Supplemental Online Content (SOC)

# A Guide to Integrating Severe Maternal Morbidity Case Review into Hospital Quality Improvement Committees

December 2020

This SOC includes resources to support health departments, hospitals and maternity care providers, or other health care entities in integrating a systematic process of SMM case review into their existing quality improvement activities. The tools included here would allow these entities to collect and review individual SMM cases, hire appropriate staff to support this process, and create sustainable systems to act upon the findings.

## TABLE OF CONTENTS

# Sample Abstractor Job Description

**JOB DESCRIPTION - SMM ABSTRACTOR**

The Fund for Public Health in New York City, (FPHNYC) is seeking a medical professional to assist with a grant-funded research project focused on Severe Maternal Morbidity (SMM) running from October 1, 2017 to December 31, 2019. FPHNYC is a 501(c)3 non-profit organization that is dedicated to the advancement of the health and well-being of all New Yorkers. To this end, in partnership with the New York City Department of Health and Mental Hygiene (DOHMH), FPHNYC incubates innovative public health initiatives implemented by DOHMH to advance community health throughout the city. The *Merck for Mothers* SMM grant will strengthen and enhance the Bureau of Maternal, Infant and Reproductive Health's (BMIRH) work on SMM. The goal of the project is to work with clinical and community partners to promote health equity and reduce racial/ethnic disparities in SMM in NYC.

The part-time SMM Abstractor, reporting to SMM Team Leader at the DOHMH will assist the SMM Project to improve maternity care for NYC families through a quality improvement-focused initiative.

**RESPONSIBILITIES**

- Complete trainings for data abstraction
- Attend meetings at hospitals to learn about the facility's quality improvement (QI) process and to plan logistics of chart review and data abstraction
- Attend meetings with DOHMH to learn about the SMM and MM work and contribute input to these processes as requested
- Travel to hospitals to review SMM patient medical records, abstract data and enter it into the relevant database provided by DOHMH
- Compose de-identified case narratives and aggregate reports for quality assurance (QA) and QI meetings; work closely with hospital to assure case narratives meet hospital standards and requirements
- Attend QA/QI meetings at the hospital (as requested by QI committee) to present SMM case narratives and answer questions regarding the cases

**QUALIFICATIONS**

- Clinical experience as a nurse, midwife or physician in maternal health with specific background in public health, with a focus on maternal and child health; familiarity with clinical terms, abbreviations, processes, medical charts, HIPAA compliance
- Background in QA/QI in clinical setting
- Ability to maintain strict confidentiality
- Strong sense of professionalism and attention to detail
- Ability to travel to and work onsite at area hospitals, as well as at DOHMH offices
- Strong attention to detail
- Excellent communication skills
- Ability to work well independently and with inter-disciplinary teams
- Proficient at writing and speaking in front of a group
- Comfortable using MS Word, MS Excel, MS PowerPoint and common data entry platforms
- Availability at consistent day/time each week

# Sample Study Protocol

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE

**Institutional Review Board**
**New York City Department of Health and Mental Hygiene**
**Gotham Center – 31A**
**42-09 28th Street, 14th Floor**
**Queens, New York 11101-4132**
**Tele: 347-396-6118**
**Fax: 347-396-6088**
irbadmin@health.nyc.gov

# Protocol Summary

**to Conduct Research with Human Subjects at the**
**New York City Department of Health and Mental Hygiene (NYC DOHMH)**

**Project Title:** Hospital Reviews of Severe Maternal Morbidity (SMM) Cases
**Principal Investigator:**

**Request for an Exempt Determination:** Yes

All sections of the protocol summary may not apply to the project. Please complete the sections that are pertinent to the project. For all sections that do not apply, please indicate "Not Applicable."

## A. Study Purpose and Rationale

*Describe the background, objective, purpose, intent, and scientific aims of the human research in a couple sentences. State the hypothesis(es) to be tested, how the information collected will be utilized. Include pertinent background description with references that are related to the need to do this study.*

**Background:** The Bureau of Maternal, Infant and Reproductive Health (BMIRH) in the Division of Family and Child Health (DFCH) is responsible for ongoing surveillance of maternal mortality and severe maternal morbidity (SMM) in New York City. Building on this surveillance work, DOHMH will work with several NYC hospitals (listed in section C) on a project to strengthen their hospital-level SMM reviews through their quality improvement (QI) teams in order to better understand the chain of events leading to the SMM and to make recommendations to prevent future SMM events. As part of this project, DOHMH will support these hospitals through development of data collection and review forms, support to the QI teams including hiring a part-time Consultant to review hospital records and prepare case summaries for presentation at the hospital QI committee meetings. In addition, de-identified data will be shared with DOHMH in order to analyze aggregate de-identified data to determine SMM causes and contributory factors across the participating hospitals. Results will be disseminated through presentations or reports to participating hospitals and to the DOHMH Maternal Mortality and Morbidity Review Committee (M3RC). All M3RC members have signed DOHMH Consultant and Non-Disclosure Agreements. M3RC is a multidisciplinary expert group convened by DOHMH on a quarterly basis to review all maternal deaths in NYC to understand the chain of events leading to each death and to make recommendations to prevent these deaths in the future. By presenting aggregate de-identified results of hospital SMM reviews, M3RC recommendations will be informed by the causes and contributions of ***both*** maternal mortality and select morbidity cases in their recommendations for improving overall maternal health.

**Objectives**: To support hospital QI processes for reviewing SMM cases, to analyze aggregate de-identified data on SMM causes and contributory factors from participating hospitals, and to disseminate results back to participating hospitals and to the Maternal Mortality and Morbidity Review Committee (M3RC) in order to inform citywide policy recommendations for improving maternal health in NYC. This project includes the following specific aims:

- To support hospital QI processes to review their SMM cases
- To analyze aggregate de-identified hospital data to determine SMM causes and contributory factors
- To present results of this aggregate de-identified analysis to participating facilities and the M3RC to inform their recommendations to improve overall maternal health in NYC
- To conduct further analysis of these data pursuant to separate, future IRB applications

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE

**Institutional Review Board**
**New York City Department of Health and Mental Hygiene**
**Gotham Center – 31A**
**42-09 28th Street, 14th Floor**
**Queens, New York 11101-4132**
**Tele: 347-396-6118**
**Fax: 347-396-6088**
irbadmin@health.nyc.gov

# Protocol Summary

**to Conduct Research with Human Subjects at the**
**New York City Department of Health and Mental Hygiene (NYC DOHMH)**

**Data Source:** DOHMH has developed three data collection forms for use at participating hospitals to abstract de-identified data from medical charts and to record hospital QI committee decision results. These forms include a SMM Abstraction Form, SMM Case Narrative Form, and SMM Committee Decision Form (attachments), each of which contain no patient identifiers. De-identified hospital data will be shared with DOHMH for analysis of aggregate de-identified data to determine SMM causes and contributory factors, which will be disseminated to participating hospitals and to the DOHMH Maternal Mortality and Morbidity Review Committee (M3RC) to inform their policy and program recommendations for improving maternal health in NYC. All M3RC members have signed DOHMH Consultant and Non-Disclosure Agreements.

**Purpose and Intent:** Project findings will help strengthen hospital QI processes to review SMM cases, as well as to understand SMM causes and contributory factors in participating hospitals. DOHMH will use these results to complement maternal death reviews conducted by the DOHMH Maternal Mortality and Morbidity Review Committee (M3RC) such that a better understanding of the causes and contributory factors to ***both*** maternal mortality and morbidity will help inform DOHMH policy recommendations for improving overall maternal health outcomes.

**B. Study Design and Statistical Procedures**

*Describe the procedures in sufficient detail so that a reviewer who is not familiar with them can comprehend what is to be done and can evaluate any risks. Delineate procedures that are already being performed for diagnostic or treatment purposes from those that are being done for research, i.e., clearly identify those procedures that would be occurring whether or not the individual was participating in this research. Describe how the data will be analyzed.*

Contingent upon DOHMH and hospital IRB approvals, each participating hospital will screen all antepartum, intrapartum and postpartum (up to 42 days from end of pregnancy) hospitalizations for a severe maternal morbidity event defined as either an ICU admission or 4+ units blood products transfused. For each identified SMM case, hospital records will be reviewed by a Consultant hired by DOHMH (through the FPHNY project grant) who will be working at the hospital up to two days per week. The Consultant will abstract data from the hospital records in order to complete the SMM Abstraction Form and SMM Case Narrative, which will be presented to the hospital QI committee for their SMM case review. The Consultant will also complete the SMM Committee Decision Form based on the results of the SMM review by the hospital QI team. Each of these forms, which contain no patient identifiers, will be shared with DOHMH who is responsible for maintaining these de-identified data across for all participating hospitals. DOHMH will analyze aggregate de-identified data to determine SMM causes and contributory factors for SMM events across hospitals. These descriptive statistics will be presented to participating hospitals and the Maternal Mortality and Morbidity Review Committee (M3RC) in order to improve their understanding of these events and ways to prevent them in the future. All M3RC members have signed DOHMH Consultant and Non-Disclosure Agreements. The Consultant will work with hospital staff to determine the number of total deliveries at the hospital during the study period in order to calculate the hospital-specific and aggregate SMM rates ([number of SMM events/number of deliveries]*10,000). Hospital-specific SMM rates will only be shared with each specific hospital, and aggregate SMM rates will be used for grant reporting. Other analyses for research purposes will be conducted pursuant to separate IRB applications including conducting qualitative interviews with women who suffered SMM at a participating hospital. For this purpose, the Consultant will maintain a separate spreadsheet linking the Study ID on these data collection forms to the patient's Medical Record Number in order to link the patient interviewed with their SMM data

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

**Institutional Review Board**
**New York City Department of Health and Mental Hygiene**
**Gotham Center – 31A**
**42-09 28th Street, 14th Floor**
**Queens, New York 11101-4132**
**Tele: 347-396-6118**
**Fax: 347-396-6088**
irbadmin@health.nyc.gov

## Protocol Summary
**to Conduct Research with Human Subjects at the**
**New York City Department of Health and Mental Hygiene (NYC DOHMH)**

forms. This spreadsheet will be maintained in a separate DOHMH secure folder that is accessible only to the Consultant, Principal Investigator and select co-investigators as denoted on the IRB application. This spreadsheet containing linked patient identifiers will be deleted from DOHMH servers by approved project staff at the completion of the data collection period for each hospital.

**C. Setting of the Human Research**

*Describe the sites at which this project will be conducted. When applicable, describe: 1) At which institutions or sites the research procedures will be performed; 2) the location(s) where potential participants may be identified and recruited; 3) Composition and involvement of any community advisory board for research conducted outside of the NYC DOHMH; and, 4) For activities conducted at a non-DOHMH facility, please identify the location and facility to be used.*

DOHMH will work with up to 24 NYC hospitals through July 2022 as part of the Maternity Hospital Quality Improvement Network including: [INSERT NAMES OF STUDY SITES]. Contingent on IRB approvals, SMM cases will be identified among patients hospitalized within the Department of Obstetrics and Gynecology during either the antepartum, intrapartum or postpartum periods (up to 42 days after the end of pregnancy) who also meet the SMM eligibility criteria: ICU admission or at least 4 units of blood products transfused. There will be no community advisory board for this research.

**D. Study Drugs or Devices** ☒ N/A

*Please list all drugs or devices to be used in this study and describe how the drug or device works and past experience.*

☐ FDA Regulated Product (Please provide the IND/IDE number below and relevant documentation)
☐ Exempt from FDA (Please provide relevant documentation)
☐ Drug Form (Appendix A) completed
☐ Device Form (Appendix C) completed

Not applicable.

**E. Study Participants**

*Indicate the total number of participants to be accrued or records to be reviewed and if applicable at each site. If applicable, distinguish between the number of participants who are expected to be screened, enrolled (consent obtained), randomized, complete the research-related procedures, and between sub-groups (healthy volunteers vs. treatment cohort)*

*Is there an intervention or interaction with a living person that would not otherwise be occurring but for research purposes?* ☐ Yes ☒ No

Target Accrual: Click here to enter text. 50 to 200 per hospital not to exceed 4,800 across all 24 potential sites
Anticipated Number of Charts to be Reviewed: 50 to 200 per hospital not to exceed 4,800 across all 24 potential sites

No contact with human subjects will be made for this project; medical records will be reviewed for cases meeting the eligibility criteria. It is anticipated that there will be 1-10 SMM cases per hospital per month depending on the hospital's delivery volume and high-risk patient load. The total number of cases identified at each hospital will further vary by the duration of each hospital's participation in this project with DOHMH.

**F. Vulnerable Populations** ☐ N/A

*Please indicate if individuals from the following populations are targeted for recruitment and/or enrollment.*

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

**Institutional Review Board**
**New York City Department of Health and Mental Hygiene**
**Gotham Center – 31A**
**42-09 28th Street, 14th Floor**
**Queens, New York 11101-4132**
**Tele: 347-396-6118**
**Fax: 347-396-6088**
irbadmin@health.nyc.gov

# Protocol Summary

**to Conduct Research with Human Subjects at the**
**New York City Department of Health and Mental Hygiene (NYC DOHMH)**

| | |
|---|---|
| ☐ Children/Adolescents | ☒ Pregnant Women/Human Fetuses and Neonates |
| ☐ Prisoners | ☐ Elderly |
| ☐ Terminally Ill | ☐ Cognitively Impaired/Mentally Ill/Disabled |
| ☐ NYC DOHMH or other City Employees | ☐ Other: Click here to enter text. |

**G. Screening and Eligibility Criteria** ☐ N/A

*Give detailed inclusion and exclusion criteria and number of potential participants to be enrolled based on the statistical description and any other considerations. Describe how participants will be screened for eligibility.*

Contingent upon IRB approvals, all patients hospitalized at one of the participating hospitals within the Department of Obstetrics and Gynecology during the antepartum, intrapartum or postpartum periods (up to 42 days from end of pregnancy) and who meets the SMM eligibility criteria: ICU admission or at least 4 units blood products transfused will be included in the project. For all identified SMM cases, hospital records will be reviewed and key data from these charts will be entered into the SMM Abstraction Form, SMM Case Narrative Form, and SMM Committee Decision Form.

**H. Recruitment Method** ☒ N/A

*Describe in detail how participants will be recruited including type (e.g., newspaper advertisements, posters) and location (e.g., private practices, clinics). Attach a copy of each written advertisement and the script for each recruitment media or method that is verbal (e.g., video, telephone script). Please identify who will be conducting the recruitment and if this person is affiliated with NYC DOHMH? Please indicate if participants will be compensated along with the amount and timing of the payments.*

Will subjects be compensated for their participation? ☐ Yes ☐ No

☐ Study Instrument(s) attached
☐ Outreach media attached (i.e. flyers, e-mails, advertisements)

Not applicable.

**I. Informed Consent Process**

*Describe how consent will be obtained, including by whom (i.e., principal investigator, co-investigator, study coordinator), when, and by what method (e.g., in-person, verbally by telephone). Be sure to describe means of communicating if non-English speaking, illiterate, or other vulnerable persons will be included among study subjects. Also if necessary, describe any visual aids or devices that may be used to help explain a complicated procedure or process.*

☐ *An **Informed Consent Document** describing the research **WILL** be provided to the subject or the subject's legally authorized representative for signature.*

☐ ***Informed Consent** will be obtained and an **information sheet** describing the research WILL be provided to the subject or the subject's legally authorized representative. **NO** signature will be obtained. (Please request for a waiver of documentation of informed consent in the text box below and describe how informed consent will be obtained)*

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

**Institutional Review Board**
**New York City Department of Health and Mental Hygiene**
**Gotham Center – 31A**
**42-09 28th Street, 14th Floor**
**Queens, New York 11101-4132**
**Tele: 347-396-6118**
**Fax: 347-396-6088**
irbadmin@health.nyc.gov

# Protocol Summary

**to Conduct Research with Human Subjects at the**
**New York City Department of Health and Mental Hygiene (NYC DOHMH)**

☐ ***Informed Consent*** *will be obtained and the participants* ***WILL NOT*** *receive an information sheet. (Please request for a waiver of documentation of consent in the text box below and describe how informed consent will be obtained)*

☒ ***No Consent*** *will be obtained. (Please request for a waiver of informed consent process in the text box below; unless exempt)*

*For all requests for a waiver of informed consent or alteration of the consent process, the following criteria must be met:*

1. *The research involves* ***no*** *more than minimal risk to the subjects;*
2. *The waiver or alteration will* ***NOT*** *adversely affect the rights and welfare of the subjects;*
3. The research could **NOT** practicably be carried out without the waiver or alteration; AND,
4. Whenever appropriate, the subjects will be provided with additional pertinent information after their participation.

*For all requests for a waiver of documentation of informed consent, the following criteria must be met:*

1. *The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subjects wants documentation linking the subject with the research and the subject's wishes will govern*

*OR*

2. *That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.*

☐ Consent document(s) attached

We are requesting a waiver of the consent process based on the criteria listed above. The main purpose of this project is for DOHMH to support the hospital QI processes to strengthen their SMM case reviews and to analyze de-identified aggregate results of the facility-level SMM reviews across the participating hospitals to inform ways to improve hospital practices and to inform M3RC expert discussions for improving overall maternal health using *both* mortality and select morbidity cases. All M3RC members have signed DOHMH Consultant and Non-Disclosure Agreements. This project poses no more than minimal risk to the subjects; granting the waiver will not adversely affect the rights or welfare of the subjects; and the project could not practicably be carried out without this waiver.

**J. Additional Informed Consent Provisions** ☒ N/A

☐ **Children/Adolescents:**

*Describe whether child subjects may be expected to attain legal age to consent to the procedures of the research prior to the completion of their participation in the research (including storage of samples). If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Describe the timing of this process, and what will occur if consent is not obtained from the now-adult subjects.*

*Parental permission will be obtained from:*

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

**Institutional Review Board**
**New York City Department of Health and Mental Hygiene**
**Gotham Center – 31A**
**42-09 28th Street, 14th Floor**
**Queens, New York 11101-4132**
**Tele: 347-396-6118**
**Fax: 347-396-6088**
irbadmin@health.nyc.gov

## Protocol Summary
**to Conduct Research with Human Subjects at the**
**New York City Department of Health and Mental Hygiene (NYC DOHMH)**

☐ *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*

☐ *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*

☐ *Permission will be obtained from individuals other than parents. Describe the process used to determine these individuals' authority to consent to each child's general medical care in the text box below.*

☐ *No parental permission will be obtained. Justification is to be provided in the text box below.*

*Assent from the children/adolescents will be obtained from:*

☐ *All of the children/adolescents.*

☐ *Some of the children/adolescents. Please indicate which children will be required to assent in the text box below.*

☐ *None of the children/adolescents. Justification is to be provided in the text box below.*

### ☐ Cognitively Impaired Adults

*If the human research involves adults who may be unable to consent, describe the process to determine whether an individual is capable of consent.*

*If the Human Research involves cognitively impaired adults:*

- *If permission of a legally authorized representative will be obtained:*
  - *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
  - *Describe the process for assent of the subjects. Indicate whether:*
    - *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.*
    - *If assent will not be obtained from some or all subjects, an explanation of why not.*
    - *Describe whether assent of the subjects will be documented and the process to document assent.*

### ☐ Non-English Speaking Subjects

*Indicate what language(s) other than English are understood by prospective subjects or representatives. If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. If you intend to exclude potential participants who do not speak English, provide a justification for doing so. Please note that an oral translator is not sufficient for the enrollment of individuals who do not speak English. The English, IRB approved consent document must be translated into another language and submitted for IRB approval before a non-English speaking participant is enrolled. Accuracy of the translation must be certified (or attested).*

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE

**Institutional Review Board**
**New York City Department of Health and Mental Hygiene**
**Gotham Center – 31A**
**42-09 28th Street, 14th Floor**
**Queens, New York 11101-4132**
**Tele: 347-396-6118**
**Fax: 347-396-6088**
irbadmin@health.nyc.gov

## Protocol Summary
**to Conduct Research with Human Subjects at the**
**New York City Department of Health and Mental Hygiene (NYC DOHMH)**

Not applicable.

### K. Study Procedures

*Provide a description of all research procedures (e.g. questionnaires, record review, medical exams), when they will be performed (e.g. baseline, initial visit, follow-up visits).*

☐ Survey(s)/Questionnaire(s) attached ☐ Case Report Form(s) attached

**SMM screening:** Contingent upon IRB approvals, all patients hospitalized at one of the participating hospitals within the Department of Obstetrics and Gynecology during the antepartum, intrapartum or postpartum periods (up to 42 days from end of pregnancy) and who meet the SMM eligibility criteria of either ICU admission or at least 4 units blood products transfused will be included in the project. A list of these patients will be provided to the Consultant within one day to 1 week of the event in order to conduct record reviews as soon as possible after the event and in preparation for routine departmental QI meetings.

**Medical record review:** For all identified SMM cases, hospital records will be reviewed by the Consultant hired by DOHMH (through the FPHNY grant) during the same week, or as close as possible, to the SMM event. Key information from hospital records will be abstracted and entered into the SMM Abstraction Form and SMM Case Narrative Form. These forms summarize key events leading up to the SMM event, which will be used to present the case to the hospital QI committee. Once the QI committee reviews the case, the Consultant will complete the SMM Committee Decision Form that records the decisions of this review. All three forms contain no identifying patient information. Importantly, the Consultant will also maintain a separate spreadsheet that links the Study ID on these forms to the patient's Medical Record Number for purposes of future analyses including qualitative interviews with SMM patients such that we will need to link the interviewed patient to their SMM forms. This spreadsheet will be maintained on DOHMH secure servers that is accessible only to the Consultant, the Principal Investigator and select co-investigators as denoted on the IRB application. This spreadsheet containing linked patient identifiers will be deleted from DOHMH servers by approved project staff at the completion of the data collection period for each hospital.

**Data analysis and dissemination:** The de-identified data from these forms will be shared with DOHMH through BISCOM or remote connection to DOHMH secured servers accessible by approved project staff. DOHMH will conduct analysis of cause and contributors to the SMM events across participating facilities in order to disseminate back to facilities, as well as to present aggregate de-identified data to the M3RC. All M3RC members have signed a DOHMH Consultant and Non-Disclosure Agreement. The ultimate goal is to use these aggregate de-identified data to help inform hospital best practices and citywide policies to improve maternal health outcomes. Any further analyses of these data for research purposes will be conducted pursuant to separate, future IRB applications.

### L. Confidentiality of Study Data

*Describe how this will be maintained (if it is to be maintained) locally, and during transmission to another site, if applicable. Include a clear description of how data will be stored, specifically indicating whether data will contain direct or indirect identifiers. Describe protections related to accessing the study data, whether in an electronic or paper form.*

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE

**Institutional Review Board**
**New York City Department of Health and Mental Hygiene**
**Gotham Center – 31A**
**42-09 28th Street, 14th Floor**
**Queens, New York 11101-4132**
**Tele: 347-396-6118**
**Fax: 347-396-6088**
irbadmin@health.nyc.gov

## Protocol Summary
**to Conduct Research with Human Subjects at the**
**New York City Department of Health and Mental Hygiene (NYC DOHMH)**

*Please note that "de-identified" means that identifiers have been removed and no one (research team or others) can identify from whom the data or sample was collected. "Coded" means that the data/specimens are labeled with a code number, and there is a link between the respondent/donor and the data/specimen, i.e., someone can identify from whom the data/sample was collected if they have the link to the code. For any coded data/samples, indicate who, if anyone on the research team has access to the identifiable data.*

*Will identifiable private information be obtained for this research in any form directly or indirectly associated with a living individual?*
☒ Yes ☐ No

*If personal identifiers are to be collected, please indicate in the text box below which identifiers will be obtained (i.e., name, date of birth, addresses, telephone numbers, social security numbers, medical records, license numbers, IP addresses, photos, images, unique identifiers and/or etc.)*

The Consultant (hired by DOHMH and based at the hospital up to 2 days per week) will be provided with a DOHMH laptop in order to remotely connect to DOHMH secured shared folders where electronic copies of the completed SMM Abstraction Form, SMM Case Narrative Form and SMM Committee Decision Form will be saved and maintained for each case. De-identified data from these forms will be entered by approved DOHMH project staff into the Maternal Mortality Review Information Application (MMRIA), which is a database stored on DOHMH secure servers to maintain SMM review results from the participating hospitals.

In addition to the SMM Forms, the Consultant will also maintain a separate spreadsheet that links the Study ID on the data collection forms to the patient's medical record number for purposes of future analyses, which will be part of a separate IRB application. This includes potential qualitative interviews with SMM patients such that we will need to link the interviewed patient to their SMM data form. This spreadsheet will be maintained on DOHMH secure folders and only accessible to the Consultant, Principal Investigator and co-investigators for data analysis (as denoted on the IRB application). This spreadsheet containing linked patient identifiers will be deleted from DOHMH servers by approved project staff at the completion of the data collection period for each hospital.

All data will be stored on secure servers with DOHMH according to the DOHMH Data Security Plan and Acceptable Use Policy. Only DOHMH staff and consultants authorized to work on this project (those who have signed and submitted affidavits) and who are listed on the IRB application will have permission to access the agency shared secured folder where these data will be maintained. Access permissions are controlled by DIIT network administrators and authorized by the Principal Investigator and co-investigators on this IRB application. Access is blocked to unauthorized personnel. As an additional precaution, analysts must change their passwords every 90 days when prompted by network messages. All BMIRH staff must complete mandatory DOHMH confidentiality training to ensure compliance with established practices.

**M. Privacy Protections**

*Describe how subject privacy will be protected, and the limits to protection. Privacy protection may be summarized as safeguarding an individual's expectation that the information they offer will be held in confidence. Protections should cover (e.g.,)*

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

**Institutional Review Board**
**New York City Department of Health and Mental Hygiene**
**Gotham Center – 31A**
**42-09 28th Street, 14th Floor**
**Queens, New York 11101-4132**
**Tele: 347-396-6118**
**Fax: 347-396-6088**
irbadmin@health.nyc.gov

## Protocol Summary
**to Conduct Research with Human Subjects at the**
**New York City Department of Health and Mental Hygiene (NYC DOHMH)**

| |
|---|
| *screening activities, HIPAA provisions, forums such as focus groups where private information may be shared, and recordings of research activities, as applicable. Limitations such as compelled disclosure and mandatory reporting should also be described.* |
| See Confidentiality of Study Data section. |
| **N. Data Safety Monitoring** ☒ N/A<br>*Describe how data and safety will be monitored locally to identify unanticipated problems (i.e., events, outcomes, or occurrences that are unexpected, at least possibly related to the research, and suggest an increase in risk of harm to subjects or others).* |
| Not applicable. |
| **O. Potential Risks**<br>*Describe risks including data on risks that have been encountered in past studies. That is, if the occurrence of a certain adverse event was 20%, include those data in this description. Please include steps that will be taken to minimize the risk or harms to protect the welfare of subjects.*<br><br>☒ No More than Minimal Risk<br>☐ Minimal Risk<br>☐ Greater than Minimal Risk |
| No more than minimal risk. |
| **P. Potential Benefits**<br>*This description should also be based on accrued data from related studies that have been completed. Anticipated benefits of this study may include to society, knowledge, and/or direct benefit to the subjects. Please note that compensation cannot be a potential benefit for participating in the study.* |
| There is no direct benefit to subjects although results could contribute to improved hospital QI processes for reviewing SMM cases that could improve overall quality care provided to patients. Results could also contribute to greater societal knowledge of the causes and contributory factors to SMM cases. Such evidence could help DOHMH improve its citywide policy and program recommendations for improving overall maternal health in NYC. |
| **Q. Alternatives**<br>*Describe alternative therapies providing data to support their efficacy or lack of efficacy. An important alternative is also not to participate in this research.* |
| Not applicable. |
| **R. External Sites** ☐ N/A<br>*If NYC DOHMH investigators will be conducting research at one or more non-DOHMH site(s), additional information is required. This includes, but is not limited to, plans for authorization and/or IRB approval at each site, explanation of funding and organizational relationships, description of procedures at each site, and plans for data and safety monitoring. Details, as applicable to the various types of situations that may occur. Describe whether results will be shared with subjects or others (e.g., the subject's or their primary care physicians), and if so, describe how it will be shared. As applicable, this may include individual patient results (genetic testing), incidental findings, or overall study findings.*<br><br>☐ *External IRB Document(s) attached – **TO BE COMPLETED*** |
| IRB approval from each participating hospital will be sought after DOHMH IRB application submission. Hospital IRB approval letters, once received, will be submitted to DOHMH IRB. Each institution will not implement the protocol |

**Institutional Review Board**
**New York City Department of Health and Mental Hygiene**
**Gotham Center – 31A**
**42-09 28th Street, 14th Floor**
**Queens, New York 11101-4132**
**Tele: 347-396-6118**
**Fax: 347-396-6088**
irbadmin@health.nyc.gov

## Protocol Summary
**to Conduct Research with Human Subjects at the**
**New York City Department of Health and Mental Hygiene (NYC DOHMH)**

until their own institution has approved the IRB project activities. DOHMH will not provide any direct funding to hospitals for participation but will hire a part-time Consultant through the FPHNY grant to work at the hospital up to 2 days per week for the project period. The Consultant will support the hospital QI process by reviewing medical records for SMM cases and by completing the SMM Abstraction Form, SMM Case Narrative Form and SMM Committee Decision Form. The procedures used in each hospital are described in the "Study Procedures" section.

**S. NYC DOHMH as Lead Institution** ☐ N/A

*If NYC DOHMH will serve as the lead institution for a multi-site study, specific information about management of information related to safety of subjects must be provided. This includes, but is not limited to: 1) obtaining and maintaining IRB approval at each site; 2) ensuring that each site follows consent procedures and utilizes consent documents approved by the designated IRB (if the designated IRB is not the NYC DOHMH IRB, then the IRB-approved consent document must be similar to the NYC DOHMH IRB-approved consent document with regards the content and style of the document); and 3) plans for data and safety monitoring.*

☐ Individual Investigator Agreement(s) attached
☐ IRB Authorization Agreement(s) attached

Not applicable. IRB approval from participating hospitals will be sought after submission of this DOHMH IRB application and hospital IRB approval letters, once received, will be submitted to the DOHMH IRB. We are requesting a waiver for the consent process. Completed forms and de-identified hospital data will be shared with DOHMH via remote connection to DOHMH secure servers accessible only to project staff.

☒ **I certify that the information I provide in this form is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Institutional Review Board. I agree to conduct Human Research in accordance with applicable regulations and agency policies and procedures.**

**This form was completed on behalf of the Principal Investigator by*:**
**Date:**

*The Principal Investigator may designate an individual on the research team to complete regulatory documents. Please cc the Principal Investigator on all electronic communications*

# Sample Data Use Agreement

# Data Use And Non-Disclosure Agreement
# Between
# The New York City Department of Health and Mental Hygiene
# And
# [INSERT HOSPITAL NAME] ("Data Provider")

This **DATA USE AND NON-DISCLOSURE AGREEMENT** ("Agreement") made as of the January 1, 2020 ("Effective Date") by and between the City of New York ("City") acting by and through its Department of Health and Mental Hygiene ("DOHMH"), Division of Child and Family Health, having its primary offices at Gotham Center, 42-09 28th Street, Queens, NY 11101-4132, and [INSERT HOSPITAL NAME] ("Data Provider"), having its primary offices at [INSERT HOSPITAL ADDRESS] (each a "Party" and, collectively, the "Parties").
.

**WHEREAS**, DOHMH's Bureau of Maternal, Infant and Reproductive Health (BMIRH) program will work with [INSERT HOSPITAL NAME] to support its quality improvement (QI) team to conduct clinical reviews of severe maternal morbidity (SMM) cases. [INSERT HOSPITAL NAME] will share de-identified results of its SMM reviews with DOHMH. DOHMH will present aggregated de-identified summaries of SMM case review results across the participating hospitals, which includes [INSERT HOSPITAL NAME], to DOHMH's Maternal Mortality and Morbidity Review Committee (M3RC). This will help inform M3RC policy recommendations for improving maternal health in NYC.

**NOW, THEREFORE**, in consideration of the mutual promises and covenants contained in this Agreement, and other valuable and good consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree to the following:

## I. TERM AND TERMINATION

**A. Term.** This Agreement shall commence as of the Effective Date and shall terminate on June 30, 2022.

**B. Termination.** Either Party may terminate this agreement without cause upon 30 days written notice to the other Party.

## II. PURPOSE OF AGREEMENT

This Agreement sets forth the terms and conditions under which the formal access to certain data, as described in Section III of this Agreement and **Attachment A** hereto, is to be provided to DOHMH by the Data Provider. This Agreement also describes, in its **Attachment B**, what use the DOHMH may make of the Data.

## III. THE DATA

**Definition of Data.** Data shall mean the data produced by the Data Provider and transmitted to DOHMH pursuant to this Agreement and will include, without limitation, the specific description and data elements set forth in **Attachment A** to this Agreement.

## IV. PERMITTED USES OF THE DATA

DOHMH agrees to use the Data solely for the purposes set forth in **Attachment B** to this Agreement, and for no other purposes.

## V. CONFIDENTIALITY AND SECURITY OF DATA

A. **Compliance with Applicable Privacy and Security Laws, Rules, and Regulations.** The Data provided under this Agreement shall be used and maintained in accordance with applicable provisions of federal, state, and local laws, rules and regulations.

B. **Security and Confidentiality.** When Data Recipient receives Data from DOHMH in accordance with this Agreement, or creates and/or uses files derived from Data, Data Recipient shall maintain the security and confidentiality of Data as required by this Agreement and applicable laws, rules and regulations. Except as otherwise provided in this Agreement, Data Recipient shall not, at any time, directly or indirectly, disclose, share, give, loan, sell, or otherwise grant access to the Data provided pursuant to this Agreement, in part or in whole, to any other person or organization.

## VI. NOTICE

All notices under this Agreement shall be in writing and shall be deemed delivered as follows: (1) if by personal delivery or electronic mail, upon receipt; (2) if by Federal Express or by another national overnight courier, upon the second business day after deposit with such courier; or (3) if by US certified mail, return receipt requested, upon the fifth day after deposit in the mail. All notices shall be sent to the names and addresses set forth below. Either Party may change its contact information by notice to the other; any such change shall take effect immediately upon delivery of such notice. Any notice pursuant to this Agreement shall be given or made to the respective Parties as follows:

For DOHMH:

New York City Department of
Health and Mental Hygiene
Attn:

Cc: (for breach notifications)
DOHMH Chief Privacy Officer
42-09 28th Street, 14th Floor, CN30
Long Island City, New York 11101
Email:

For Data Provider:

[INSERT HOSPITAL NAME]
[INSERT HOSPITAL ADDRESS]

Attn: [INSERT NAME]
Chief Executive Officer
Click here to enter text.

## VII. PUBLICATION AND PUBLIC RELEASE OF DATA

Subject to the terms of this Agreement, including without limitation, **Attachment B** to this Agreement, which describes the uses that DOHMH may make of the Data, DOHMH may publish or publicly present its work as described in **Attachment B**, which must not contain any individually identifiable information, of the use undertaken in accord with **Attachment B**.

## VIII. MERGER CLAUSE

This Agreement and the Attachments hereto constitute the entire understanding of the Parties and merges all prior discussions, agreements or understandings into it. No prior agreement, oral or otherwise, regarding the subject matter of this Agreement shall be deemed to exist or to bind any of the Parties.

## IX. MODIFICATION

A. This Agreement may, from time to time, be modified by a writing signed by authorized representatives of the Parties. It may not be altered, modified, rescinded or extended orally.

B. The Attachments hereto may be modified upon written agreement by the Parties without the need to formally amend this Agreement. Each attachment that is modified shall be deemed to be part of this Agreement and will supersede any prior

Attachment, or Attachment modification, as applicable. Upon the modification of any Attachment, all references in this Agreement to such attachment shall be deemed to be references to the Attachment as modified.

## X. NO THIRD PARTY BENEFICIARY

Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the Parties, any rights, remedies, obligations, or liabilities whatsoever.

## XI. ADDITIONAL PROVISIONS

A. **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York (without regard to choice of law or conflict of law principles) and the laws of the United States, where applicable.

B. **Jurisdiction and Venue.** The Parties agree that any and all claims arising under or related to this Agreement shall solely be heard and determined either in the courts of the United States located in the City of New York or in the courts of the State of New York located in the City and County of New York. Data Recipient hereby waives personal service by personal delivery and agrees that service of process may be made by post-paid certified mail directed to Data Recipient at Data Recipient's address set forth in the Notice section of this Agreement, to be effective with the same effect as though personally served.

C. **Agency.** For purposes of this Agreement, Data Recipient shall be deemed to be acting as an independent entity, and not as an agent, of DOHMH or the City.

D. **Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same Agreement. This Agreement may also be executed in counterpart facsimile or scanned signatures, each of which facsimile or scanned signature of a Party shall be deemed to be the original signature of such Party.

E. **Headings.** The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement.

**IN WITNESS WHEREOF,** and intending to be legally bound, the Parties hereto have executed this Agreement as of the day and date first written above.

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

By: _____

Deputy Commissioner
Division of Family and Child Health

[INSERT HOSPITAL NAME]

By: _____
Chief Executive Officer

## Data Use And Non-Disclosure Agreement

### ATTACHMENT A – DATA POINTS

In accordance with Section III(A) of this Agreement, Data shall mean the data produced by DOHMH and transmitted to Data Recipient pursuant to this Agreement and will include, without limitation, the specific description and data elements set forth below:

**Data shared with DOHMH will include all data elements listed in the attached forms:**

1. **SMM Abstraction Form**
2. **SMM Case Narrative Form**
3. **SMM Committee Decision Form**

## Data Use And Non-Disclosure Agreement

### ATTACHMENT B – Project Description and Data Use

In accordance with Section IV(A) of this Agreement, Data Recipient agrees to use the Data solely for the purposes and project set forth below, and for no other purposes:

**Project Description** The Bureau of Maternal, Infant and Reproductive Health (BMIRH) in the Division of Family and Child Health (DFCH) within the NYC Department of Health and Mental Hygiene (DOHMH) is responsible for ongoing surveillance of maternal mortality and severe maternal morbidity (SMM) in New York City (DOHMH IRB 16-150 and 14-052). Building on this surveillance work, DOHMH will work with three NYC hospitals on a project to strengthen their hospital-level SMM reviews through their quality improvement (QI) teams in order to better understand the chain of events leading to the SMM and to make recommendations to prevent future SMM events. As part of this project, DOHMH will support these three hospitals through development of data collection and review forms, support to the QI teams including hiring a part-time Consultant to review hospital records and prepare case summaries for presentation at the hospital QI committee meetings. De-identified results of the SMM case reviews will be shared with DOHMH in order to analyze aggregate de-identified data to determine SMM causes and contributory factors across the participating hospitals, including [INSERT HOSPITAL NAME]. In addition, the Principal Investigator at [INSERT HOSPITAL NAME] will maintain a separate spreadsheet that links the Study ID to the patient's Medical Record Number for purposes of proposed future analyses (pursuant to separate IRB applications) including potential qualitative interviews with SMM patients such that the interviewed patient can be linked to their SMM data form.

**Project Objectives**: To support hospital QI processes for reviewing SMM cases, to analyze aggregate de-identified data on SMM causes and contributory factors from participating hospitals, and to disseminate results back to participating hospitals and to the Maternal Mortality and Morbidity Review Committee (M3RC) in order to inform citywide policy recommendations for improving maternal health in NYC. This project includes the following specific aims:

- To support hospital QI processes to review their SMM cases
- To analyze aggregate de-identified hospital data to determine SMM causes and contributory factors
- To present results of this aggregate de-identified analysis to participating facilities and the M3RC to inform their recommendations to improve overall maternal health in NYC
- To conduct further analysis of these data pursuant to separate IRB applications

**Data Source:** DOHMH has developed three data collection forms for use at participating hospitals, including [INSERT HOSPITAL NAME], to abstract de-identified data from medical charts and to record hospital QI committee decision results. These forms include a SMM

Abstraction Form, SMM Case Narrative Form, and SMM Committee Decision Form (attachments), each of which contain no patient identifiers. De-identified hospital data will be shared with DOHMH for analysis of aggregate de-identified data to determine SMM causes and contributory factors, which will be disseminated to participating hospitals and to the DOHMH Maternal Mortality and Morbidity Review Committee (M3RC) to inform their policy and program recommendations for improving maternal health in NYC. All M3RC members have signed DOHMH Consultant and Non-Disclosure Agreements. In addition, the Principal Investigator at [INSERT HOSPITAL NAME] will maintain a separate spreadsheet that links the Study ID to the patient's Medical Record Number for purposes of proposed future analyses (pursuant to separate IRB applications) including potential qualitative interviews with SMM patients such that the interviewed patient can be linked to their SMM data form.

**Data Use:** Results will be disseminated through presentations or reports to participating hospitals and to the DOHMH Maternal Mortality and Morbidity Review Committee (M3RC). All M3RC members have signed DOHMH Consultant and Non-Disclosure Agreements. M3RC is a multidisciplinary expert group convened by DOHMH on a quarterly basis to review all maternal deaths in NYC to understand the chain of events leading to each death and to make recommendations to prevent these deaths in the future. By presenting aggregate de-identified results of hospital SMM reviews, M3RC recommendations will be informed by the causes and contributions of ***both*** maternal mortality and select morbidity cases in their recommendations for improving overall maternal health.

**Purpose and Intent:** Project findings will help strengthen hospital QI processes to review SMM cases, as well as to understand SMM causes and contributory factors in participating hospitals. DOHMH will use these results to complement maternal death reviews conducted by the DOHMH Maternal Mortality and Morbidity Review Committee (M3RC) such that a better understanding of the causes and contributory factors to ***both*** maternal mortality and select morbidity reviews will help inform DOHMH policy recommendations for improving overall maternal health outcomes.

# SMM Abstractor Confidentiality Agreement

**New York City Department of Health and Mental Hygiene**

**Severe Maternal Morbidity (SMM) Abstractor Confidentiality Agreement**

This Confidentiality Agreement ("Agreement") is between the New York City Department of Health and Mental Hygiene ("DOHMH") and the Severe Maternal Morbidity Abstractor whose signature is placed below ("SMM" or "you" or "your"). On behalf of DOHMH and the healthcare provider that DOHMH assigns to you, you will access, use, transfer and/or disclose patient records, including individually identifiable patient medical records, from healthcare providers and from DOHMH's Bureau of Vital Statistics Confidential Information") for the purpose of severe maternal morbidity reviews ("SMM reviews"). You are therefore subject to the confidentiality provisions of this Agreement and applicable laws and regulations of the state and city of New York.

You agree to the following:

1. The term of this Agreement shall be _____ through _____.
2. You shall not have any current or past relationships with patients or healthcare providers that are the subjects of the maternal morbidity review for which you access, use, transfer, or disclose Confidential Information.
3. You shall not access, use, transfer or disclose Confidential Information where you are personally familiar or have a relationship with a patient or healthcare provider that is the subject of the maternal morbidity review.
4. You shall disclose to the supervisor of the SMM Abstractor Team any relationship that you have with a patient or healthcare provider that is the subject of the maternal morbidity review before you access Confidential Information pertaining to such maternal morbidity review.
5. You shall access, use, transfer or disclose Confidential Information according to DOHMH's protocols and only for the purpose of reviewing maternal morbidity data provided by DOHMH's Bureau of Vital Statistics ("OVS") and the healthcare provider that DOHMH assigns to you.
6. You shall access, use, transfer or disclose only the minimum amount of Confidential Information that is necessary to fulfill your obligations to DOHMH to meet the objectives of the SSM review.
7. You shall keep all Confidential Information confidential, regardless of its form (hard copy, electronic, or verbal) and shall not disclose Confidential Information except as authorized by DOHMH. All Confidential Information is the sole property the healthcare provider.
8. You shall not at any time, including before and after the completion, expiration, or termination of this Agreement publish or present any Confidential Information or

issue any Confidential Information for publication through any media of communication.

9. You shall not at any time, including before and after the completion, expiration, or termination of this Agreement, through any media of communication, publish or present any recommendations of the Maternal Morbidity Committee or of the healthcare provider related to the Confidential Information.
10. You shall not at any time, including before and after the completion, expiration, or termination of this Agreement, disclose any Confidential Information to the press, or make any statement to the press or issue any material for publication through any media of communication bearing on the work performed or the Confidential Information collected under this Agreement.
11. You shall not at any time, including before and after the completion, expiration, or termination of this Agreement, conduct any research using the Confidential Information.
12. You shall protect Confidential Information from loss, misuse, alteration, unauthorized disclosure, and/or modification, by taking the following measures:
    - never creating duplicate copies of Confidential Information;
    - never creating electronic copies of Confidential Information, or electronically transmitting Confidential Information except as permitted and authorized by DOHMH;
    - securing any hardcopy versions of records containing Confidential Information following the protocols of DOHMH or the healthcare provider to which you are assigned;
    - appropriately disposing of Confidential Information that you generate or use at your assigned healthcare provider following the protocols of your assigned health care provider to prevent a breach of confidentiality./
    - disposing of paper copies of Confidential Information that you use at DOHMH by shredding Confidential Information in a multi-directional shredder located at DOHMH;
    - using only DOHMH-issued or approved computers, laptops and/or mobile devices (collectively, “Devices”) to access, store, transmit or disclose Confidential Information;
    - inputting Confidential Information only onto the DOHMH-designated data collection form or into the Maternal Mortality Review Information Application (MMRIA) on DOHMH secure database, which is accessible on laptops or desktops provided by DOHMH to SMM Abstractors;
    - using password protection, screensavers, automatic time-outs or other appropriate security measures as directed by DOHMH and your assigned healthcare provider so that no unauthorized person accesses Confidential

Information from your workstation or from any SMM Abstractor mobile device that DOHMH issues to you;

- safeguarding and protecting electronic devices (portable or not portable) and media containing Confidential Information including but not limited to computers, laptops, smartphones, tablets, PDAs, CDs, and USB drives;
- never leaving unattended laptops or mobile devices that are used to access, store, transmit or disclose Confidential Information;
- never using personal laptops or mobile devices to access, store, transmit, or disclose Confidential Information;
- never removing or transporting Confidential Information off-site from healthcare provider or DOHMH; and
- complying with any additional DOHMH or healthcare provider security requirements for ensuring the security of the Confidential Information and minimizing the risks of a confidentiality breach

13. You shall not disclose Confidential Information to anyone outside of the DOHMH SMM Team and only to authorized members of such team.
14. In the event that you receive a request to produce Confidential Information pursuant to an order of a court of competent jurisdiction or a facially valid administrative, Congressional, state or local legislative or other subpoena, or believe that you are otherwise required by law to disclose Confidential Information, then you shall promptly notify DOHMH prior to making such disclosure, and shall afford DOHMH the opportunity to challenge or otherwise lawfully seek limits upon such disclosure of Confidential Information.
15. You agree and acknowledge that any unauthorized or wrongful access, use, recording, copying, transmitting or disclosure of any Confidential Information, or any breach of the terms of this Agreement, whether intentional or unintentional, may result in civil or criminal action against you and/or termination of this Agreement.
16. You agree to report to DOHMH in writing any unauthorized or inadvertent use or disclosure of Confidential Information. You agree to cooperate with any investigation by DOHMH regarding such unauthorized or inadvertent use or disclosure and adopt any remedial measures recommended by DOHMH.
17. This Agreement may be modified and/or amended, in writing, as mutually agreed upon by DOHMH and SMM Abstractor.
18. This Agreement shall be governed by and construed in accordance with the laws of the state of New York (without regard to choice of law or conflict of law principles) and the laws of the United States, where applicable.
19. Wherever a practicable meaning can be applied, you agree that all the terms and conditions of this Agreement shall remain in full force and effect after the expiration, completion, or termination of this Agreement.

20. You agree that any and all claims arising under or related to this Agreement shall solely be heard and determined either in the courts of the United States located in the city of New York or in the courts of the state of New York located in the city and county of New York. You hereby waive personal service by personal delivery and agree that service of process may be made by post-paid, certified mail directed to you at your address below, to be effective with the same effect as though personally served.

By signing below, I acknowledge that I have read this Agreement and agree to comply with all the terms of this Agreement.

_____

SMM ABSTRACTOR'S NAME (PRINT)

_____ DATE: _____

SMM ABSTRACTOR'S SIGNATURE:

SMM ABSTRACTOR'S ADDRESS (PRINT):

_____

_____

_____

_____

NEW YORK CITY DEPARTMENT OF HEALTH
AND MENTAL HYGIENE

_____ DATE: _____

# QI Committe Assesment Tool

**Ob/Gyn Department QI Assessment Tool**

Hospital Name_____ Date _____

Name of Person completing form _____

**Specific Questions regarding QI committee in the Department of Ob/Gyn**.

Is there an Ob/Gyn departmental QI committee? Yes or No

What is the name and job title of the Chair of the Committee*? (ex. Attending Ob/gyn. Vice Chair of Dept. Ob/Gyn, etc.)* _____

Who are the members of the committee? *(by category, not individual names)*

| Member | Yes # | No | Ad hoc | Comments |
|---|---|---|---|---|
| Senior Attending Ob/Gyn | | | | |
| Junior Attending Ob/Gyn | | | | |
| Subspecialists *(ex. MFM, neonatologists)* | | | | |
| Ob Anesthesiologist | | | | |
| Midwives | | | | |
| Registered Nurses | | | | |
| House Staff | | | | |
| Dept. Chair | | | | |

What establishes a quorum for the meeting? *(Ex. 3 attending Ob/Gyn's at minimum)*

_____

Meeting frequency? Weekly, monthly, bi-monthly, quarterly, other _____

Date of last meeting? _____ Number in attendance? _____

Number of cases peer-reviewed? _____ Date of next scheduled QI committee meeting? _____

**QI Committee Process**

Does the committee have a list of clinical indicators that triggers need for peer review? Yes or No

If yes, list triggers _____

How are hemorrhage cases (> 4 units of blood) and ICU admits identified? Describe *(Ex. electronic health record, blood bank reports, ICU admission logs, etc.)*

Version1 6/10/19

_____
_____
_____

| | Name | Job Title |
|---|---|---|
| Who is responsible for finding the cases? | | |
| | | |
| Who currently abstracts cases? | | |
| | | |
| Who presents the case to the committee? | | |
| | | |
| When there is an opportunity to improve with a specific recommendations, who is responsible for: | | |
| Implementation | | |
| | | |
| Dissemination/Education of staff | | |
| | | |
| Follow-up monitoring | | |
| | | |

Is there a process to refer cases to other departments in the hospital? Yes or No

If yes, who is responsible? _____

**For DOHMH Staff**

Date of follow-up phone call _____

Names and job titles of those on call

_____
_____
_____

Version1 6/10/19

# SMM Abstraction Form

# ABSTRACTION FORM

| **Abstraction Date:** | **Hospital:** Jamaica | **Study ID:** | **MMRIA ID:** |
|---|---|---|---|

**SMM Screening:** 1) ≥4 Units Blood Products Transfused? ☐Yes ☐No **OR** 2) ICU Admission: ☐Yes ☐No

## A. PATIENT CHARACTERISTICS [Primary Source: Birth Certificate Worksheet]

| **Age (yrs):** | **Zip Code of Residence:** | **City of Birth:** | **State of Birth:** |
|---|---|---|---|

| **Race:** | **Hispanic Origin:** | **Marital Status (Select One):** |
|---|---|---|
| ☐ American Indian/Alaska Native | ☐ Mexican, Chicano ☐ Not Hispanic | ☐ Never Married ☐ Unknown |
| ☐ Asian/Pacific Islander | ☐ Puerto Rican ☐ Unknown | ☐ Married |
| ☐ Black or African American | ☐ Dominican | ☐ Married, but Separated |
| ☐ White | ☐ Yes Hispanic, Origin Unknown | ☐ Divorced |
| ☐ Not Specified | ☐ Other Hispanic *(specify)*: | ☐ Widowed |
| ☐ Other *(specify)*: | | ☐ Domestic Partnership |

| **Primary Payer Source (Select One):** | **Education Completed (Select One):** | **Country of Birth (If Foreign Born):** |
|---|---|---|
| ☐ Private Insurance | ☐ Less Than High School; No Diploma | *If foreign born, time living in US (yrs):* |
| ☐ Self-pay | ☐ High School Graduate/GED | *(Note: Enter "0" if less than 1 year living in US)* |
| ☐ Medicaid | ☐ Some College; No Degree | **Primary Language Spoken:** |
| ☐ Unknown | ☐ College Graduate or Higher | **Limited English Proficiency:** ☐ Yes ☐ No ☐ Unknown |
| ☐ Other *(specify)*: | ☐ Unknown | *If yes, any documented translation services?* ☐ Yes ☐ No |

| **Feeling About Becoming Pregnant (Select One):** | **Participated in WIC During This Pregnancy? (Select One)** |
|---|---|
| ☐Wanted to Be Pregnant Sooner ☐Wanted to Be Pregnant Later | ☐Yes ☐No ☐ Unknown |
| ☐Wanted to Be Pregnant Then ☐Didn't Want to Be Pregnant Then or Any Time in The Future | |

## B. PRENATAL CARE (PNC) [Primary Source: Prenatal Records]

| **PNC Received:** ☐ Yes ☐ No | **Access to PNC Records:** ☐ Yes ☐ No | **PNC Located at An Affiliated Clinic Site?** ☐ Yes ☐ No ☐ Unknown |
|---|---|---|

**Provider Discipline:** ☐ OBGYN ☐ Midwife ☐ MFM ☐ Family Medicine ☐ Unknown ☐ Other *(specify)*:

| **Gravida:** | **Height (ft/in):** / | **Pregnancy Interval (mos):** | **Week PNC Began:** |
|---|---|---|---|
| **Para:** | **Pre-pregnancy Weight (lbs):** | **Number Prior Cesareans:** | ☐ Week Unknown |
| **Term:** **Preterm:** | **Pre-pregnancy BMI:** | **Multiple Gestation:** ☐ Yes ☐ No | *If unknown, trimester:* |
| **ITOP/STOP:** **Living:** | **Highest Blood Pressure:** / | *If yes, how many?* | **Number of PNC Visits:** ☐ Unknown |

## C. OBSTETRICAL RISK FACTORS [Primary Source: Prenatal and Hospital Records]

**History of:**

| | | | |
|---|---|---|---|
| ☐ No Risk Factors | ☐ Pre-pregnancy Diabetes | ☐ Previous Fetal Demise | ☐ Abnormal Placentation |
| ☐ Pre-term Delivery | ☐ Postpartum Hemorrhage | ☐ Anemia | ☐ Prior Uterine Surgery |
| ☐ Pre-pregnancy Hypertension | ☐ Pre-eclampsia/HELLP | ☐ Asthma | |
| ☐ Cardiac Disease | ☐ Prior Shoulder Dystocia | | |

☐ Other *(specify)*:

**Current Pregnancy:**

| | | | |
|---|---|---|---|
| ☐ No Risk Factors | ☐ Infertility Treatment | ☐ DVT/PE | ☐ Multiple Gestation |
| ☐ Gestational Diabetes | ☐ Pre-eclampsia | ☐ Polyhydramnios | ☐ Altered Mental State or Loss of Consciousness |
| ☐ Gestational Hypertension | ☐ Eclampsia | ☐ Oligohydramnios | |

☐ Acute Cardio-pulmonary Event *(specify)*:

☐ Other *(specify)*:

## D. SMM EVENT [Primary Source: Hospital Records]

**Transferred from Other Facility?** ☐ Yes ☐ No *(If yes, why?)*:

**If Not Transferred, Admission Reason:**

☐ Labor ☐ Planned Induction/Cesarean ☐ Unknown

☐ Medical Reasons Not Related to Pregnancy ☐ Complications of Pregnancy/Not in Labor

☐ Other *(specify)*:

| **Timing of Maternal Morbidity (Select One):** | **Pregnancy Outcome (Select One):** | | |
|---|---|---|---|
| ☐ Antepartum (*enter gestational age in weeks*): | ☐ Live Birth | ☐ AB: Spontaneous | ☐ Molar Pregnancy |
| ☐ Intrapartum ☐ Postpartum (8 to 72 hours) | ☐ AB: Induced | ☐ Ectopic | ☐ Not Delivered |
| ☐ Postpartum (< 8 hours) ☐ Postpartum (73 hours to 42 days) | ☐ Stillbirth/Fetal Demise (≥20 weeks) | | |

## E. COMPLETE ONLY IF PREGNANCY OUTCOME WAS "DELIVERED (LIVE BIRTH/STILLBIRTH)"

***Complete this section for each live birth or stillbirth (use separate form)***

| | | |
|---|---|---|
| **Access to Delivery Records:** ☐ Yes ☐ No | **NICU admit?** ☐ Yes ☐ No ☐ Unknown | **Place of Delivery (Select One):** |
| **Apgar at 1 min**: | **Neonatal Death (as of today)?** ☐ Yes ☐ No ☐ Unknown | ☐ Hospital ☐ Birthing Center |
| **Apgar at 5 min**: | **Birthweight (g):** | ☐ Home Delivery ☐ Unknown |
| **Apgar at 10 min:** | **Mothers Weight at Delivery (lbs):** | ☐ Other *(specify):* |
| **Gestational Age (weeks):** | | |

**Did the Patient Experience Any of The Following?**

| | | |
|---|---|---|
| ☐ None Specified | ☐ Laceration (e.g. Vaginal Sidewalls/Cervical/4th Degree) | ☐ Febrile (>100.4° F or 38°C) |
| ☐ Uterine Atony | ☐ Vulvovaginal Hematoma | ☐ Arrested Dilation or Descent |
| ☐ Uterine Inversion | ☐ Abnormally Adherent Placenta (Accreta Spectrum) | ☐ Shoulder Dystocia |
| ☐ Uterine Rupture | ☐ Retained Placenta or Products of Conception | ☐ Pre-term Labor |
| ☐ Retro-peritoneal Bleeding | ☐ Other Intraperitoneal Bleeding (Uterine Rupture Excluded) | ☐ Chorioamnionitis |
| ☐ Suspected Abruption | | |
| ☐ Other *(specify)*: | | |

| | | |
|---|---|---|
| **Labor:** | **Final Delivery Route (Select One):** | **Type of Anesthesia:** |
| ☐ None ☐ Spontaneous | ☐ Vaginal/Spontaneous ☐ Cesarean | ☐ None ☐ General ☐ Local |
| ☐ Augmented ☐ Unknown | ☐ Vaginal Vacuum/Forceps ☐ Unknown | ☐ Epidural ☐ Spinal ☐ Unknown |
| ☐ Induced | ☐ Vaginal/Not Specified | ☐ Other *(specify)*: |

| | |
|---|---|
| **Type of Cesarean (If Applicable):** | **Primary Reason for Cesarean (If Applicable):** |
| ☐ Scheduled ☐ Not Applicable | ☐ Scheduled Repeat ☐ Previa ☐ Not Applicable |
| ☐ Unplanned ☐ Unknown | ☐ Dystocia/Failure to Progress ☐ Accreta ☐ Unknown |
| ☐ Emergency | ☐ Elective-patient Request ☐ Malpresentation |
| **Labor After Cesarean Attempted?** | ☐ Fetal Indications *(specify)*: |
| ☐ Yes ☐ No ☐ Not Applicable ☐ Unknown | ☐ Maternal Condition *(specify)*: |

**Was Delivery with Forceps/Vacuum Attempted?** ☐ Yes, Successful ☐ Yes, Unsuccessful ☐ No, Not Attempted ☐ Unknown

**Were There Complications of Delivery?** ☐ Yes ☐ No (*If yes, specify)*:

## F. ICU-RELATED QUESTION [Primary Source: Hospital Records]

**Reason for ICU Admission:**

☐ Respiratory ☐ Cardiovascular ☐ Neurologic ☐ Pre-eclampsia/Eclampsia ☐ Hemorrhage ☐ Sepsis

☐ Other *(specify)*:

## G. HEMORRHAGE-RELATED QUESTIONS [Primary Source: Hospital Records]

| | |
|---|---|
| **Documented Risk Assessment on Admission:** ☐ Yes ☐ No ☐ Unknown | **Uterotonic Medications Used to Treat Hemorrhage:** |
| **Was Blood Typed and Cross-Matched on Admission?** ☐ Yes ☐ No ☐ Unknown | ☐ None Used |
| **Were Non-Surgical Interventions Applied?** | ☐ Oxytocin |
| ☐ None Applied ☐ Uterine Massage ☐ Bakri Balloon ☐ Uterotonics ☐ Unknown | ☐ Methylergonovine (Methergine) |
| **Were Surgical Interventions Applied?** | ☐ Misoprostol (Cytotec) |
| ☐ None Applied ☐ B-lynch Suture ☐ Hysterectomy | ☐ Carboprost Tromethamine (Hemabate) IM |
| ☐ D&C ☐ Hypogastric Artery Ligation ☐ Unknown | ☐ Tranexamic Acid (TXA) |
| ☐ Laparotomy ☐ Uterine Artery Ligation | ☐ Unknown |
| ☐ Other (*specify*): | |

| | | |
|---|---|---|
| **Was Massive Transfusion Protocol Activated?** | **Total Units Packed RBC's Transfused:** | **Total EBL (mL)**: |
| ☐ Yes ☐ No ☐ Unknown | **Total Units Blood Products Transfused:** | **Total QBL (mL):** |

## H. SOCIAL AND ENVIRONMENTAL INFORMATION [Primary Source: Prenatal and Hospital Records]

| **Employment Status:** | **Current Living Arrangements:** | **Homelessness:** |
|---|---|---|
| ☐ Full Time ☐ Unemployed | ☐ Own ☐ Homeless (Shelter) ☐ Public Housing | ☐ Never |
| ☐ Part Time ☐ Unknown | ☐ Rent ☐ Homeless (Street) ☐ Unknown | ☐ Yes, In Last 12 Months |
| ☐ Self-employed | ☐ Live w/ Relative | ☐ Yes, More Than 12 Months Ago |
| ☐ Other *(specify)*: | ☐ Shelter Type *(specify)*: | ☐ Unknown |
| | ☐ Other *(specify)*: | |

| **Primary Occupation**: | **Documented Number of Moves in Previous 6 Months**: |
|---|---|

| **Documented Barriers to Health Care Access:** | **Documented Barriers to Communications:** |
|---|---|
| ☐ None Documented ☐ Transportation ☐ Childcare | ☐ None Documented ☐ Limited English Proficiency ☐ Hearing Impaired |
| ☐ Cultural Norms ☐ Mobility ☐ Financial | ☐ Functional Illiteracy ☐ Vision Impaired ☐ Speech Impaired |
| ☐ Distance | ☐ Other *(specify)*: |
| ☐ Other *(specify)*: | |

**Documented Evidence of Other Social or Emotional Stress:**

| | | |
|---|---|---|
| ☐ None Documented | ☐ Hx of Domestic Violence | ☐ Hx of Substance Use |
| ☐ Hx of Psychiatric Hospitalizations or Treatment | ☐ Prior Suicide Attempts | ☐ Recent Trauma |
| ☐ Child Protective Services Involvement | ☐ Hx of Substance Use Treatment | ☐ Hx of Abuse (Physical, Sexual, Verbal) |
| ☐ Hx of Childhood Trauma (e.g. abuse, neglect, foster care, or criminal legal system involvement) | ☐ Criminal Justice Involvement (adulthood) | ☐ Unemployment |
| ☐ Other *(specify)*: | | |

| **Adherence to Care Issues:** | **If Yes, Documented Reasons:** |
|---|---|
| ☐ Missed Appointments ☐ Delays in Care | ☐ Appointment Conflict ☐ Financial ☐ Childcare |
| ☐ Medication | ☐ Provider Conflict (lack of agreement, dislike) ☐ Transportation |
| ☐ Other *(specify)*: | ☐ Other *(specify)*: |

| **Documented Screenings For:** | **If Screened Positive, Was Patient Referred?** |
|---|---|
| **Mental Health Conditions:** ☐ Yes ☐ No ☐ Unknown | ☐ Yes ☐ No ☐ Unknown |
| **Domestic Violence:** ☐ Yes ☐ No ☐ Unknown | ☐ Yes ☐ No ☐ Unknown |
| **Substance Use:** ☐ Yes, Verbal ☐ Yes, Toxicology ☐ No ☐ Unknown | ☐ Yes ☐ No ☐ Unknown |
| *If toxicology was collected, was consent documented?* ☐ Yes ☐ No | |

## I. ADDITIONAL NOTES TO INFORM SMM CASE NARRATIVE:

# Case Narrative Template

| CASE NARRATIVE TEMPLATE | | | |
|---|---|---|---|
| **Review Date:** | **Hospital:** | **Study ID:** | **MMRIA ID:** |

## A. SUMMARY

She is a (**AGE, RACE/ETHNICITY, PLACE OF BIRTH, MARRIAGE STATUS, EDUCATIONAL LEVEL**), who at (**WEEKS**) of pregnancy [or (**DAYS**) postpartum] presented to the (**HOSPITAL/EMERGENCY DEPT/CLINIC/OTHER**) with _____. She developed _____ and was treated with _____and discharged (**DAYS**) after admission.

## B. PRENATAL CARE

She is ___ years old, gravida ____ para _____ with a past obstetric history of _____. Prior surgical history includes_____. Her family medical history was positive for _____. Pre-existing medical conditions included_____. She was (**HEIGHT**) and (**WEIGHT**) at her first prenatal visit at (**WEEKS**). Her pre-pregnancy BMI was _____.

She attended ___ visits at a (**HOSPITAL CLINIC/HEALTH CENTER/PRIVATE OFFICE**) with an (**OBGYN/MIDWIFE/FP**) and had (**MEDICAID/PRIVATE/NO**) insurance coverage. Screening for substance [alcohol, tobacco, illicit or prescription drugs] use was (**POSITIVE/NEGATIVE/NOT FOUND IN RECORDS**). [If positive state condition]. Screening for mental health conditions was (**POSITIVE/NEGATIVE/NOT FOUND IN RECORDS**). [If positive state condition]. Screening for domestic violence was (**POSITIVE/NEGATIVE/NOT FOUND IN RECORDS**). [If positive state condition]. Screening for abuse [sexual, physical, verbal, childhood] was (**POSITIVE/NEGATIVE/NOT FOUND IN RECORDS**). [If positive state condition]. Patient's primary language is _____. She (**IS/IS NOT**) proficient in English. [If not proficient in English, translation services were (**DOCUMENTED/NOT DOCUMENTED**)]. She lives with (**PARTNER/FRIEND(S)/PARENT(S)/CHILDREN/ETC**) in a (**HOME/SHELTER TYPE**). Additional social determinant factors are _____.

The pregnancy was complicated by (**SUMMARIZE ANY PRENATAL CARE PROBLEMS**). Her highest systolic blood pressure during prenatal care was ____ and her highest diastolic blood pressure during prenatal care was ____. The majority of her diastolic blood pressures were [**INSERT RANGE**]. During the sentinel pregnancy she was taking (**LIST MEDICATIONS/VITAMINS/SUPPLEMENTS**).

## C. DELIVERY AND EVENTS OF SEVERE MORBIDITY

She presented at (**WEEKS**) gestation to the (**HOSPITAL/EMERGENCY DEPT/CLINIC/OTHER**) via (**PRIVATE CAR/EMS/OTHER**). Her chief complaint was _____. History of present illness include (**SUMMARIZE PERTINENT RISK FACTORS**). Pertinent physical exam findings include (**SUMMARIZE PHYSICAL EXAM FINDINGS**).

## D. CHRONOLOGICAL SEQUENCE OF EVENTS (NO ACTUAL DATES OR TIMES)

Include the following pertinent data (**VITAL SIGNS, PHYSICAL FINDINGS, LABORATORY RESULTS, RADIOLOGY RESULTS, WORKING DIAGNOSES, MEDICAL AND SURGICAL TREATMENTS, TRANSFER TO ICU, USE OF CONSULTANTS**). Include delivery method and indication, birthweight and Apgar scores.

***Example:***

*Cesarean delivery of a 4500g infant, Apgars 7,8, for arrest of dilation after oxytocin stimulation for 12 hours.*

*5 hours after delivery by cesarean for fetal bradycardia, heavy bleeding was noted in the PACU by RN. Pulse 120, BP100/50. Resident physician (PGY2) at bedside. Uterine atony noted and treated by fundal massage, methergine and hemabate.*

*6 hours PP, 1st unit of blood hung, bleeding continued. Total EBL (intraop & postpartum) 2.5 liters. VS P140, BP 90/50*

*7 hours PP, back to the OR for D&C and balloon tamponade. Gyn oncologist called. Interventional radiologist alerted.*

*7.5 hours PP Hct 21%, platelets 38,000. Massive transfusion protocol activated. Gyn oncologist arrived, hysterectomy performed and hemostasis achieved. Postop transfer to ICU VS: P100, BP 120/78; Hct 30%, platelets 93,000.*

*Total blood products replaced: 7U PRCs; 4U FFP, 1 6-pack of platelets.*

*Total ICU stay of 2 days. Discharged home on PP day 6.*

# Committee Decision Form

## COMMITTEE DECISION FORM

| Review Date: | Hospital: Jamaica | Study ID: | MMRIA ID: |
|---|---|---|---|

### A. PRIMARY CAUSE OF MORBIDITY (SELECT ONE)

**Cause (Description)**

**CODE FOR PRIMARY CAUSE**
(Select code on pp.3 and list here)

| | | | | |
|---|---|---|---|---|
| Did **Obesity** Contribute to The Event? | ☐ Yes | ☐ Probably | ☐ No | ☐ Unknown |
| Did **Mental Health Conditions** Contribute to The Event? | ☐ Yes | ☐ Probably | ☐ No | ☐ Unknown |
| Did **Substance Use Disorder** Contribute to The Event? | ☐ Yes | ☐ Probably | ☐ No | ☐ Unknown |

### B. PREVENTABILITY

"An SMM event is considered preventable if there was some chance that:

1. the event could have been averted or
2. the patient did not have to get as sick as she did.

In other words, one or more reasonable changes to patient, family, provider, system or community factors could have had some chance to alter the outcome. "

**Was This Event Preventable?** ☐ Yes ☐ No

**Was There A Chance to Alter the Outcome?**

☐ Good Chance ☐ Some Chance

☐ No Chance ☐ Unable to Determine

**Did Any Actions Positively Alter the Outcome?** ☐ Yes ☐ No

**Was the Escalation Policy/Chain of Command Invoked (i.e. Senior Staff Called) Pursuant to Hospital Protocol?**

☐ Yes ☐ No ☐ Unknown

### Describe Practices That Were Done Well and Should Be Reinforced:

### Additional Notes or Comments:

| **COMMITTEE DECISION FORM** | | | |
|---|---|---|---|
| **Review Date:** | **Hospital:** Jamaica | **Study ID:** | **MMRIA ID:** |

| **LEVEL** | **CONTRIBUTING FACTORS WORKSHEET** | **RECOMMENDATIONS OF THE COMMITTEE (Describe Recommendations to Help Prevent Similar Events In The Future)** |
|---|---|---|
| **PATIENT / FAMILY** | ☐ Failure to Seek Care<br>☐ Adherence with Treatment<br>☐ Cultural/Religious<br>☐ Smoking<br>☐ Substance Use Disorder *(specify):*<br><br>☐ Other *(specify):* | |
| **PROVIDER** | ☐ Assessment of High Risk<br>☐ Lack of Referral<br>☐ Delay in Diagnosis<br>☐ Delay in Treatment<br>☐ Inadequate Knowledge (Inappropriate Treatment)<br>☐ Failure to Provide Follow Up<br>☐ Other *(specify):* | |
| **FACILITY** | ☐ Staff Knowledge Training Deficit<br>☐ Inadequate Equipment<br>☐ Policy Issue (No Policy)<br>☐ Policy Not Followed | |
| **SYSTEM** | ☐ Lack of Access/Financial Resources<br>☐ Poor Communication/Lack of Case Coordination Among Facilities and Agencies<br>☐ Other *(specify):* | |
| **COMMUNITY** | ☐ Inadequate Communication Outreach/Resources<br>☐ Other *(specify):* | |

## PRIMARY CAUSE OF MORBIDITY (SELECT ONE) **

| | | | | | |
|---|---|---|---|---|---|
| ☐ **10** | Hemorrhage (excluding aneurysms or CVA) | ☐ **82** | Hematologic | ☐ **91** | Pulmonary conditions (excludes ARDS-Adult Respiratory Distress Syndrome) |
| ☐ **10.1** | Hemorrhage – rupture/laceration/intra-abdominal bleeding | ☐ **82.1** | Sickle cell anemia | ☐ **91.1** | Chronic lung disease |
| ☐ **10.2** | Placental abruption | ☐ **82.9** | Other hematologic conditions including thrombophilias / TTP / HUS / NOS | ☐ **91.2** | Cystic fibrosis |
| ☐ **10.3** | Placenta previa | ☐ **83** | Collagen vascular / autoimmune diseases | ☐ **91.3** | Asthma |
| ☐ **10.4** | Ruptured ectopic pregnancy | ☐ **83.1** | Systemic lupus erythematosis (SLE) | ☐ **91.9** | Other pulmonary disease / NOS |
| ☐ **10.5** | Hemorrhage – uterine atony/postpartum hemorrhage | ☐ **83.9** | Other collagen vascular diseases / NOS | ☐ **92** | Neurologic / neurovascular conditions (excluding CVAs) |
| ☐ **10.6** | Placenta accreta/increta/percreta | ☐ **85** | Conditions unique to pregnancy (e.g. gestational diabetes, hyperemesis, liver disease of pregnancy) | ☐ **92.1** | Epilepsy / seizure disorder |
| ☐ **10.7** | Hemorrhage due to retained placenta | ☐ **88** | Injury | ☐ **92.9** | Other neurologic diseases / NOS |
| ☐ **10.8** | Hemorrhage due to primary DIC | ☐ **88.1** | Intentional (homicide) | ☐ **93** | Renal disease |
| ☐ **10.9** | Other hemorrhage / NOS | ☐ **88.2** | Unintentional | ☐ **93.1** | Chronic renal failure / end-stage renal disease (ESRD) |
| ☐ **20** | Infection | ☐ **88.9** | Unknown / NOS | ☐ **93.9** | Other renal disease / NOS |
| ☐ **20.1** | Postpartum genital tract (e.g. of the uterus / pelvis / perineum / necrotizing fasciitis) | ☐ **89** | Cancer | ☐ **95** | Cerebrovascular accident (hemorrhage / thrombosis / aneurysm / malformation) not secondary to hypertensive disease |
| ☐ **20.2** | Sepsis / septic shock | ☐ **89.1** | Gestational trophoblastic disease (GTD) | ☐ **96** | Metabolic / endocrine |
| ☐ **20.4** | Chorioamnionitis / antepartum infection | ☐ **89.3** | Malignant melanoma | ☐ **96.1** | Obesity |
| ☐ **20.5** | Non-pelvic infections (e.g. pneumonia, TB, meningitis, HIV) | ☐ **89.9** | Other malignancies / NOS | ☐ **96.2** | Diabetes mellitus |
| ☐ **20.6** | Urinary tract infection | ☐ **90** | Cardiovascular conditions | ☐ **96.9** | Other metabolic / endocrine disorders |
| ☐ **20.9** | Other infections / NOS | ☐ **90.1** | Coronary artery disease / myocardial infarction (MI) / atherosclerotic cardiovascular disease | ☐ **97** | Gastrointestinal disorders |
| ☐ **30** | Embolism – thrombotic (non-cerebral) | ☐ **90.2** | Pulmonary hypertension | ☐ **97.1** | Crohn's disease / ulcerative colitis |
| ☐ **30.9** | Other embolism / NOS | ☐ **90.3** | Valvular heart disease congenital and acquired | ☐ **97.2** | Liver disease / failure / transplant |
| ☐ **31** | Embolism – amniotic fluid | ☐ **90.4** | Vascular aneurysm / dissection (non-cerebral) | ☐ **97.9** | Other gastrointestinal diseases / NOS |
| ☐ **40** | Pre-eclampsia | ☐ **90.5** | Hypertensive cardiovascular disease | ☐ **100** | Mental health conditions |
| ☐ **50** | Eclampsia | ☐ **90.6** | Marfan syndrome | ☐ **100.1** | Depression |
| ☐ **60** | Chronic hypertension with superimposed pre-eclampsia | ☐ **90.7** | Conduction defects / arrhythmias | ☐ **100.9** | Other psychiatric conditions / NOS |
| ☐ **70** | Anesthesia complications | ☐ **90.8** | Vascular malformations outside head and coronary arteries | ☐ **999** | Unknown cause |
| ☐ **80** | Cardiomyopathy | ☐ **90.9** | Other cardiovascular diseases including CHF, cardiomegaly, cardiac hypertrophy, cardiac fibrosis, non-acute myocarditis/NOS | | |
| ☐ **80.1** | Postpartum/peripartum cardiomyopathy | | | | |
| ☐ **80.2** | Hypertrophic cardiomyopathy | | | | |
| ☐ **80.9** | Other cardiomyopathy / NOS | | | | |

** Codes for the primary cause of the SMM event are based on the Pregnancy Mortality Surveillance System (PMSS-MM), which was developed by the CDC and the American College of Obstetrics and Gynecology to promote standardization and consistency in classifying pregnancy-related deaths in a clinically meaningful way. This coding is also applicable to the primary cause of SMM events and is used in this form to harmonize with the established PMSS-MM system.

# Standard Report Template

***SAMPLE ABSTRACTION FORM REPORT***

| Characteristic | Value | Hospital | All Network Hospitals |
|---|---|---|---|
| Counts | Case Narratives Reviewed by Committee | 0 | 0 |
| | Abstractions Forms Completed | 0 | 0 |
| SMM Screening | Both ICU and Transfusion | % | % |
| | Intensive Care Unit Admission | % | % |
| | ≥ 4 Units Blood Products Transfused | % | % |
| Mean Age | Mean Age | 00.0 | 00.0 |
| Age | ≤19 | % | % |
| | 20–24 | % | % |
| | 25–29 | % | % |
| | 30–34 | % | % |
| | 35–39 | % | % |
| | 40+ | % | % |
| Race/Ethnicity | Non-Hispanic American Indian/Alaska Native | % | % |
| | Non-Hispanic Asian/Pacific Islander | % | % |
| | Non-Hispanic Black or African American | % | % |
| | Non-Hispanic White | % | % |
| | Hispanic | % | % |
| | Other/Unknown/Not Specified | % | % |
| Primary Payer Source | Private Insurance | % | % |
| | Self-pay | % | % |
| | Medicaid | % | % |
| | Unknown | % | % |
| | Other | % | % |
| Birth Country | U.S.-born | % | % |
| | Foreign-born | % | % |
| | Unknown | % | % |
| Primary Language Spoken | English | % | % |
| | Not English | % | % |
| | Unknown | % | % |
| Pre-pregnancy BMI | Underweight (<18.5) | % | % |
| | Normal weight (18.5–24.9) | % | % |
| | Overweight (25–29.9) | % | % |
| | Class 1 (30–34.9) | % | % |
| | Class 2 (35–39.9) | % | % |
| | Class 3 (≥40) | % | % |
| | Unknown | % | % |
| Number of Prior Cesareans | 0 | % | % |
| | 1 | % | % |
| | 2 | % | % |
| | 3+ | % | % |
| | Unknown | % | % |
| Trimester of Entry to PNC | First Trimester | % | % |
| | Second Trimester | % | % |
| | Third Trimester | % | % |
| | Unknown | % | % |

***[1] Not mutually exclusive***
***[2] Data is only available for abstractions that began after 12/1/2019***

***SAMPLE ABSTRACTION FORM REPORT***

| Characteristic | Value | Hospital | All Network Hospitals |
|---|---|---|---|
| Current Pregnancy Obstetrical Risk Factors[1] | No Risk Factors | % | % |
| | Gestational Diabetes | % | % |
| | Gestational Hypertension | % | % |
| | Infertility Treatment | % | % |
| | Pre-eclampsia | % | % |
| | Eclampsia | % | % |
| | DVT | % | % |
| | Polyhydramnios | % | % |
| | Oligohydramnios | % | % |
| | Multiple Gestation | % | % |
| | Altered Mental State or Loss of Consciousness | % | % |
| | Acute Cardio-pulmonary Event | % | % |
| | Other | % | % |
| Transferred from Other Facility | Yes | % | % |
| | No | % | % |
| Admission Reason[1] | Complications of Pregnancy/Not in Labor | % | % |
| | Labor | % | % |
| | Medical Reasons Not Related to Pregnancy | % | % |
| | Other | % | % |
| | Planned Induction/Cesarean | % | % |
| | Unknown | % | % |
| Timing of Morbidity | Antepartum | % | % |
| | Intrapartum | % | % |
| | Postpartum (<8 hours) | % | % |
| | Postpartum (8–72 hours) | % | % |
| | Postpartum (73 hours–42 days) | % | % |
| Gestational Age | Less than 28 weeks | % | % |
| | 28–32 weeks | % | % |
| | 33–36 weeks | % | % |
| | 37+ weeks | % | % |
| | Unknown | % | % |
| Birth Weight | Less than 1500 grams | % | % |
| | 1500–2499 grams | % | % |
| | 2500–4000 grams | % | % |
| | 4000+ grams | % | % |
| Final Delivery Route | Vaginal/Spontaneous | % | % |
| | Vaginal Vacuum/Forceps | % | % |
| | Vaginal/Not Specified | % | % |
| | Cesarean | % | % |
| | Unknown | % | % |
| Reason for ICU Admission[2] | Cardiovascular | % | % |
| | Hemorrhage | % | % |
| | Neurologic | % | % |
| | Other | % | % |
| | Pre-eclampsia | % | % |

***[1] Not mutually exclusive***
***[2] Data is only available for abstractions that began after 12/1/2019***

***SAMPLE ABSTRACTION FORM REPORT***

| Characteristic | Value | Hospital | All Network Hospitals |
|---|---|---|---|
| | Respiratory | % | % |
| | Sepsis | % | % |
| Documented Hemorrhage Risk Assessment on Admission | Yes | % | % |
| | No | % | % |
| | Unknown | % | % |
| Blood Typed and Cross-Matched on Admission | Yes | % | % |
| | No | % | % |
| | Unknown | % | % |
| Uterotonic Medications Used[1] | None used | % | % |
| | Oxytocin | % | % |
| | Methylergonovine (Methergine) | % | % |
| | Misoprostol (Cytotec) | % | % |
| | Carboprost Tromethamine (Hemabate) IM | % | % |
| | Tranexamic Acid (TXA) | % | % |
| | Unknown | % | % |
| PRBC's Transfused | 0 Units | % | % |
| | 1–3 Units | % | % |
| | 4–6 Units | % | % |
| | 7+ Units | % | % |
| | Unknown | % | % |
| Total Units Transfused | 0 Units | % | % |
| | 1–3 Units | % | % |
| | 4–6 Units | % | % |
| | 7+ Units | % | % |
| | Unknown | % | % |

***[1] Not mutually exclusive***
***[2] Data is only available for abstractions that began after 12/1/2019***

***SAMPLE COMMITTEE DECISION FORM REPORT***

| Characteristic | Value | Hospital | All Network Hospitals |
|---|---|---|---|
| Primary Cause of Morbidity | Anesthesia Complications | 0.0% | 0.0% |
| | Cancer | 0.0% | 0.0% |
| | Cardiomyopathy | 0.0% | 0.0% |
| | Cardiovascular conditions | 0.0% | 0.0% |
| | Cerebrovascular accident | 0.0% | 0.0% |
| | Chronic Hypertension | 0.0% | 0.0% |
| | Collagen vascular/auto immune diseases | 0.0% | 0.0% |
| | Conditions unique to pregnancy | 0.0% | 0.0% |
| | Eclampsia | 0.0% | 0.0% |
| | Embolism | 0.0% | 0.0% |
| | Gastrointestinal disorders | 0.0% | 0.0% |
| | Hematologic | 0.0% | 0.0% |
| | Hemorrhage | 0.0% | 0.0% |
| | Infection | 0.0% | 0.0% |
| | Injury | 0.0% | 0.0% |
| | Mental health conditions | 0.0% | 0.0% |
| | Metabolic/endocrine | 0.0% | 0.0% |
| | Neurologic conditions | 0.0% | 0.0% |
| | Pre-eclampsia | 0.0% | 0.0% |
| | Pulmonary conditions | 0.0% | 0.0% |
| | Renal disease | 0.0% | 0.0% |
| | Unknown cause | 0.0% | 0.0% |
| Did Obesity Contribute to Morbidity? | Yes | 0.0% | 0.0% |
| | Probably | 0.0% | 0.0% |
| | No | 0.0% | 0.0% |
| | Unknown | 0.0% | 0.0% |
| Did Mental Health Contribute to Morbidity? | Yes | 0.0% | 0.0% |
| | Probably | 0.0% | 0.0% |
| | No | 0.0% | 0.0% |
| | Unknown | 0.0% | 0.0% |
| Did Substance Use Contribute to Morbidity? | Yes | 0.0% | 0.0% |
| | Probably | 0.0% | 0.0% |
| | No | 0.0% | 0.0% |
| | Unknown | 0.0% | 0.0% |
| Was This Event Preventable? | Yes | 0.0% | 0.0% |
| | No | 0.0% | 0.0% |
| Was There a Chance to Alter the Outcome? | Good Chance | 0.0% | 0.0% |
| | Some Chance | 0.0% | 0.0% |
| | No Chance | 0.0% | 0.0% |
| | Unable to Determine | 0.0% | 0.0% |
| Did Any Actions Positively Alter the Outcome? | Yes | 0.0% | 0.0% |
| | No | 0.0% | 0.0% |
| Was the Escalation Policy/Chain of Command Invoked Pursuant to Hospital Protocol?[2] | Yes | 0.0% | 0.0% |
| | No | 0.0% | 0.0% |
| | Unknown | 0.0% | 0.0% |

***[1] Not mutually exclusive***
***[2] Data is only available for cases reviewed after 12/1/2019***

***SAMPLE COMMITTEE DECISION FORM REPORT***

| Characteristic | Value | Hospital | All Network Hospitals |
|---|---|---|---|
| Cases with At Least One Contributing Factor Per Level[1] | Patient/Family | 0.0% | 0.0% |
| | Provider | 0.0% | 0.0% |
| | Facility | 0.0% | 0.0% |
| | System | 0.0% | 0.0% |
| | Community | 0.0% | 0.0% |

***[1] Not mutually exclusive***
***[2] Data is only available for cases reviewed after 12/1/2019***

# Abstraction Process Documentation and Guidance

# QI Committee Review of SMM Cases Documentation

## Contents



Last Updated: 5/18/2020

## Timeline of Events


## Identifying SMM events

SMM events are identified by a two-factor method—transfusion of 4 or more units of any blood product and/or admission to an intensive care unit (ICU). It is important to have a robust, standardized method to identify SMM events. Please work with the clinical contacts at your site to determine the best way to identify all cases meeting the criteria for SMM review. It is preferable to use automated reports from the electronic medical record (EMR) than to rely on human reporting systems which may be prone to miss some cases. Some examples of sources for SMM event identification from the EMR include standard or customized reports, dashboards, blood bank records, ICU admission logs, delivery logs, and incident reporting systems. Human reporting systems like provider notification or supervisor reports are less reliable than EMR sources of information. Regardless of what systems are used to identify SMM events, it is important to perform double-checks to ensure complete case finding.

Although SMM events may occur at any time during pregnancy or up to 42 days after delivery, the hospitals in the MHQIN will only be reviewing cases that occur during the delivery hospitalization. The abstractor should keep a list of cases that occur during hospital admissions that occur during pregnancy where the woman is discharged without having delivered or during postpartum readmissions, but those cases do not need to be abstracted and reviewed by the hospital quality improvement (QI) committee. DOHMH will ask for a count of SMM events occurring during hospitalizations that include delivery, separated into those that occur prior to delivery and those that occur during post-partum readmissions.

While most cases that meet the criteria for SMM abstraction and review will qualify in the course of one critical clinical event, cases may qualify in the course of multiple events across the entire delivery hospitalization. For example, if a woman receives 2 units of blood products during a cesarean delivery then receives 2 more units of blood products on postpartum day 2 (during the same hospitalization as the delivery), that qualifies as an SMM event that should be abstracted and reviewed. Please ensure that the systems in place for case identification will be able to pick up cases where the total amount of blood products transfused are equal or greater than 4 units, even if they are administered at different times during the hospitalization. It will usually be clear which cases meet the criteria for abstraction and QI committee review, which cases should be counted only, and which hospitalizations do not meet the criteria at all, but some situations are complicated and not easy to categorize. If there are any questions at all, please contact us.

Last Updated: 5/18/2020

## BISCOM (DOHMH Data Delivery Service)

BISCOM is a data delivery service used by DOHMH to send confidential information securely. This service will be used to send all completed forms from hospitals to the DOHMH staff, as well as hospital reporting and other confidential materials from DOHMH staff to hospitals. Please reach out to us for any BISCOM issues.

### Accessing BISCOM

- Once DOHMH IT creates a BISCOM account for you, you can access the BISCOM website here: [*insert URL of secure document transfer server*]
    - Tip: Bookmark this website on your browser – you will use it often
- Login with your username and password
    - Note: If you forget your password, the "Forgot your password?" feature will not work. Please email us to request DOHMH IT to reset your password.
    - Note: Please try to login once every 30 days. BISCOM automatically temporarily deactivates account not used within 30 days. If your account becomes deactivated, please reach out to us to request DOHMH IT to re-active your account.

### Sending files through BISCOM

- Go to **Express Delivery**
- Send all file deliveries to:
    - Note: If it does not allow you to send, add the email address to your BISCOM contacts list first.
- Attach all files ready for delivery
    - Note: Please remember to not include any confidential/identifying information in the forms or in the body of the BISCOM delivery, including MRN's.
- For questions requiring guidance, please consult with and send any documents directly through BISCOM only

### Receiving files through BISCOM

- When a file is sent to you, you should receive an email stating that you received a delivery. You can simply login to download it
    - Note: Please try to retrieve the delivery within a week as the deliveries expire after 7 days.

Last Updated: 5/18/2020

## What to Send and When

### Abstraction Form

- Please send the abstraction form on a rolling basis as soon as you have completed it for each case.
- If there are changes made to the abstraction form after it has been sent, please send again when complete and make note that the new version is the updated version for that case.

### Case Narrative/Committee Decision Form

- The case narrative and committee decision form can be sent after the hospital committee has reviewed the case and all the questions on the committee decision form have been answered.

## Abstraction Form Guidance

### General notes

- **Guidance document for abstraction form V9**
- Abstractors **must** maintain a separate excel file linking the Study ID to the Medical Record Number (for hospital use only)
- **For multiple births**, fill out section "**COMPLETE ONLY IF PREGNANCY STATUS WAS DELIVERED"** for **each** live birth/stillbirth.
- All fields should be filled in and not left blank
    - For string fields with unknown/missing data, please write in NA
    - For numeric fields with unknown/missing data, please fill in all 9's (ex. Age = 99, Zip code = 99999)

| Field | Data Entry | Primary Source | Notes |
|---|---|---|---|
| ***ABSTRACTION FORM*** | | | |
| Abstraction date | MM-DD-YYYY | | Enter date the abstraction began |
| Hospital | Name of Hospital | | |
| Study ID | XXX (XXX = 3-digit number) starting from 001 | | Entered by abstractor |
| MMRIA ID | DOHMH staff to generate this database ID | | Entered by DOHMH |
| SMM screening | Select criteria used to identify the SMM indication (one or both) | | |
| **PATIENT CHARACTERISTICS** [Primary Source: Birth Certificate Worksheet] | | | |
| Age | Enter patient's age (years) on admission date for SMM hospitalization | | Do not enter date of birth |
| Zip code of residence | Enter 5-digit zip code of patient's current usual residence | | |
| City/State of birth | Enter city and state of the patient's birth | | City and state of the mother's birth, not the current delivery |
| Race | Select patient's race(s) recorded | | If possible, use race as listed on the birth certificate |
| Hispanic Origin | Select patient's Hispanic origin(s) recorded | | If possible, use Hispanic origin as listed on the birth certificate |
| Marital status | Select patient's marital status recorded | | |
| Primary payer source | Select patient's primary payer source recorded | | |
| Education | Select patient's highest level of education completed | | |
| Country of birth | Enter patient's country of birth and years living in US (if foreign born). If less than one year living in US, enter "0" | | |
| Primary language spoken | Enter patient's primary spoken language | | |
| Limited English proficiency | If yes, select if translation services were documented in the medical records | | |
| Feeling About Becoming Pregnant | Select patient's feeling about becoming pregnant | | |
| Participated in WIC During This Pregnancy | Select patient's participation in WIC during this pregnancy | | |
| **PRENATAL CARE** [Primary Source: Prenatal Records] | | | |
| PNC Received | Select if prenatal care was received by patient | | |
| Access to PNC Records | Select if hospital has access to prenatal care records | | Attempt to obtain all hospital records if not readily accessible |

| | | | |
|---|---|---|---|
| PNC Located at An Affiliated Clinic Site | Select if prenatal care was located at a clinic site affiliated with the delivery hospital | | |
| Provider Discipline | Select prenatal care provider discipline/s | | |
| Gravida | Enter number of pregnancies regardless of outcome(s) | | |
| Term | Enter number of deliveries at term | | |
| Preterm | Enter number of preterm deliveries (20-36 weeks) | | |
| ITOP/STOP | Enter number of abortions (spontaneous or induced, <20 weeks) | | |
| Living | Enter number of living children | | |
| Height | Enter patient's height in feet/inches | | |
| Pre-pregnancy weight | Enter patient's pre-pregnancy weight in lbs. | | Please convert to lbs if in kg |
| Pre-pregnancy BMI | Enter patient's pre-pregnancy body mass index | | |
| Highest blood pressure | Enter patient's highest systolic and highest diastolic blood pressure from prenatal care records | | Can be from multiple readings |
| Pregnancy interval | Enter estimated months from end of last pregnancy (regardless of pregnancy outcome) to index pregnancy | | If exact month is not provided, and over two years, please estimate. Ex. Last pregnancy in 2016 = 36 months. |
| Number prior cesareans | Enter number of prior cesareans | | |
| Multiple gestation | Select if this pregnancy has multiple gestations and if so, how many | | |
| Week PNC began | Enter gestational week of first prenatal care visit, of if unknown, enter the trimester of first prenatal care visit | | |
| Number PNC visits | Enter number of documented prenatal care visits | | Do not include visits where a provider may not be seen (ex. ultrasound, nutrition visits) |
| **OBSTETRICAL RISK FACTORS** [Primary Source: Prenatal and Hospital Records] | | | |
| Obstetrical risk factors (history) | Select documented history of obstetrical risk factors | | |
| Obstetrical risk factors (current pregnancy) | Select documented obstetrical risk factors in the current pregnancy | | Enter fibroids as "Other" only if it impacted the delivery. |
| **SMM EVENT** [Primary Source: Hospital Records] | | | |
| Transferred from Other Facility | Select if the hospitalization originated in a different facility and a transfer occurred; if yes, specify the reason | | |
| If not transferred, admission reason | Select reason for admission at facility where SMM occurred | | |
| Timing of morbidity | Select timing of maternal morbidity | | |
| Pregnancy outcome | Select pregnancy outcome | | |
| **COMPLETE IF PREGNANCY OUTCOME WAS "DELIVERED (LIVE BIRTH /STILLBIRTH)"** ***Complete this section for each live birth or stillbirth (use separate form)*** | | | |
| Access to delivery records | Select if delivery records were accessible to abstractor | | Attempt to obtain all hospital records if not readily accessible. |
| Apgar scores | Enter Apgar score at 1, 5 and 10 minutes | | |
| Gestational age | Enter gestational age in weeks at time of delivery | | |
| NICU admit | Select if the newborn was admitted to the NICU as of current date | | |

| | | | |
|---|---|---|---|
| Neonatal death | Select if newborn death occurred as of current date | | |
| Birthweight | Enter infant's birthweight in grams | | |
| Mother's weight at delivery | Enter mother's weights at the time of delivery in lbs. | | Please convert to lbs if in kg |
| Place of Delivery | Select the final place of delivery | | |
| Delivery complications | Select any complications experienced by the patient during delivery | | |
| Labor | Select the type of labor | | |
| Final delivery route | Select final delivery route | | |
| Type of anesthesia | Select type of anesthesia used during delivery | | |
| Type of cesarean | If applicable, select the type of cesarean performed (Select one) | | |
| Primary reason for cesarean | If applicable, select the primary reason for cesarean (Select one) | | |
| Labor after cesarean | Select if labor after cesarean was attempted (Select one) | | |
| Forceps/vacuum attempt | Select if delivery with forceps/vacuum was attempted (Select one) | | |
| Delivery complications | Select if delivery complications occurred, and if so, describe in detail (Select one) | | |
| **ICU-RELATED QUESTIONS** [Primary Source: Hospital Records] | | | |
| Reason for ICU Admission | Select the reason/s for ICU admission (if applicable) | | If not admitted to ICU, select Other and write in "NA" |
| **HEMORRHAGE-RELATED QUESTIONS** [Primary Source: Hospital Records] | | | |
| Risk assessment | Was there a documented risk assessment on admission? | | |
| Blood typed cross-matched | Was blood typed and cross-matched on admission | | |
| Non-surgical interventions | Select any non-surgical interventions applied | | |
| Surgical interventions | Select any surgical interventions applied | | |
| Uterotonic medications | Select any uterotonic medications used | | |
| Massive transfusion protocol | Was massive transfusion protocol activated? | | |
| Packed RBCs transfused | Enter total packed red blood cells transfused during hospitalization up to and including SMM event | | |
| Blood products transfused | Enter total blood products transfused during hospitalization (including total number of packed RBCs transfused) up to and including SMM event | | |
| Estimated blood loss (EBL and QBL) | Enter total estimated and total quantified blood loss during hospitalization in mL up to and including SMM event | | |
| **SOCIAL AND ENVIRONMENTAL PROFILE** [Primary Source: Prenatal and Hospital Records, Social Work notes] | | | |
| Employment status | Select patient's employment status at time of hospitalization | | |
| Current living arrangement | Select patient's current living arrangements | | |
| Homelessness | Select patient's history of homelessness (Select one) | | |
| Occupation | Enter patient's primary occupation at time of hospitalization | | |
| Number of moves | Enter the number of documented times the patient moved residences within the previous 6 months | | |
| Health care access | Select any documented barriers to health care access for the patient | | |
| Communications | Select any documented barriers to communications | | |
| Social or emotional stress | Select any documented social or emotional stressors | | |
| Adherence to Care Issues | Select any documented reasons for adherence to care issues | | If none documented, select Other and write in "None Documented" |

| | | | |
|---|---|---|---|
| Mental health screenings | Select if there was a documented screening for mental health conditions, and if positive, was there a documented referral? | | |
| Substance use screenings | Select if there was a documented screening for substance use, and if positive, was there a documented referral? | | |
| Domestic violence screenings | Select if there was a documented screening for domestic violence, and if positive, was there a documented referral? | | |

## Abstraction Form – Color Coded

**Color Key**

- Green: All efforts should be made to acquire this data. If not found in the "usual" place, look in alternate areas. Check unknown if these data are not available after all efforts.
- Yellow: In the course of reading the chart, keep these in mind. Do not exhaust your options in looking for these.
- Red: If not easily available at first look, skip these and move on.

### ABSTRACTION FORM

| **Abstraction Date:** | **Hospital:** | **Study ID:** | **MMRIA ID:** |
|---|---|---|---|
| **SMM Screening:** 1) ≥4 Units Blood Products Transfused? ☐Yes ☐No **OR** 2) ICU Admission: ☐Yes ☐No | | | |

### A. PATIENT CHARACTERISTICS [Primary Source: Birth Certificate Worksheet]

| **Age (yrs):** | **Zip Code of Residence:** | **City of Birth:** | **State of Birth:** |
|---|---|---|---|

| **Race:** | **Hispanic Origin:** | **Marital Status (Select One):** |
|---|---|---|
| ☐ American Indian/Alaska Native | ☐ Mexican, Chicano ☐ Not Hispanic | ☐ Never Married ☐ Unknown |
| ☐ Asian/Pacific Islander | ☐ Puerto Rican ☐ Unknown | ☐ Married |
| ☐ Black or African American | ☐ Dominican | ☐ Married, but Separated |
| ☐ White | ☐ Yes Hispanic, Origin Unknown | ☐ Divorced |
| ☐ Not Specified | ☐ Other Hispanic *(specify)*: | ☐ Widowed |
| ☐ Other *(specify)*: | | ☐ Domestic Partnership |

| **Primary Payer Source (Select One):** | **Education Completed (Select One):** | **Country of Birth (If Foreign Born):** |
|---|---|---|
| ☐ Private Insurance | ☐ Less Than High School; No Diploma | *If foreign born, time living in US (yrs):* |
| ☐ Self-pay | ☐ High School Graduate/GED | *(Note: Enter "0" if less than 1 year living in US)* |
| ☐ Medicaid | ☐ Some College; No Degree | **Primary Language Spoken:** |
| ☐ Unknown | ☐ College Graduate or Higher | **Limited English Proficiency:** ☐ Yes ☐ No ☐ Unknown |
| ☐ Other *(specify)*: | ☐ Unknown | *If yes, any documented translation services?* ☐ Yes ☐ No |

| **Feeling About Becoming Pregnant (Select One):** | **Participated in WIC During This Pregnancy? (Select One)** |
|---|---|
| ☐Wanted to Be Pregnant Sooner ☐Wanted to Be Pregnant Later | |
| ☐Wanted to Be Pregnant Then ☐Didn't Want to Be Pregnant Then or Any Time in The Future | ☐Yes ☐No ☐ Unknown |

### B. PRENATAL CARE (PNC) [Primary Source: Prenatal Records]

| **PNC Received:** ☐ Yes ☐ No | **Access to PNC Records:** ☐ Yes ☐ No | **PNC Located at An Affiliated Clinic Site?** ☐ Yes ☐ No ☐ Unknown |
|---|---|---|
| **Provider Discipline:** ☐ OBGYN ☐ Midwife ☐ MFM ☐ Family Medicine ☐ Unknown ☐ Other *(specify)*: | | |

| **Gravida:** | | **Height (ft/in):** | **Pregnancy Interval (mos):** | **Week PNC Began:** |
|---|---|---|---|---|
| **Para:** | | **Pre-pregnancy Weight (lbs):** | **Number Prior Cesareans:** | ☐ Week Unknown |
| **Term:** | **Preterm:** | **Pre-pregnancy BMI:** | **Multiple Gestation:** ☐ Yes ☐ No | *If unknown, trimester:* |
| **ITOP/STOP:** | **Living:** | **Highest Blood Pressure:** | *If yes, how many?* | **Number of PNC Visits:** ☐ Unknown |

### C. OBSTETRICAL RISK FACTORS [Primary Source: Prenatal and Hospital Records]

**History of:**

| | | | |
|---|---|---|---|
| ☐ No Risk Factors | ☐ Pre-pregnancy Diabetes | ☐ Previous Fetal Demise | ☐ Abnormal Placentation |
| ☐ Pre-term Delivery | ☐ Postpartum Hemorrhage | ☐ Anemia | ☐ Prior Uterine Surgery |
| ☐ Pre-pregnancy Hypertension | ☐ Pre-eclampsia/HELLP | ☐ Asthma | |
| ☐ Cardiac Disease | ☐ Prior Shoulder Dystocia | | |
| ☐ Other *(specify)*: | | | |

**Current Pregnancy:**

| | | | |
|---|---|---|---|
| ☐ No Risk Factors | ☐ Infertility Treatment | ☐ DVT/PE | ☐ Multiple Gestation |
| ☐ Gestational Diabetes | ☐ Pre-eclampsia | ☐ Polyhydramnios | ☐ Altered Mental State or Loss of Consciousness |
| ☐ Gestational Hypertension | ☐ Eclampsia | ☐ Oligohydramnios | |
| ☐ Acute Cardio-pulmonary Event *(specify)*: | | | |
| ☐ Other *(specify)*: | | | |

## D. SMM EVENT [Primary Source: Hospital Records]

**Transferred from Other Facility?** ☐ Yes ☐ No *(If yes, why?)*:

**If Not Transferred, Admission Reason:**

☐ Labor ☐ Planned Induction/Cesarean ☐ Unknown
☐ Medical Reasons Not Related to Pregnancy ☐ Complications of Pregnancy/Not in Labor
☐ Other *(specify)*:

| **Timing of Maternal Morbidity (Select One):** | **Pregnancy Outcome (Select One):** | | |
|---|---|---|---|
| ☐ Antepartum (*enter gestational age in weeks*): | ☐ Live Birth | ☐ AB: Spontaneous | ☐ Molar Pregnancy |
| ☐ Intrapartum ☐ Postpartum (8 to 72 hours) | ☐ AB: Induced | ☐ Ectopic | ☐ Not Delivered |
| ☐ Postpartum (< 8 hours) ☐ Postpartum (73 hours to 42 days) | ☐ Stillbirth/Fetal Demise (≥20 weeks) | | |

## E. COMPLETE ONLY IF PREGNANCY OUTCOME WAS "DELIVERED (LIVE BIRTH/STILLBIRTH)"

***Complete this section for each live birth or stillbirth (use separate form)***

| **Access to Delivery Records:** ☐ Yes ☐ No | **NICU admit?** ☐ Yes ☐ No ☐ Unknown | **Place of Delivery (Select One):** |
|---|---|---|
| **Apgar at 1 min**: | **Neonatal Death (as of today)?** ☐ Yes ☐ No ☐ Unknown | ☐ Hospital ☐ Birthing Center |
| **Apgar at 5 min**: | **Birthweight (g):** | ☐ Home Delivery ☐ Unknown |
| **Apgar at 10 min:** | **Mothers Weight at Delivery (lbs):** | ☐ Other *(specify):* |
| **Gestational Age (weeks):** | | |

**Did the Patient Experience Any of The Following?**

| | | |
|---|---|---|
| ☐ None Specified | ☐ Laceration (e.g. Vaginal Sidewalls/Cervical/4th Degree) | ☐ Febrile (>100.4° F or 38°C) |
| ☐ Uterine Atony | ☐ Vulvovaginal Hematoma | ☐ Arrested Dilation or Descent |
| ☐ Uterine Inversion | ☐ Abnormally Adherent Placenta (Accreta Spectrum) | ☐ Shoulder Dystocia |
| ☐ Uterine Rupture | ☐ Retained Placenta or Products of Conception | ☐ Pre-term Labor |
| ☐ Retro-peritoneal Bleeding | ☐ Other Intraperitoneal Bleeding (Uterine Rupture Excluded) | ☐ Chorioamnionitis |
| ☐ Suspected Abruption | | |
| ☐ Other *(specify)*: | | |

| **Labor:** | **Final Delivery Route (Select One):** | **Type of Anesthesia:** |
|---|---|---|
| ☐ None ☐ Spontaneous | ☐ Vaginal/Spontaneous ☐ Cesarean | ☐ None ☐ General ☐ Local |
| ☐ Augmented ☐ Unknown | ☐ Vaginal Vacuum/Forceps ☐ Unknown | ☐ Epidural ☐ Spinal ☐ Unknown |
| ☐ Induced | ☐ Vaginal/Not Specified | ☐ Other *(specify)*: |

| **Type of Cesarean (If Applicable):** | **Primary Reason for Cesarean (If Applicable):** |
|---|---|
| ☐ Scheduled ☐ Not Applicable | ☐ Repeat (Not failed VBAC) ☐ Previa ☐ Not Applicable |
| ☐ Unplanned ☐ Unknown | ☐ Dystocia/Failure to Progress ☐ Accreta ☐ Unknown |
| ☐ Emergency | ☐ Elective-patient Request ☐ Malpresentation |
| **Labor After Cesarean Attempted?** | ☐ Fetal Indications *(specify)*: |
| ☐ Yes ☐ No ☐ Not Applicable ☐ Unknown | ☐ Maternal Condition *(specify)*: |

**Was Delivery with Forceps/Vacuum Attempted?** ☐ Yes, Successful ☐ Yes, Unsuccessful ☐ No, Not Attempted ☐ Unknown

**Were There Complications of Delivery?** ☐ Yes ☐ No (*If yes, specify*):

## F. ICU-RELATED QUESTION [Primary Source: Hospital Records]

**Reason for ICU Admission:**

☐ Respiratory ☐ Cardiovascular ☐ Neurologic ☐ Pre-eclampsia/Eclampsia ☐ Hemorrhage ☐ Sepsis
☐ Other *(specify)*:

## G. HEMORRHAGE-RELATED QUESTIONS [Primary Source: Hospital Records]

| | | |
|---|---|---|
| **Documented Risk Assessment on Admission:** ☐ Yes ☐ No ☐ Unknown | | **Uterotonic Medications Used to Treat Hemorrhage:** |
| **Was Blood Typed and Cross-Matched on Admission?** ☐ Yes ☐ No ☐ Unknown | | ☐ None Used |
| **Were Non-Surgical Interventions Applied?** | | ☐ Oxytocin |
| ☐ None Applied ☐ Uterine Massage ☐ Bakri Balloon ☐ Uterotonics ☐ Unknown | | ☐ Methylergonovine (Methergine) |
| **Were Surgical Interventions Applied?** | | ☐ Misoprostol (Cytotec) |
| ☐ None Applied ☐ B-lynch Suture ☐ Hysterectomy | | ☐ Carboprost Tromethamine (Hemabate) IM |
| ☐ D&C ☐ Hypogastric Artery Ligation ☐ Unknown | | ☐ Tranexamic Acid (TXA) |
| ☐ Laparotomy ☐ Uterine Artery Ligation | | ☐ Unknown |
| ☐ Other (*specify*): | | |
| **Was Massive Transfusion Protocol Activated?** | **Total Units Packed RBC's Transfused:** | **Total EBL (mL)**: |
| ☐ Yes ☐ No ☐ Unknown | **Total Units Blood Products Transfused:** | **Total QBL (mL):** |

## H. SOCIAL AND ENVIRONMENTAL INFORMATION [Primary Source: Prenatal and Hospital Records]

| | | |
|---|---|---|
| **Employment Status:** | **Current Living Arrangements:** | **Homelessness:** |
| ☐ Full Time ☐ Unemployed | ☐ Own ☐ Homeless (Shelter) ☐ Public Housing | ☐ Never |
| ☐ Part Time ☐ Unknown | ☐ Rent ☐ Homeless (Street) ☐ Unknown | ☐ Yes, In Last 12 Months |
| ☐ Self-employed | ☐ Live w/ Relative | ☐ Yes, More Than 12 Months Ago |
| ☐ Other *(specify)*: | ☐ Shelter Type (*specify*): | ☐ Unknown |
| | ☐ Other *(specify)*: | |
| **Primary Occupation**: | | **Documented Number of Moves in Previous 6 Months**: |
| **Documented Barriers to Health Care Access:** | | **Documented Barriers to Communications:** |
| ☐ None Documented ☐ Transportation ☐ Childcare | | ☐ None Documented ☐ Limited English Proficiency ☐ Hearing Impaired |
| ☐ Cultural Norms ☐ Mobility ☐ Financial | | ☐ Functional Illiteracy ☐ Vision Impaired ☐ Speech Impaired |
| ☐ Distance | | ☐ Other (*specify*): |
| ☐ Other (*specify*): | | |
| **Documented Evidence of Other Social or Emotional Stress:** | | |
| ☐ None Documented | ☐ Hx of Domestic Violence | ☐ Hx of Substance Use |
| ☐ Hx of Psychiatric Hospitalizations or Treatment | ☐ Prior Suicide Attempts | ☐ Recent Trauma |
| ☐ Child Protective Services Involvement | ☐ Hx of Substance Use Treatment | ☐ Hx of Abuse (Physical, Sexual, Verbal) |
| ☐ Hx of Childhood Trauma (e.g. abuse, neglect, foster care, or criminal legal system involvement) | ☐ Criminal Justice Involvement (adulthood) | ☐ Unemployment |
| ☐ Other (*specify*): | | |
| **Adherence to Care Issues:** | **If Yes, Documented Reasons:** | |
| ☐ Missed Appointments ☐ Delays in Care | ☐ Appointment Conflict ☐ Financial ☐ Childcare | |
| ☐ Medication | ☐ Provider Conflict (lack of agreement, dislike) ☐ Transportation | |
| ☐ Other (*specify*): | ☐ Other (*specify*): | |
| **Documented Screenings For:** | | **If Screened Positive, Was Patient Referred?** |
| **Mental Health Conditions:** ☐ Yes ☐ No ☐ Unknown | | ☐ Yes ☐ No ☐ Unknown |
| **Domestic Violence:** ☐ Yes ☐ No ☐ Unknown | | ☐ Yes ☐ No ☐ Unknown |
| **Substance Use:** ☐ Yes, Verbal ☐ Yes, Toxicology ☐ No ☐ Unknown | | ☐ Yes ☐ No ☐ Unknown |
| *If toxicology was collected, was consent documented?* ☐ Yes ☐ No | | |

## I. ADDITIONAL NOTES TO INFORM SMM CASE NARRATIVE:

## Case Narrative Template

| CASE NARRATIVE TEMPLATE | | | |
|---|---|---|---|
| **Review Date:** | **Hospital:** | **Study ID:** | **MMRIA ID:** |

### A. SUMMARY

She is a (**AGE, RACE/ETHNICITY, PLACE OF BIRTH, MARRIAGE STATUS, EDUCATIONAL LEVEL**), who at (**WEEKS**) of pregnancy [or (**DAYS**) postpartum] presented to the (**HOSPITAL/EMERGENCY DEPT/CLINIC/OTHER**) with _____. She developed _____ and was treated with _____and discharged (**DAYS**) after admission.

### B. PRENATAL CARE

She is ___ years old, gravida ____ para _____ with a past obstetric history of _____. Prior surgical history includes_____. Her family medical history was positive for _____. Pre-existing medical conditions included_____. She was (**HEIGHT**) and (**WEIGHT**) at her first prenatal visit at (**WEEKS**). Her pre-pregnancy BMI was _____.

She attended ___ visits at a (**HOSPITAL CLINIC/HEALTH CENTER/PRIVATE OFFICE**) with an (**OBGYN/MIDWIFE/FP**) and had (**MEDICAID/PRIVATE/NO**) insurance coverage. Screening for substance [alcohol, tobacco, illicit or prescription drugs] use was (**POSITIVE/NEGATIVE/NOT FOUND IN RECORDS**). [If positive state condition]. Screening for mental health conditions was (**POSITIVE/NEGATIVE/NOT FOUND IN RECORDS**). [If positive state condition]. Screening for domestic violence was (**POSITIVE/NEGATIVE/NOT FOUND IN RECORDS**). [If positive state condition]. Screening for abuse [sexual, physical, verbal, childhood] was (**POSITIVE/NEGATIVE/NOT FOUND IN RECORDS**). [If positive state condition]. Patient's primary language is _____. She (**IS/IS NOT**) proficient in English. [If not proficient in English, translation services were (**DOCUMENTED/NOT DOCUMENTED**)]. She lives with (**PARTNER/FRIEND(S)/PARENT(S)/CHILDREN/ETC**) in a (**HOME/SHELTER TYPE**). Additional social determinant factors are _____.

The pregnancy was complicated by (**SUMMARIZE ANY PRENATAL CARE PROBLEMS**). Her highest systolic blood pressure during prenatal care was ____ and her highest diastolic blood pressure during prenatal care was ____. The majority of her diastolic blood pressures were [**INSERT RANGE**]. During the sentinel pregnancy she was taking (**LIST MEDICATIONS/VITAMINS/SUPPLEMENTS**).

## C. DELIVERY AND EVENTS OF SEVERE MORBIDITY

She presented at (**WEEKS**) gestation **to** the (**HOSPITAL/EMERGENCY DEPT/CLINIC/OTHER**) via (**PRIVATE CAR/EMS/OTHER**). Her chief complaint was _____. History of present illness include (**SUMMARIZE PERTINENT RISK FACTORS**). Pertinent physical exam findings include (**SUMMARIZE PHYSICAL EXAM FINDINGS**).

## D. CHRONOLOGICAL SEQUENCE OF EVENTS (NO ACTUAL DATES OR TIMES)

Include the following pertinent data (**VITAL SIGNS, PHYSICAL FINDINGS, LABORATORY RESULTS, RADIOLOGY RESULTS, WORKING DIAGNOSES, MEDICAL AND SURGICAL TREATMENTS, TRANSFER TO ICU, USE OF CONSULTANTS**). Include delivery method and indication, birthweight and Apgar scores.

***Example:***

*Cesarean delivery of a 4500g infant, Apgars 7,8, for arrest of dilation after oxytocin stimulation for 12 hours.*

*5 hours after delivery by cesarean for fetal bradycardia, heavy bleeding was noted in the PACU by RN. Pulse 120, BP100/50. Resident physician (PGY2) at bedside. Uterine atony noted and treated by fundal massage, methergine and hemabate.*

*6 hours PP, 1st unit of blood hung, bleeding continued. Total EBL (intraop & postpartum) 2.5 liters. VS P140, BP 90/50*

*7 hours PP, back to the OR for D&C and balloon tamponade. Gyn oncologist called. Interventional radiologist alerted.*

*7.5 hours PP Hct 21%, platelets 38,000. Massive transfusion protocol activated. Gyn oncologist arrived, hysterectomy performed and hemostasis achieved. Postop transfer to ICU VS: P100, BP 120/78; Hct 30%, platelets 93,000.*

*Total blood products replaced: 7U PRCs; 4U FFP, 1 6-pack of platelets.*

*Total ICU stay of 2 days. Discharged home on PP day 6.*

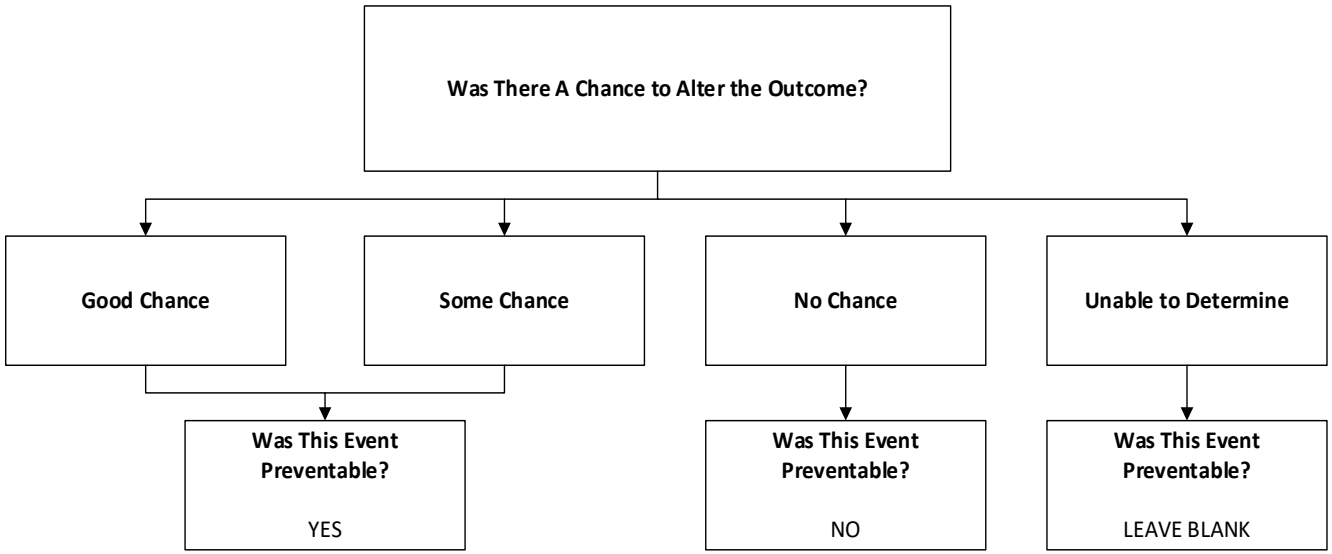
## Committee Decision Form Guidance

### General notes

- **Guidance document for committee decision form V6**
- Abstractors **must** maintain a separate excel file linking the Study ID to the Medical Record Number (for hospital use only)

| Field | Data Entry | Notes |
|---|---|---|
| **COMPLETENESS OF CASE RECORDS** | | |
| Review date | MM-DD-YYYY | If a case gets carried over to next meeting, enter date of final review |
| Hospital | Name of hospital | |
| Study ID | XXX (XXX = 3-digit number) starting from 001 | Entered by abstractor |
| MMRIA ID | DOHMH staff to generate this database ID | Entered by DOHMH |
| **A. PRIMARY CAUSE OF MORBIDITY** | | |
| Cause | Enter description of primary cause of morbidity | |
| Code for primary cause | Enter PMSS code for primary cause of morbidity (see pp. 3-4) | |
| Obesity | Select if obesity contributed to the SMM event | |
| Mental health conditions | Select if mental health conditions contributed to the SMM event | |
| Substance use | Select if substance use contributed to the SMM event | |
| **B. PREVENTABILITY** | | |
| Was event preventable? | Select if the event was deemed preventable.<br>"An SMM event is considered preventable if there was some chance that:<br><br>1. the event could have been averted or<br>2. the patient did not have to get as sick as she did.<br><br>In other words, one or more reasonable changes to patient, family, provider, system or community factors could have had some chance to alter the outcome. " | See preventability guide below for answering these questions.<br><br>If the committee is having difficulty coming to consensus about whether the event was preventable, it may be helpful to answer whether there was any chance to alter the outcome first. |
| Chance to alter outcome? | Select if there was a chance to alter the outcome.<br><br>Chance to alter the outcome speaks to the degree to which the event was potentially preventable. Was there a chance to reduce the severity of the event? Did the woman need to get as sick as she did? | |
| Positively alter outcome? | Select if any actions positively altered the outcome. | |
| Escalation policy/chain of command | Select if the escalation policy/chain of command invoked was pursuant to hospital protocol | |
| Practices that were done well and be reinforced | Describe all practices that were done well during this event and should be reinforced at the patient/family, provider, facility, system and community levels | |
| **CONTRIBUTING FACTORS WORKSHEET** | | |
| Contributory factors | Select all factors that contributed to the severity of the event at patient/family, provider, facility, system and community levels. | |
| Recommendations to prevent similar events | Describe all recommendations that could help prevent similar events in the future at patient/family, provider, facility, system and community levels<br>If there was at least some chance to alter the severity of the outcome, were there specific and feasible actions which, if implemented or altered, might have changed the course of events? | |

# Section B. Preventability Guide



## Frequently Asked Questions (FAQs)

1. **What should I name the documents?**
    - Abstraction form: AF_Hospital_StudyID.pdf (Ex: AF_DOH_001.pdf)
        i. For multiples: AF_Hospital_StudyID_Twin.pdf (Ex. AF_DOH_001_TwinB.pdf)
    - Case narrative: CN_Hospital_StudyID.docx (Ex. CN_DOH_001.docx)
    - Committee decision form: CD_Hospital_StudyID.pdf (Ex. CD_DOH_001.pdf)
2. **What should I do about the abstraction form if there are multiple births?**
    - Fill out the abstraction form to completion. Section E should focus on one of the multiple births. For each additional birth (live birth/stillbirth), create a new abstraction form and only fill out Section E.
3. **What should I do about unknown/missing data?**
    - Please try to fill out every field and not leave any blank.
    - If an "Unknown" option is not available, please fill in **NA** for character fields, or all **9**'s for numeric fields (Ex. Age=99, Zip code=99999).
4. **Can I use a different template for the case narrative?**
    - The template provided is an example and should be customized according to the hospital needs. Feel free to discuss with your hospital PI the preferred case narrative format to bring to the hospital QI committee. Some previously used templates include paragraph format, bulleted chain of events, or a combination of both.
5. **Is it ok if the Committee deliberations do not follow the exact order of the Committee Decision Form?**
    - Yes, it's ok to go out of order and record answers to each question as the discussion flows.
6. **Should I include blood transfusion information if the person does not meet the indicator criteria for blood transfusions?**
    - Yes, include all available information even if the person receives less than four units of blood products.
7. **Should we use the PDF or Word DOC version of the forms?**
    - It is preferred to use the PDF since it is designed to make data entry simpler. If you cannot use the PDF, feel free to use the Word DOC version.
8. **Do the study ID numbers have to be sequential?**
    - Make the study ID numbers sequential in the manner they are identified, not on the date of the SMM event.
9. **What should I do if the same information is found in multiple places but differs?**
    - Since some information will be available in multiple areas of the medical record, we leave it up to you to determine the most accurate source. Information from the birth certificate worksheet is preferred over other sources since this information is self-reported.


NYC
Health