMT to communicate with Participant's Facility Administrator to assist the Participant in providing the submitted data.

f. ACMT may, at its option, audit Participant's submitted data to review its accuracy and completeness. ACMT will notify Participant within forty-five (45) days of the completion of the audit process (completion and return of data from the auditor) of the results of the audit and any action that the Participant may need to take as a result of the audit and may take any actions in response as provided in Section 2e of this agreement.

4) This Agreement shall be effective until December 31, 2018, then renew automatically for additional one (1) year terms unless Participant provides ACMT with ninety (90) days advance written notice of its desire to terminate this Agreement in its entirety or withdraw from participation in any of the other registries.

a. Either Party may terminate this Agreement without cause by providing the other with at least ninety (90) days written notice.

b. ACMT reserves the right to immediately terminate this Agreement and Participant's participation in the TQCDR if it determines that any one year of the Participant's data are noncompliant with TQCDR standards or otherwise unacceptable for inclusion in TQCDR national reporting data. ACMT may, in its sole discretion, provide Participant with the opportunity to cure the inadequate data as stated in Section 2e without affecting ACMT 's rights to terminate this Agreement under this Section or otherwise.

c. Upon termination of this Agreement Participant agrees that it shall not use TQCDR software or the TRQCDR dataset for collecting and reporting data or any other purpose without ACMT 's express written consent, except as necessary to wind down Participant's participation in the registry.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be

executed as of _____ (Date)

AMERICAN COLLEGE OF MEDICAL TOXICOLOGY

Date: _____ By: _____

Name: Paul M. Wax, MD, FACMAT

Title: Executive Director

SITE LEAD PARTICIPANT

Date: _____

By: _____ (Signature)

Name: _____

Title: _____

Primary Institution: _____

Contact Address: _____

Email: _____

OTHER PARTICIPANTS - Please add more participant signatures as needed

1) Date: _____

By: _____ (Signature)

Name: _____

Title: _____

Primary Institution: _____

Contact Address: _____

Email: _____

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2) Date: _____

By: _____ (Signature)

Name: _____

Title: _____

Primary Institution: _____

Contact Address: _____

Email: _____

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3) Date: _____

By: _____ (Signature)

Name: _____

Title: _____

Primary Institution: _____

Contact Address: _____

Email: _____