## **DATA SHARING AGREEMENT**

This Data Sharing Agreement ("Agreement") is entered into as of Dec. 17, 2019 (the "Effective Date") by and between Accreditation Council for Graduate Medical Education, an Illinois not for profit corporation (the "ACGME") and The Regents of the University of Michigan ("UM") on behalf of Brian George, MD ("Investigator"),. The ACGME and UM are individually a "Party" and collectively the "Parties."

#### **PURPOSE**

- A. Investigator is an Assistant Professor of Surgery and Director of the Center for Surgical Training and Research (C-STAR) at the University of Michigan.
- B. The ACGME accredits graduate medical education programs (i.e., residency and fellowship) programs in the United States (the "**Programs**").
- C. As part of its accreditation services, ACGME collects certain data as further described on <a href="Exhibit A">Exhibit A</a> attached hereto (the "ACGME Data") from the Programs and/or the resident physicians participating in the Programs (the "Residents") for accreditation and related purposes.
- D. Investigator wishes to use the ACGME Data to examine the relationships between training activities and assessments during surgical specialty training and performance in clinical practice after graduation from residency.

NOW THEREFORE, in consideration of the mutual covenants and agreements set forth herein, and other good and valuable consideration, the sufficiency of which is hereby acknowledged by the Parties, the Parties agree as follows:

#### 1. DATA SHARING.

- a. <u>ACGME Data</u>. The ACGME agrees to provide ACGME Data to Investigator in such format and at such intervals as detailed in <u>Exhibit A</u>. The ACGME Data has been provided to ACGME by Programs and Residents and ACGME does not vouch for, nor is it responsible for, its accuracy.
- b. Compiled Data. Investigator will link the ACGME Data to UM data to create a deidentified combined data set ("Compiled Data") on which to conduct analysis in support of
  Investigator's research goals and the ACGME's research goals. UM will set up a secure HIPAAcompliant University of Michigan secure storage location (e.g., specialized HIPAA-compliant
  MBox or similar) for sensitive surgical education data. There will be two individuals with access
  to the identified ACGME data. The first will be a data manager who manages the secure account
  and ensures that one data analyst (a different individual) will have access to the identified data.
  This analyst will merge the identified ACGME Data with other UM-managed data and de-identify
  it prior to analysis. The data manager will ensure that the analyst accesses the data on an encrypted
  work device and that any data is de-identified prior to sharing with anyone else on the Research
  Team as defined herein. At no point should anyone other than these designated individuals (i.e.,
  the data manager and the data analyst) have access to identified ACGME Data and the analysis
  team will only receive a file that has removed identified data. UM agrees to maintain the

confidentiality of the data and remove any identifying information from Compiled Data files after the merge has been completed.

- c. <u>IRB Approval</u>. The provisions of this Section 1 are contingent upon securing approval or waiver from an appropriate institutional review board ("IRB") for each project that uses the ACGME Data and UM Data.
- d. Research Team. The Research Team shall be defined as individual(s) at UM and the ACGME conducting the Research. The initial Research team is comprised of Brian George, MD and Eric Holmboe, MD (the "Research Team").

## 2. CONFIDENTIAL AND PROTECTED INFORMATION.

- a. <u>Confidentiality and Proprietary Information</u>.
  - i. The Parties acknowledge and agree that the ACGME Data is "Confidential and Proprietary Information" of ACGME.
  - ii. Investigator and UM agree (i) that they will use the ACGME Data only for non-commercial purposes in connection with the proposed research and (ii) that they will not disclose ACGME Data that they receive from the ACGME in a manner that would allow a third party to re-identify or connect a Resident's identity with the Resident's identified ACGME Data (unless the Resident has consented to such disclosure) for a period of five (5) years from disclosure. Confidential and Proprietary Information shall be disclosed in writing or, if disclosed orally, reduced to writing within twenty (20) days of disclosure to UM.
  - Investigator and UM agree that they will not, directly or indirectly: (i) use the ACGME's Confidential and Proprietary Information except as contemplated herein or (ii) disclose any of the ACGME's Confidential and Proprietary Information to any third party, except to the extent that such Confidential and Proprietary Information: (a) was already in the public domain as of the date of disclosure or passes into the public domain before the date of disclosure other than through a violation of this Section by the receiving Party; (b) was rightfully in the Party's possession without obligation of confidence prior to receipt from the other Party or was lawfully obtained from a third party who was under no obligation of confidence to the disclosing Party; (c) is received by UM from a third party with authorization to make such disclosure; (d) was independently developed by employees or other agents of the receiving Party without use of or reference to the disclosed Confidential and Proprietary Information; (e) is released with ACGME's written consent; or (e) is required to be disclosed to comply with a judicial order or decree or to comply with applicable law (provided, however, that the Parties agree to give prior written notice of such prospective disclosure to the extent possible and to take any commercially reasonable and lawful actions available to avoid and/or minimize the extent of such disclosure).
  - iv. Investigator and UM will treat the ACGME's Confidential and Proprietary Information with the same degree of care to avoid disclosure to third parties in violation of this Agreement as they use to protect their own confidential or

proprietary information and only individuals with a need to know in each respective organization shall have access to such confidential and proprietary information.

- b. <u>Notification of Breach</u>. In the event either Party discovers a breach of this Section which has resulted or may result in the unauthorized dissemination or use of data obtained from the other Party that has not been de-identified, the Party which discovers the data breach shall promptly provide written notice to the other Party and the Parties shall work together to ensure any and all other parties affected by the breach are notified. Each of the Parties agrees that he shall comply with the requirements of any applicable federal, state, or local law governing the provision of notice in the event of breaches of data security.
- c. Equitable Relief. The Parties acknowledge and agree that any breach of the terms of this Section will result in irreparable harm to the non-breaching Party, that the non-breaching Party cannot be reasonably or adequately compensated in damages for such breach or threatened breach, and that the non-breaching Party will therefore be entitled, in addition to any other remedies that may be available to him, to seek any and all equitable remedies including, without limitation, injunctive relief, to prevent such breach or threatened breach and to secure the enforcement thereof.

## 3. OWNERSHIP AND LICENSE

- a. <u>ACGME</u>. The Parties acknowledge and agree that ACGME owns the system and interface it has developed for collecting the ACGME Data. They further acknowledge that ACGME retains any ownership or licensure rights it has been granted in the ACGME Data. The ACGME grants a nonexclusive, royalty-free, fee-free, nontransferable, worldwide, limited, and partially revocable license to Investigator and UM to use the ACGME Data contained in the Compiled Data for the purposes described herein. This Agreement does not restrict ACGME's use of its ACGME Data or its ability to publish its own research or analysis of ACGME Data.
- b. Ownership of Outcomes. All right, title, and interest in the copyright or other intellectual property rights to the analysis and findings of the Compiled Data by Investigator and UM, including any publication of the findings (the "Outcomes"), in whatever media now known or hereinafter developed throughout the world, shall be owned by Investigator and UM. Investigator and UM shall grant ACGME an unrestricted, perpetual license to use the Outcomes for its internal, non-commercial research, and educational purposes.
- c. <u>Exploitation of the Outcomes</u>. Investigator and UM shall not have the right to license the ACGME Data to a third party for any purpose.

#### d. <u>Publication</u>.

i. The Parties acknowledge and agree that Investigator shall have the right to communicate the Outcomes in any fashion, including but not limited to, publish, reproduce, prepare derivative works based upon, distribute, display, or present the Outcomes without the prior written consent of ACGME. Notwithstanding the foregoing, Investigator and UM shall provide ACGME with a copy of the publication thirty (30) days prior to disclosure to a third party so that ACGME can request the removal of Conficential Information of ACGME (which definition shall not include the Outcomes).

- ii. Each Party agrees it will acknowledge the other's contribution to the Outcomes in any publication that includes the Outcomes.
- iii. Neither Party, nor any investigator, has any right or license to use the other Party's or its employees, names, trademarks, service marks, trade names, logos, symbols or brand names. Notwithstanding the foregoing, ACGME agrees that Investigator may disclose the study title, ACGME's name, the nature and scope of the project, and duration of the study for institutional reporting purposes (including publicly accessible websites), mandatory conflict of interest disclosures, and when required by applicable law or for federal and other funding applications.
- e. <u>No Fees</u>. Neither Party owes fees or other compensation to the other Party for the disclosure and licenses granted under this Agreement, and each Party will be responsible for its own costs.
- f. <u>Prospective Revocation of License</u>. Each of the licenses granted in this Section is revocable prospectively effective as of the expiration or termination of this Agreement with respect to ACGME Data not yet delivered to the other Party. The ACGME may not revoke a license with respect to ACGME Data previously delivered, except due to Investigator's material breach of this Agreement.

# 4. REPRESENTATIONS AND WARRANTIES, LIMITATION OF LIABILITY

#### a. ACGME

- i. ACGME represents and warrants that (i) it has the right and power to enter into this Agreement and (ii) there is no outstanding contract, commitment, or legal impediment that may materially limit, restrict or impair its ability to enter into and perform its obligations under this Agreement.
- ii. ACGME does not warrant that the ACGME Data provided pursuant to this Agreement is error-free or that it will be useable for any particular purpose.
- iii. ACGME will not be liable to the other under or in connection with this Agreement for any special, indirect, incidental, or consequential damages. In no event will ACGME's liability under this agreement exceed Five Hundred Dollars (\$500).

#### b. UM

- i. UM represent and warrant that (i) they will use ACGME Data received from ACGME in a de-identified manner pursuant to this Agreement only for research and education in connection with Investigator's mission and purposes and not for any commercial purposes and (ii) when they present comparative data they will only do so in aggregate form.
- ii. UM represent and warrant that (i) they have the right and power to enter into this Agreement and (ii) there is no outstanding contract, commitment, or legal impediment that may materially limit, restrict or impair their ability to enter into and perform its obligations under this Agreement.

## 5. INSURANCE AND INDEMNIFICATION

- a. <u>Insurance</u>. JM represents that UM has adequate liability insurance, such protection being applicable to officers, employees, and agents while acting within the scope of their employment by UM. UM has no insurance policy as such that can extend protection to any other person. Each Party hereby assumes any and all risks of personal injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees, and agents thereof.
- b. <u>Indemnification</u>. Each party is responsible for their own negligence, acts, or omissions.

### 6. MISCELLANEOUS

- a. <u>Compliance with Applicable Laws</u>. Each Party represents that it shall comply with all applicable laws in connection with its respective storage, distribution and use of the ACGME Data and Pass Rate Data.
- b. <u>Right to Use Independently Obtained Data</u>. The Parties agree that this Agreement will have no application to any data obtained by either Party independently from the data provided to it by the other Party.
- c. <u>Entire Agreement</u>. This Agreement constitutes the entire agreement between the Parties regarding the sharing of ACGME Data and supersedes all prior understandings and agreements (whether written or oral) regarding such subject matter. The Parties agree that all ACGME Data that was disclosed to the other Party prior to the execution of this Agreement will be treated as ACGME Data disclosed under this Agreement.
- d. <u>Survival</u>. All provisions of this Agreement that, by their nature, should survive termination, including, without limitation, confidential and protected information, ownership and license, limitation of liability, and indemnification.
- e. <u>No Assignment</u>. Neither Party may assign its rights or obligations under this Agreement without the advance written consent of the other Party, which may be withheld in its discretion.
- f. Governing Law. This Agreement shall be governed, interpreted and construed in accordance with the laws of Michigan.
- g. <u>Amendments</u>. This Agreement may not be amended unless the amendments are made in a writing signed by both Investigator and the ACGME.
- h. <u>Severability</u>. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of the remainder of this Agreement.
- i. <u>No Third-Party Beneficiaries</u>. Nothing in this Agreement, express or implied, is intended to or shall confer upon any other person who is not a Party to this Agreement any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

j. <u>Execution in Counterparts</u>. This Agreement may be executed in any number of counterparts and by different Parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart of a signature page to this Agreement by pdf or facsimile shall be effective as delivery of a manually-executed counterpart of this Agreement.

[Signature Page Immediately Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement to be effective as of the Effective Date.

THE RE	GENTS OF THE	EUNIVERSITY
OF MIC	HIGAN ,	
By:	ESM	
Name: Er	ic S. Ward	
Title: Pro	ject Representativ	a Office of
Rese	earch and Sponsor	ed Projects
Date:	DECEMBER	2019
	Acknowledged: EORGE, MD	
BC		
Date: De	cember 3, 2019	
-uv-		

ACCREDITATION COUNCIL FOR GRADUATE MEDICAL EDUCATION

Eric Holmboe, Chief, Research, Milestones Development and Evaluation Officer

Date: 17 DEC 2019

# EXHIBIT A DATA

ACGME shall provide Investigator with the following final Milestones Assessment Data for surgery residents who graduated (categorical) in 2016, 2017, and 2018, such formats and at such intervals as described below:

Milestone Data - ACGME collects competency based developmental outcomes data ("Milestone Data") from each Program. ACGME shall provide Investigator three (3) files: Milestone Data by resident; Specialty List; and Question Key and Response Values for General Surgery one time within reasonable timeframe upon execution of this Agreement.

# EXHIBIT A-1 MILESTONE DATA FILES for General Surgery

# Candidate File

Field Name	Data Type	Max	Field Description		
ScheduleWindowDescription	VARCHAR	200	General Description of Evaluation period		
SurveyDefinitionID	int	14	Id for evaluation period		
SurveyName	VARCHAR	150	Specific name for evaluation period		
AcademicYear	Int	4	Academic year of evaluation		
Program ORGID	VARCHAR	10	10 digit ACGME program number		
SpecialtyCode	VARCHAR	3	3 digit specialty identifier		
SpecialtyName	VARCHAR	255	Name of the specialty		
SponsorCode	VARCHAR	6	6 character ACGME code identifying sponsoring institution. Make sure to n drop leading zeros.		
PersonID	Number	38	Resident unique ID that is not identifiable		
NPI	Number		National Provider ID (as available)		
Resident full name	VARCHAR	?	Full name (first, middle, last)		
Last4SSN	Number	3)	Last 4 digits of Social Security Number		
Birthdate	Date		Date of birth		
Medical School Code	VARCHAR	6	6 digit medical school code (of graduation)		
DegreeDate	date	10	Date resident graduated from medical school		
ResidentYear	CHAR	1	Year of training in the program at time of evaluation		
	VARCHAR		Type of position (preliminary, categorical, Board combined track/pathway approved for this individual trainee)		
ResidentStatus	ARCHAR	100	Resident status in the program		

StartDate	Date	10	Date resident started training in the program
ExpectedCompletionDate	Date	10	Date resident expected to complete the program
EvaluationCompletionDate	Date	10	Date evaluation completed
QuestionID	INT		ACGME ID of evaluation question
QuestionKey	VARCHAR	100	Text abbreviation of question
ReportCategory	VARCHAR	100	Which category the evaluation question belongs (systems based practice, professionalism, etc.)
QuestionText	VARCHAR	1000	Full text of the evaluation question
IntResponseValue	Decimal	1	Numeric value for response to evaluation question
ResponseText	VARCHAR	Max	Description of what the integer response value refers to

# Specialties List

Field Name	Data Type	Max	Field Description
SpecialtyCode	VARCHAR	3	3 Character code for specialty
Name1	VARCHAR	255	Name of the specialty

# Question Key and Response Values

Field Name	Datatype	Max Leng th	Field Description
SpecialtyCode	VARCHAR	3	Numeric 3 digit specialty code
QuestionID	INT		ACGME ID of evaluation question
QuestionKey	VARCHAR	100	Text abbreviation of question
ReportCategory	VARCHAR	100	Which category the evaluation question belongs (systems based practice, professionalism, etc.)

QuestionText	VARCHAR	1000	Full text of the evaluation question	
IntResponseValue	Int		Numeric value for response to evaluation question	
ResponseText	VARCHAR	Max	Description of what the integer response value refers to	