Submission ID:
For CEO's Office Use Only

University Medical Service Association, Inc. (UMSA)

New:	☐	**Revised:**	☐	**Supercedes:**	

Policy Name:	Requirements for Observers in Patient Care or Clinical Research Areas		
Responsible Office:	USF Health Professional Integrity Office		
Submitted By:	Barbara Wolodzko	**Title:**	Privacy Officer

Review/Approvals:	***Committee Name and/or CEO Name:***	**Date Approved:**
Oversight Committee ***(if applicable):***	Practice Leadership Team USF Health Endoscopy & Surgery Center Medical Executive Committee	9/19/18 9/19/18
USFHC CEO:	Mark Moseley MD, Chief Clinical Officer	9/19/18
USFHC Finance, EMC or CLB ***(if applicable)*****:**		

OBJECTIVES AND PURPOSES: To establish a process to ensure all individuals who request to observe in a patient care setting or in a clinical research area are properly vetted for their safety along with the safety of our patients and workforce members. This standard practice and procedure ("SPP") applies to all individuals who request to observe at any USF Health clinical or research locations, as well as all USF Health affiliates where USF Health conducts patient care and/or clinical research activity. This SPP does not apply to those individuals who are part of the Medical Observer Program for International Physicians or are part of an established training program conducted by or in coordination with USF Health. This SPP does not override Policy Number 6-038, Minors in Laboratories, Studios/Shops, Clinics or Animal Facilities.

STATEMENT OF INTERNAL GUIDELINES. An "Observer" is an individual age eighteen (18) or older who is observing or shadowing a USF Health faculty, credentialed provider, nurse or administrator ("Sponsor"). Prior to the Observer being present when the Sponsor is engaged in direct patient care, oral consent from the patient must be obtained by the Sponsor and noted in writing in the electronic medical record. Consent is not required for incidental exposure to patients not under the direct care of the Sponsor. Observers are not permitted to have hands on contact with a patient nor shall an Observer participate in any direct patient communications. For any observation at a USF Affiliate site (e.g., TGH, ACH, Moffitt, VA), Sponsor shall be responsible for contacting the Affiliate for information about any additional requirements of the Affiliate and shall confirm all requirements are met by the Sponsor and the Observer.

In no case is an Observer permitted to shadow or observe the same Sponsor for more than five (5) consecutive business days (for a total of 40 hours or less) during a calendar year. Every Observer must be assigned to a designated Sponsor and remain in the physical presence of the Sponsor at all times while observing. An Observer shall not be permitted to access a patient's electronic medical record for any reason. An Observer is not permitted in the operating room or any sterile environment.

AREAS OF RESPONSIBILITY FOR IMPLEMENTATION. All Observers in USF Health patient care and clinical research areas must be approved in accordance with the procedures described herein prior to the requested observation actively beginning.

1. The potential Observer must complete the following forms:
   - **USF Health Request to Observe in Patient Care or Clinical Research Area(s) Form** (Sections 1-3) (Attachment 1) and the
   - **USF Health Communicable Disease Screening Questionnaire** (Attachment 2).
2. Once the above-mentioned forms are completed, the potential Observer should forward them to their Sponsor.
3. The Sponsor then must complete section 4 only of the USF Health Request to Observe in Patient Care or Clinical Research Area(s) Form (Attachment 1) and email both of the above mentioned documents to the USF Health Privacy Officer ("Privacy Officer") Barbara Wolodzko at bwolodzko@usf.edu or privacy@usf.edu and the Observer for his/her records.
4. The Privacy Officer will then email the completed USF Health Communicable Disease Screening Questionnaire for Observers (Attachment 2) to Medical Health Administration at mha@usf.edu for approval. Once approved, Medical Health Administration will notify the Privacy Officer at privacy@usf.edu of such via email.
5. The Privacy Officer will then email both the Observer and the Sponsor informing them the approval is finalized. The clinical department should then prepare a temporary badge for the Observer that should state the Observer's full name, Sponsor's full name, and the dates of observation.
6. Sponsor should communicate with the Observer the start date and location to being the observation.
7. The USF Health Privacy & Healthcare Civil Rights Compliance office shall retain a copy of the documents for its records.

Violations of this Standard Practices and Procedures may result in suspension and or termination of observation activity. In addition, the federal statute known as the Health Insurance Portability and Accountability Act (HIPAA) provides for civil and criminal penalties, including fines, for HIPAA privacy violations.

ATTACHMENTS:
USF Health Request to Observe in Patient Care or Clinical Research Area(s) Form
USF Health Communicable Disease Screening Questionnaire for Observers

STANDARD OWNER:
USF Health Privacy & Healthcare Civil Rights Compliance

LAST REVIEWED/UPDATED BY:
Barbara J. Wolodzko, J.D., LL.M., LL.M., Privacy Officer 09/06/18

RESPONSIBLE OFFICE: The preceding was developed by USF Health Privacy & Healthcare Civil Rights Compliance. Any questions or concerns should be directed to Barbara Wolodzko at 813-974-7413.

(Attachment 1)

REQUEST TO OBSERVE IN PATIENT CARE OR CLINICAL RESEARCH AREA(S)

Directions: Potential Observer completes Sections 1-3 and Sponsor completes Section 4

Observer Section 1: Observer Information

Name:	
Address:	
City, State, Zip:	
Email:	
Phone Number:	
Date of Birth:	

Reason for Requesting to Observe:

_____ Considering a health care career

_____ Required for a college course (Please provide name of college): ____

_____ Other (Please provide specific reason): ________________________

By signing below, if I am permitted to observe, I agree that I am observing only and will not provide any "hands on" patient care. I agree that I must be in the physical presence of the Sponsor while in the clinical or laboratory setting. I understand that prior to directly observing a patient while under the care of the Sponsor, the patient must consent to my observation of care. I also agree to wear a badge while I am observing that identifies me as an Observer, states the name of my Sponsor, and provides the dates of my observation period. I also acknowledge that USF does not provide me with health insurance solely for acting as an Observer.

_______________ ______________________________

Date **Observer's Signature**

Background Question:

Have you ever pleaded nolo contendere (no contest) to, or been convicted of, a first degree misdemeanor, a felony, a criminal traffic infraction, or a drug related offense?

____ Yes ____ No

Only if you answered yes, then please fully explain and attach additional sheets if necessary: ____

Requests by Observer applicants who answer "yes" to the Background question above, must submit this form to the USF Health Privacy Officer ("Privacy Officer") via email to privacy@usf.edu and the Privacy Officer will coordinate with the USF Office of General Counsel ("OGC") regarding whether the potential Observer is permitted to seek approval by the Department Chair/Director or designee.

________________	______________________________
Date	Barbara Wolodzko, Privacy Officer
________________	______________________________
Date	Office of General Counsel

<u>Observer Section 2:</u> USF HEALTH PRIVACY TRAINING

This abbreviated training is specifically meant for Observers accompanying a Sponsor for up to five (5) days (for a maximum of 40 hours) during a calendar year.

<u>HIPAA Overview</u>

Privacy of patient health information is of utmost importance to USF Health.

From an ethical perspective, ensuring the privacy of patients encourages their trust. Patients who trust that their physicians, other healthcare providers and staff will maintain their privacy can be open in sharing information needed to provide high quality of care.

There are laws that protect patient information. State of Florida laws protect the confidentiality of medical records. State and Federal laws protect "super confidential" health information, including HIV/AIDS tests, drug or alcohol abuse treatment, genetic testing and psychological/psychiatric evaluation and treatment. The Health Insurance Portability and Accountability Act ("HIPAA") is a federal law that establishes a U.S. Civil Right to the protection of health information within USF Health and other "covered entities" subject to HIPAA.

<u>Frequently Asked Questions and Answers about HIPAA</u>

- What information does HIPAA protect?
  HIPAA protects any health information that may be used to directly or indirectly identify the individual patient. This information is called Protected Health Information, or "PHI".

- What format of information is protected?
  PHI is protected in any form: electronic medical record, documents, email, handwritten notes, images or x-rays, and <u>conversations</u>.

- How can PHI be used and disclosed?
  PHI may be used and disclosed for:
  - Treatment by healthcare providers, with no restriction; or for

    - Payment and healthcare operations, restricted to the minimum necessary to perform the task.

- Any other use or disclosure of PHI must be:
    - With patient consent and/or authorization;
    - In accordance with certain Research related rules; or As required by law.

This means that you, as an observer, may learn confidential information about a patient while observing. However, you do not have the right to disclose any patient information outside the observation setting.

As an observer, how do I comply with HIPAA?

- Perform your activities in accordance with this written training.
- Read the Notice of Privacy Practices to be familiar with patient rights under HIPAA.
- Whatever a patient may share with you about their health must be kept strictly confidential and not shared with others, including your family or friends.

What if a friend or family member is also a patient?

Inform your sponsor who will arrange for you to be involved in the observation of another patient, if appropriate.

All our patients have a legal right to privacy, and you have an obligation to maintain that privacy.

What if I believe a HIPAA/privacy violation has occurred?

USF may be required to report HIPAA Privacy breaches to the individual(s) affected and to the Health and Human Services Office of Civil Rights. USF is also required to ensure that there is no retaliatory action against an individual for reporting a concern. You should report any incident that you believe may have been a violation of HIPAA or other privacy laws to:

- Your Sponsor
- The USF Health Privacy & Healthcare Civil Rights Helpline at (813) 974-2222.
- The USF Health Privacy Officer at (813) 974-7413.
- You may also make an anonymous report to the USF EthicsPoint hotline at 1-866-974-8411.

Are there penalties for HIPAA Privacy violations?

Yes. USF is required to apply appropriate and consistent sanctions against workforce members who fail to comply with HIPAA or related policies and standards. Additionally, there are individual civil monetary penalties per violation. There also are criminal penalties for wrongful disclosure that can include jail time and fines.

By signing below, I agree to the following:

- I have read and understand the above Privacy Training materials.
- I have read the USF Notice of Privacy Practices and am familiar with patient's rights under HIPAA.

- I understand that I am responsible for reporting incidents that I believe violate HIPAA or other privacy laws, and that I am not to be retaliated against for making good faith reports.

_______________ _______________________________

Date **Observer's Signature**

<u>Observer Section 3:</u> SECURITY& CONFIDENTIALY AGREEMENT

As an Observer, and as a condition of my participation, I recognize that I may have access to certain information that is confidential and constitutes valuable, special and unique property of the University of South Florida or USF Health.

<u>I agree to the following:</u>
I understand that I am responsible for complying with the HIPAA regulations, state law, USF policies and USF Health Standard Practices and Procedures, and that I must protect patient privacy and confidential information.

- I will treat all information received which relates to the patients of USF Health and its affiliated hospitals as confidential and privileged information.
- I will not disclose information regarding USF Health patients to any person or entity.
- During or subsequent to my time spent as an Observer, I agree that I will not disclose to others any confidential or proprietary information which concerns the University or its patients, including but not limited to costs, prices and treatment methods at any time used, developed or made by the University and which is not otherwise available to the public.
- Upon leaving, I agree to continue to maintain the confidentiality of any information I learned while at the USF/USFHealth or its affiliates.
- I understand that violation of this agreement could result in suspension or termination of the approved observation activity.

_______________ _______________________________

Date **Observer's Signature**

Sponsor Section 4: TO BE COMPLETED BY THE SPONSOR

Sponsor's Name:	
Department/Division	
Phone Number:	
USF Health email:	

Observation Dates:
Please remember an observer may only observe for five consecutive business days.

Start date: _________________ **End Date:** _______________________

Observation Location(s):
Please list all USF Health clinical sites for observation:
____

Procedures/Services: Please list all medical procedures or services to be observed (e.g., x-rays, labs, hospital rounds).
____

By signing below as Sponsor, I understand that I am responsible for accompanying and supervising this individual at all times as indicated above. I understand that I may not delegate this responsibility to another individual. I also will ensure that all patients are notified in advance of the observation, giving the patient an opportunity to agree with or decline to the observation. I will also document consent in the medical record. I will ensure that the Observer does not engage in any "hands on" patient care. I will ensure that the Observer wears the Observer identification badge at all times while serving in an Observer role.

________________ _________________________________
Date **Sponsor's Signature**

Medical Health Administration

Department of Clinical Affairs

Employee/Student Health and Wellness

Communicable Disease Screening Questionnaire
Clinic Observers (Shadowers)

Printed Name: ________________________________ Date of Birth: _____/____/_____

Address: ____

Phone: _____________________________________ Email Address: __________________________

Supervisor/Preceptor: ___________________________ Department: ________________

Anticipated Dates of Visit: From: _____/_____/____ To: _____/_____/____

Please answer the following questions to determine screening requirements:

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1. Will you be in an area where there are patients? Yes No Unknown* (ask your supervisor/preceptor if this is a possibility)

(circle response)

If you circled "Yes", you must complete all Communicable Disease screening requirements listed on the Certification Form. No patient contact will be permitted until this screening is complete!

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2. In your **normal** course of your observation, will you have the potential to come in contact with **Human** blood, body fluids, tissue or sharps such as needles? Yes No Unknown* (ask your supervisor/preceptor if this is a possibility)

EXAMPLES: Examine patients; Administer treatments; Draw blood; Test blood, body fluids or unfixed human tissue; Handle specimens such as blood, urine, tissue before it is properly bagged; Dispose of linen or trash that might accidentally expose you to needles, or body fluids; Respond to emergency situations that may expose you to blood or body fluids.

(circle response)

If you responded "Yes", you must show documentation that you have either completed the Hepatitis B vaccine series and have a "Positive" Hepatitis B surface antibody titer (Quantitative) or have declined the vaccine. You will also need to complete the OSHA Bloodborne Pathogen Training prior to your visit. Email mha@usf.edu for instructions on how to complete the training.

Morsani College of Medicine
Medical Health Administration
University of South Florida

13220 USF Laurel Drive MDC 33
Tampa, FL 33612
Phone: (813) 974-3163
Fax: (813) 974-3415

Medical Health Administration
Department of Clinical Affairs

Completion of the Communicable Disease Prevention Certification is required if you responded **"Yes" to question #1** on the screening Questionnaire. Prior to your visit to a **Clinical Area** at the University of South Florida Clinics, and/or its affiliated institutions, you must complete and return the attached form and supportive documentation **30 days prior to your arrival**.

You will not be permitted in patient care areas until the form and documentation are complete

The completed Communicable Disease Prevention Certification form along with the required, supportive documentation specified should be emailed or faxed to:

Email: mha@usf.edu **(PREFERRED)**

Fax: 813-974-3415

The University of South Florida Morsani College of Medicine is unable to provide the vaccines and laboratory titers required. These immunizations and/or laboratory tests must be completed prior to your visit. If you are not able to receive certain immunizations i.e. they are contraindicated; please contact us directly to discuss your situation. All required vaccines are readily available through your local Health Department.

If you have any questions regarding the communicable disease prevention certification process, please contact us directly.

Phone: **(813) 974-3163**
Email: mha@usf.edu

ANNUAL TUBERCULOSIS SCREENING QUESTIONNAIRE

Employee/Student Health and Wellness
Department of Clinical Affairs
USF Health Morsani College of Medicine
Phone: 813-974-3163 Fax: 813-974-3415

DATE: ___________________________

Last Name: __ __ __ __ __ __ __ __ __ (Please Print) **First Name**: __ __ __ __ __ __ __ __ __ __ (Please Print) Date of Birth____/____/____

Email Address: ____________________________ **Phone:** _______________________

☐**USF Health STUDENT: College:**_______________**Graduation Year:**_________________

☐**EMPLOYEE** **Department**: ______________________________

Have you ever received BCG Vaccine? ☐No ☐ Yes → If YES, date of BCG: ______________

Have you ever had a Positive Tb Skin Test ☐No ☐ Yes If YES, when________________

Did you take any medication associated with the positive TB skin test? ☐No ☐Yes → Dates: ____________

What medication(s) did you take? ____________ Did you complete the course of Medication ☐No ☐ Yes

Please check (√) your response for any of the following **Unexplained Symptoms/Questions**

Unexplained fatigue	☐ Yes ☐ No	Night sweats (drenching)	☐ Yes ☐ No
Unexplained weight loss	☐ Yes ☐ No	Unexplained Persistent cough (>2 weeks)	☐ Yes ☐ No
Loss of appetite	☐ Yes ☐ No	Spitting/coughing up blood	☐ Yes ☐ No
Fever (usually at night)	☐ Yes ☐ No	Pain in chest	☐ Yes ☐ No

Have you had temporary or permanent residence (for ≥ 1 month) in a country with a high TB rate (i.e., any country **other than** Australia, Canada, New Zealand, the United States and those in western or northern Europe)?	☐ Yes ☐ No
Current or planned immunosuppression, including human immunodeficiency virus infection, receipt of an organ transplant, treatment with a TNF-alpha antagonist (e.g., infliximab, etanercept, or other), chronic steroids (equivalent of prednisone ≥ 15 mg/day for ≥ 1 month), or other immunosuppressive medication?	☐ Yes ☐ No
Close contact with someone who has had infectious TB disease since the last TB test?	☐ Yes ☐ No

Box: MHA, Forms, TB

Morsani College of Medicine
Medical Health Administration
University of South Florida

13330 USF Laurel Drive MDC33
Tampa, FL 33612
Phone: (813) 974-3163
Fax: (813) 974-3415

Communicable Disease Prevention Certification: Clinic Observers

Prior to your visit to a **Clinical Area** at the University of South Florida this form ***must*** be completed and submitted with ***all required documentation attached 30 days prior to your arrival***. You will not be permitted in patient care areas until the form and documentation are complete. **All documentation must be in English.**

PRINTED NAME:______________________________________ DATE:______________________

STREET: _____________________________ CITY:_____________ STATE: _____ ZIP:____________

PHONE NUMBER(S): _________________Date of Birth:__________EMAIL:_______________________

SPONSORING DEPARTMENT/SUPERVISOR______________________________PHONE_____________

COMPLETE ITEMS A-H

A. **TUBERCULOSIS (TB) Screening:** To meet the USF requirement, you must submit documentation of **ONE** of the following:

1. Results of NEGATIVE **TB Skin Testing (TST/PPD).** The last TST must be within 3 months of your start date.
   Attach provider documentation.

TST #1	Date Placed	Date Read	Result	TST #2	Date Placed	Date Read	Result
			________mm induration				________mm induration

2. **OR** Lab Copy showing a "NEGATIVE" Interferon Gamma Release Assay (IGRA) blood test **(QFT or T-Spot)** within 6 months of start date (accepted in lieu of the "Two-Step" TST).

   OR
   I am submitting NEGATIVE Interferon Gamma Release Assay (IGRA) blood test results (QFT/T-Spot) in lieu of the "Two-Step" TST. **Copy of the Lab report required**. Date of test:____________

3. **OR Individuals with a history of a POSITIVE TB skin test must follow-up with a QFT(IGRA). If IGRA is POSITIVE,** then the QFT(IGRA) lab report along with the following:
   a. Verification of a NEGATIVE Chest X-ray within 12 months of start date.
      Date of Chest X-ray_______________ Result_____________(Attach report)

B. MEASLES (RUBEOLA): Positive Titer or 2 vaccines

	Result	**Date**	**Required Documentation**
Rubeola Titer (IgG Blood Test)	Pos ☐ Neg ☐	___/___/___	Lab Report Copy

Or
Two live Rubeola or **Two** MMR vaccines 1 year after birthdate #1 ___/___/___ #2 ___/___/___ Vaccine Documentation Copy

C. MUMPS: Positive Titer or 2 vaccines

	Result	**Date**	**Required Documentation**
Mumps Titer (IgG Blood Test)	Pos ☐ Neg ☐	___/___/___	Lab Report Copy

Or
Two live Mumps or **Two** MMR vaccines 1 year after birthdate #1 ___/___/___ #2 ___/___/___ Vaccine Documentation Copy

D. RUBELLA (German Measles): Positive Titer or 1 vaccine

	Result	**Date**	**Required Documentation**
Rubella Titer (IgG Blood Test)	Pos ☐ Neg ☐	___/___/___	Lab Report Copy

Or
One live Rubella or MMR vaccine 1 year after birthdate ___/___/___ Vaccine Documentation Copy

Morsani College of Medicine
Medical Health Administration
University of South Florida

13330 USF Laurel Drive MDC33
Tampa, FL 33612
Phone: (813) 974-3163
Fax: (813) 974-3415

Communicable Disease Prevention Certification: Visitors, Volunteers, Observers

Name ____

E. VARICELLA (Chicken Pox): *Serologic documentation of a positive Varicella titer **OR** two Varicella immunizations (given at least 4 to 8 weeks apart).* ***** A history of chicken pox does* NOT *satisfy this requirement *****

	Result	Date	Required Documentation
Varicella Titer (IgG Blood Test)	Pos ☐ Neg ☐	___/___/___	Lab Report Copy
Or Two Varicella immunizations	#1___/___/___	#2___/___/___	Vaccine Documentation Copy

F. TETANUS/DIPHTHERIA/PERTUSSIS (Tdap): *Documentation of an Adult* **TETANUS/diphtheria/acellular pertussis (Tdap)** vaccine booster is required.

	Date	Required Documentation
Tdap (Adacel™ or BOOSTRIX®) vaccine	___/___/___	Vaccine Documentation Copy

Lab Personnel Only:
Td **or** Tdap vaccine (Booster within the past 10 years) ___/___/___ Vaccine Documentation Copy

G. HEPATITIS B: (Required only if you will have a risk of exposure to blood and/or body fluids)
*Serologic documentation of a Positive **(Quantitative) Hepatitis B surface antibody titer** following completion of the Hepatitis B vaccination series of 3 injections.*
*You must provide documentation of the Vaccine series **AND** the Positive Antibody Titer to meet this requirement.*

Hepatitis B vaccine series #1___/___/___ #2 ___/___/___ #3 ___/___/___ Vaccine Documentation Copy

	Result	Date	Required Documentation
Hepatitis B Surface Antibody Titer (IgG) (**Quantitative**)	Pos ☐ Neg ☐	___/___/___	Lab Report Copy

If the antibody titer is Negative, you will need to have Hepatitis B vaccine dose #4 and then a titer 30 days later.

#4 Dose of Hepatitis B Vaccination Date __/__/______ Submit Vaccine Documentation

Quantitative Antibody Titer Pos ☐ Neg ☐ ___/___/___ Lab Report Copy

If your titer is still negative, contact us.

H. Influenza Vaccine (Current Year) Date______/_____/_________
(August – June of the Current Influenza year)

COVID-19 Vaccination: Please scan card or documentation if vaccinated

Two Series Dates: Name of Manufacturer: ___________ #1___/___/___ #2 ___/___/___

One Series Date: Janssen (Johnson & Johnson): #1 ___/___/___

Booster (if received): Name of Manufacturer : ___________ booster date: ___/___/___

Do you give permission for USF MHA to share your COVID status with affiliate sites that you may rotate at while at USF:

___ Yes, I give permission to USF MHA to share my COVID status with affiliate sites

___ No, I do not give permission to USF MHA to share my COVID status with affiliate sites

If you have not been vaccinated, you will need to sign the attached religious or medical exemption form and submit it along with your Communicable Disease Form to Medical Health Administration (MHA) at University of South Florida at mha@usf.edu

Please return completed from and supportive documents to:

Email: mha@usf.edu (PREFERRED)
Fax: 813-974-3415

Rev 2.2022