## Standard Operating Procedure

## Access to UM Electronic Sources for non-permanent personnel through OBGYN

## VERSION 5.0 (7-31-18)

1. **Purpose**

This procedure describes the requirements and process necessary for non-permanent personnel to gain access to electronic sources (such as Level 1, Level 2, OBGYN Servers, MiChart, Care Web) for the purposes of research through the Department of Obstetrics and Gynecology.

1. **Scope**

This procedure applies to all visiting scholars, temporary employees, students, and volunteer staff who are involved in research with the Department of Obstetrics and Gynecology at Michigan Medicine.

1. **Responsibility**

Permanent staff and/or faculty in the Department of Obstetrics and Gynecology who have oversight of the above described groups are responsible for assuring compliance with this SOP. This includes ensuring all required institution training are current; ensuring that devices used to access sensitive data have appropriate encryption; ensuring that research personnel you have oversight of are appropriate on-boarded and off-boarded from your projects, which include project specific data handling practices and electronic wiping of mobile devices at end of project service; and ensuring individuals do not remove data from UMHS and access is appropriately terminated.

1. **Procedure**
	1. **INITIAL ACCEPTANCE/ACCESS (Level 1 and/or Level 2 computer access):**

Volunteers/Non-UMHS Study Team Members

* Must obtain an appointment at Michigan Medicine through Volunteer Services (eg. Special Placement). <http://www.med.umich.edu/volunteer/>

Special Placement tab:

<http://www.med.umich.edu/volunteer/pdf/Pre-Approved%20Volunteer%20Placements%20Information.pdf>

* Faculty member/Supervisor completes the “Pre-approved Volunteer Application form” which includes Volunteer information, Department information with a specific Description of Volunteer Duties and appointment dates.
* Once all documentation is complete and volunteer status has been obtained, provide documentation to the Research Compliance Manager.
* Meet with Research Compliance Manager in OBGYN to review data security and finalize access documentation.

Visiting Scholars

* Provide documentation to the Research Compliance Manager of appointment at the University of Michigan.

Temporary Employees and UROP Students

* To gain access to UMHS Electronic Systems, anyone involved in research is expected to have complete the following:

o HIPAA for Research:

<http://www.med.umich.edu/u/compliance/area/privacy/training.htm> o Code of Conduct Attestation, read/signed/returned (See attached). o Memorandum, read/signed/returned (See attached)

* Completed documentation must be returned to the Research Compliance Manager in OBGYN.
* Meet with Research Compliance Manager in OBGYN to review data security and finalize access documentation.
	1. **ELECTRONIC ACCESS FOR RESEARCH REQUEST FORM:**
* Complete the Computer Access Request form (attached) and return to the Research Compliance Manager:
	+ Provide UMID
	+ Provide Name and Date of Birth (required)
	+ Indicate Specific Access needed (servers, folders, MiChart, Careweb, etc)
	+ Supervisor will need to sign the computer access form OR send an email to the Research Compliance Manager stating approval for access request.
	1. **PEERRS CERTIFICATION**
* Anyone involved in human subjects research within the Department of Obstetrics and Gynecology must complete and maintain PEERRS certification.
* UM Students who have Level 1 access can complete PEERRS prior to obtaining Level 2/UMHS access. All others will need to wait for computer access completion before this can be completed.
* At minimum take the Human Subjects-Biomedical & Health module
* PEERRS certification link
	+ [http://my.research.umich.edu/peerrs/](https://email.med.umich.edu/owa/redir.aspx?C=rGoIGW574kWdJUDjy6zYGVqC3wWrJdII9-4H7vL8otvxJ_e75QNtCcX5DQ40bMCxSE-e3WD_4tE.&amp;URL=http%3a%2f%2fmy.research.umich.edu%2fpeerrs%2f)
* Once completed, your supervisor must add you to any IRB-regulated applications associated with the research you will be involved in
	1. **MICHART ACCESS**
* Non-Michigan Medicine Study Team members (Volunteers, UM Students, UROP Students and Visiting Scholars) are required to get approval from the Office of Compliance Prior to receiving access to MiChart.
* PI/Study teams should complete the “Request for Research Access to MiChart” 3 page Form (See Attached)
* UROP and Temporary employees: PI should indicate “other” in question #1 and identify the student as UROP or Temporary employee
* New Study Team member needs to be listed on IRB approved application, at minimum, as “Research Staff”. This requires submission and approval of an amendment to the IRB.
* Send request to Compliance-Group@med.umich.edu and CC Research Compliance Manager (Julie Tumbarello) on the request. Email must include the following documents:
	+ Request for Research Access to MiChart (Sections A & B must be completely filled out)
	+ Signed Code of Conduct Attestation (see attached)
	+ Certificate from HIPPA for Research Training

<http://www.med.umich.edu/u/compliance/area/privacy/training.htm>

* Once Compliance Office grants MiChart approval, Study Team or Research Manager will submit ticket to HITS requesting access
* Enroll in MLearning Module will be scheduled and need to be completed prior to full access
	1. **MEETING WITH THE RESEARCH COMPLIANCE MANAGER**
* All new research team members must schedule a meeting with the Research Compliance Manager within 1-2 weeks of start date
* During this meeting, the following topics will be covered:
	+ Completion of above paperwork
	+ Data security and encryption
	+ Servers and research data storage
	+ Study roles/responsibilities
	+ Research structure within the Department of Obstetrics and Gynecology

**5.References/Resources** [**https://medicine.umich.edu/dept/obgyn/research/research-resources**](https://medicine.umich.edu/dept/obgyn/research/research-resources)

[**http://www.med.umich.edu/volunteer/**](http://www.med.umich.edu/volunteer/)

[**http://my.research.umich.edu/peerrs/**](http://my.research.umich.edu/peerrs/)

[**http://www.med.umich.edu/u/compliance/area/privacy/training.htm**](http://www.med.umich.edu/u/compliance/area/privacy/training.htm)

**DEPARTMENT OF OBSTETRICS AND GYNECOLOGY NEW REQUEST FOR ELECTRONIC ACCESS RESEARCH TEMPORARY & VOLUNTEERS**

This form must be completed and returned to the Research Compliance Manager along with other required materials and proof of HIPPA training. Other additional training may be required. The choices on this form supercede all previously granted access.

Request Date:

Access end date (must be 1 year or less):

Name

Uniquename

Date of Birth

UMID (or SSN if you do not have a UMID)

Job Title

Gender M/F

Phone#

E-mail Address Supervisor’s Name

Please check the type of access needed:

 Level 2 Access – UMHS

 REDCap

 CareWeb

 MiChart & Training (please circle the level needed) Study Coordinator – View Only (online training)

Data Manager Research Administrator Limited Study Coordinator

 Shared Drive (\\corefs.med.umich.edu\Shared1\OBGYN\_SHARED)

Please List Folder Names (eg. Public, RESTRICTED\GYN, RESTRICTED\Oncology, etc)

Maize Server (\\maize.umhsnas.med.umich.edu)

Please List Specific server and folders (eg. OBGYN-Research\D.Morgan Studies)

Signature of Requester Date

Signature of Supervisor Date

**The** [**University of Michigan Health System**](http://www.med.umich.edu/) **(UMHS) is committed to excellence and leadership in patient care, education and research.** As an employee, faculty member, student, trainee, visitor, scholar, volunteer or vendor, I understand that I play a vital role in the success of the UMHS [mission](http://www.med.umich.edu/1busi/mission.htm) and that I will be held accountable for compliance with applicable law and University and UMHS policies and procedures. This statement summarizes the standards of conduct that UMHS requires me to uphold:

**Knowledge, understanding and compliance with the policies and procedures that apply to my work.** I agree to comply with all of the policies and procedures that relate to my work at UMHS, including the [Code of Conduct](http://www.med.umich.edu/u/compliance/resources/code/index.htm). I agree that if I do not know whether an action is permitted, I will ask my supervisor or review the relevant policies. Sources include the U-M [Standard Practice Guide](http://spg.umich.edu/), [UMHS policies](http://www.med.umich.edu/i/policies/), and unit (e.g., Medical School, Hospital), department, and division-level policies and procedures. The UMHS  [compliance website](http://www.med.umich.edu/u/compliance/) has additional information. If I do not know what is permitted or required, I may contact the [UMHS Compliance Office](http://www.med.umich.edu/compliance/index.htm) at (734) 615-4400 or the [Health System Legal Office](http://www.med.umich.edu/u/attorney/) at (734) 764-

2178 for guidance.

**Avoiding fraud, waste and abuse**. I will accurately and honestly perform my work for UMHS, and will not engage in any activity intended to defraud anyone of money, property or services. I will not request or accept payment, either directly or indirectly, that is intended to induce referrals, or to induce the purchasing, leasing, ordering or arranging for any item or service at or from any organization or facility. I will comply with [UMHS](http://www.med.umich.edu/i/policies/umh/01-04-003.html) and [University](http://spg.umich.edu/pdf/201.65-1.pdf) policies on conflicts of interest and on [interactions between](http://www.med.umich.edu/i/policies/umh/01-04-008.htm)  [vendors and faculty/staff.](http://www.med.umich.edu/i/policies/umh/01-04-008.htm) I have reviewed and understand the [summary](http://www.med.umich.edu/u/medlaw/false.htm) of federal and state false claims and whistleblower protection laws. I will report any potential fraudulent or false claims, inappropriate billing practices, or similar concerns to my supervisor or the Compliance Office.

**Protecting the confidentiality and security of information.** I may have access to proprietary or confidential information (including [protected health information)](http://www.med.umich.edu/i/policies/umh/01-04-300.htm) about UMHS operations, workforce members, subjects, and/or patients (“[sensitive information](http://spg.umich.edu/pdf/601.12.pdf)”). All of this information, in whatever form transmitted or received (e.g., oral, fax, photographic, written, electronic), must be treated by me in a confidential and secure fashion. I have completed and understand any [UMHS HIPAA training](http://www.med.umich.edu/u/compliance/areas/privacy/training.htm) required for my position.

* I will not access, release, or share sensitive information – even demographic screens with addresses and phone numbers – unless doing so is necessary as a part of my assigned duties, or I am authorized to do so by a Release of Information form. **I understand that my access to UMHS systems containing sensitive information may be audited at any time**, with or without cause. I understand that I am responsible for any access that occurs using my password.
* I will protect sensitive information. **I will not share my passwords or access to any UMHS systems or applications with any other person.** I will be careful to avoid inadvertently revealing sensitive information, including avoiding discussions of sensitive information in public places. I will not remove sensitive information from UMHS without my supervisor’s permission and I understand that I am responsible for maintaining the security of such information in accord with UMHS standards. **If I use a portable electronic device (e.g., laptop, PDA), I will ensure that it meets** [**UMHS security**](http://www.med.umich.edu/u/compliance/areas/privacy/security.htm) [**standards**](http://www.med.umich.edu/u/compliance/areas/privacy/security.htm)**.**
* I understand that when my employment, affiliation, visitation or assignment with UMHS ends, I may not take any sensitive information with me and I may not reveal any UMHS sensitive information to any third person except as permitted by a Release of Information form (in the case of individually

identifiable private information) or by written release from an [authorized UMHS representative](http://www.umich.edu/~avpf/signauth.html) (in the case of proprietary information).

**Disclosing actual and potential conflicts of interest or commitment and complying with any plans imposed to manage those conflicts. I agree to report any potential or actual conflicts of interest or commitment, and I have reported any current potential or actual conflicts of which I am aware**. An actual or potential conflict occurs if I or a family or household member has an outside personal, professional, commercial, or financial interest. While outside relationships and activities that further the University’s academic and clinical missions are encouraged, conflicts can arise. The existence of a conflict is not inappropriate in and of itself. However, in an academic or clinical setting, these relationships or activities can compromise or be perceived to compromise basic values of openness, scientific integrity, independence, and public trust. I understand that for these reasons, actual or potential conflicts must be disclosed and managed to assure that they do not compromise my judgment, bias my research, influence my decisions with respect to academic or clinical matters or University business, result in personal advancement at the expense of the University, or otherwise interfere or compete with the University’s educational, research, or service missions, or with my ability or willingness to fulfill my responsibilities. I will disclose actual or potential conflicts of interest and conflicts of commitment as required by University and Health System policies. [If I am a vendor employee, I have reported and will continue to disclose any such conflicts to my employer.]

**I agree to treat all UMHS personnel with respect, courtesy, and dignity** and will conduct myself in a professional and cooperative manner. I understand that collaboration, communication and collegiality in the workplace are essential for the provision of safe and competent patient care. Examples of appropriate and inappropriate behavior are provided in UMHS Policy 04-06-047, Disruptive or Inappropriate Behavior by UMHS Personnel. I also agree to report any disruptive or inappropriate behavior that I am subjected to or that I observe in the workplace.

**I understand that if I do not comply with University or UMHS policies and procedures or applicable law, I may be subject to immediate disciplinary or corrective action, up to and including dismissal, termination of contract, and/or loss of access to UMHS property or resources.** I understand that noncompliance with federal or state law may result in criminal and civil penalties against the University, my employer (if I am employed by another entity) and/or me personally.

**I agree to immediately report suspected noncompliance** to my supervisor, or to the UMHS Compliance Office at (734) 615-4400. I understand that I may also make such a report anonymously to (866-990-0111) or through the [compliance website.](http://www.med.umich.edu/compliance/contact.htm) I agree to cooperate with any investigation of possible noncompliance and not to withhold relevant information. UMHS does not tolerate retribution or retaliation against anyone reporting suspected noncompliance in good faith. I will immediately report to my supervisor and [Medical Staff Services](http://www.med.umich.edu/i/oca/mss/index.htm) (if I am a member of the medical staff, physician’s assistant, or advanced practice nurse) or [Human Resources](http://www.med.umich.edu/umhshr/) (if I am licensed, certified, or registered as a health professional) any suspension, restriction, termination, or change in status of any health professions license that I hold.

### BY SIGNING BELOW, I CERTIFY THAT I AM IN COMPLIANCE WITH ALL UNIVERSITY AND UMHS POLICIES AND PROCEDURES, INCLUDING THOSE THAT REQUIRE ME TO REPORT ANY SUSPECTED NON-COMPLIANCE.

|  |  |
| --- | --- |
| **Name** | **Date** |
| **Signature** | **Employee ID # or Vendor Employer ID #** |

**M E M O R A N D U M**

**To**: University of Michigan Health System (UMHS) Compliance Office **From: Date: Subject:** Requirements for access to UMHS Electronic Systems

As a prerequisite to gaining access to UMHS electronic system(s), I have read and agree to the requirements outlined below.

I have completed the HIPAA for Researchers power point within the past 12 months.

<http://www.med.umich.edu/hipaa/ppt/ClinicalResearch/index_files/HIPAA-ClinicalResearch.pdf>

I have read and signed the current Code of Conduct Attestation within the past 12 months. <http://www.med.umich.edu/umhshr/doc/CODE_OF_CONDUCT_ATTESTATION_STATEMENT_0109.doc>

When the reason for my access is Preparatory to Research, for Recruitment, for a Retrospective study, or where the Consent/Authorization has been waived for other reasons, the disclosure is accountable under HIIPAA. A record of the study subjects, serving as the disclosure log, will be maintained in the local study records and will be made available upon request. Refer to Policy 01-4-335. Additionally, the data I view cannot leave UMHS. Refer to Policy 01-04-360.

My access to Protected Health Information (PHI) must be limited to the minimum necessary and restricted to the study subjects’ information. Access is solely for the purpose outlined in the study. Identifiable data will remain secure physically and technically. Permission will be sought before identifiable information is removed from UMHS.

I understand my access to UMHS electronic systems will expire on the renewal date of this study.

Study Number: HUM

Amendment: Ame

Name of Study Team Member

Signature of Study Team Member

### These requirements have been reviewed with the Study Team Member.

Signature of Primary Investigator or Co-Investigator

Date

Master Study Team v12 Attestation.docx

### This form may be used to request access to MiChart for study team members when:

* Individual’s access to MiChart is critical to the conduct of the research,
* Individual is identified as an IRBMED approved study team member (at a minimum listed as “Research Staff”) and completed PEERRS,
* Study team member is confirmed as an approved data extractor by the principal investigator, and
* All alternative (indirect) methods to source data were explored and determined not feasible, e.g., source data being provided to the individual rather than the individual directly accessing patient medical records in MiChart.

### Note:

* Temporary staff, non-student and UM student temporary staff must complete new employee orientation (Michigan Traditions and Values) and other required UMHS Human Resources on-boarding processes.
* Volunteers (non-UM students and other non-paid persons) must go through Volunteer Services on- boarding processes. See:
	+ <http://www.med.umich.edu/volunteer/>
	+ <http://www.med.umich.edu/volunteer/images/Pre-Approved%20Volunteer%20Placements%20Information.pdf>
* Access to MiChart will NOT be granted to individuals not affiliated with UMHS.
* Access to MiChart requires on-site supervision; no remote (off-site) access is permitted.
* Access to MiChart is the responsibility of the sponsoring unit;
* All MiChart access requests are subject to auditing by the UMHS Compliance Office.

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*Instructions: Complete sections A and B. Section C contains requirements for education and training required if access is approved. Email the form to* *Compliance-Group@med.umich.edu**.*

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## SECTION A: Applicant Information

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| --- |
| **Applicant Information (all fields required)** |
| **Name** | **First** | **Middle** | **Last** | ***Do not complete gray shaded sections below.*** |
|  |  |  |
| **UM ID or SSN** |  | Access Grant Date |  |
| **Address** |  | Termination Date |  |
| Comments: |
| **Phone #** |  |
| **E-mail** |  |
| **UMHS****Employment Job Title** | (Job title assigned in UMHS HR System) |

**SECTION B: Access Request Detail (MUST FILL OUT ALL SECTIONS)**

1. Identify if the individual completed HR or volunteer services on-boarding processes?
* Individual completed Volunteer Services on-boarding processes, including HIPAA training and signed code of conduct.
* Individual completed new employee orientation (established HR on-boarding processes), including HIPAA training and signed code of conduct.
* Other (explain, but see requirements listed above):
1. Identify applicant’s affiliation with UMHS if applicant is not employed by UMHS or UMMS.
2. Were all alternative (indirect) methods to source data explored? Provide explanation for why indirect method(s) were determined impracticable?
3. Identify the UMHS unit sponsoring applicant’s MiChart access.
4. Identify the UMMS faculty member *and* UMHS Supervisor (if not the faculty member) who will have responsibility for and direct oversight of applicant’s MiChart access.
5. Identify active project(s) that applicant is listed as a study team member and for which MiChart access is requested (include IRB # and title, as applicable).
6. Identify Principal Investigator(s) associated with the study (ies) listed for question #3.
7. Type of access requested (scheduler or view only)?
8. Reason for access request (research rotation, healthcare quality review, etc.).
9. If research rotation, identify applicant’s sponsoring UMHS unit or home institution (Medical School affiliation, etc.).
10. Identify what the UMHS/UMMS sponsor is requesting that applicant’s view or document from the medical records.
11. Have patients’ signed a written consent/authorization for the use of medical record data in the studies for which access is requested? If no, please explain.
12. Specify sponsored access time period (must limit to actual timeframe needed).
13. Confirm if applicant was ever been investigated and/or disciplined for a HIPAA privacy violation (confirm with applicant’s home educational institution or relevant employer (including UM if ever been employed at UM – consult with your unit’s HR representative for assistance). If yes, describe.

**SECTION C: Training and Education Requirements**

*Note that completing these trainings in advance to final review is fine, but doing so in no way guarantees applicant will be approved.*

* Read code of conduct and sign attestation. UMHS MiChart Sponsor must keep applicant’s current signed attestation on file and provide a copy to the UMHS Compliance Office upon request <http://www.med.umich.edu/u/compliance/doc/ConductStatement.pdf>.
* Complete PEERS training per IRBMED requirements.
* Complete HIPAA training for Researchers. UMHS MiChart Sponsor must keep applicant’s current HIPAA training certificate on file and provide a copy to the UMHS Compliance Office upon request. <http://www.med.umich.edu/u/compliance/area/privacy/training.htm>
* Complete MiChart training.

UMHS MiChart Sponsor must provide a copy of the applicant’s signed code of conduct attestation and HIPAA training certificate before access will be activated.