

<b>STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH</b>  <b>Title: University Hospitals (UH) Research Credentialing</b>	<b>Last Revised:</b> <b>8/2017</b> <b>Prior Version:</b> <b>4/2016,</b> <b>12/2014,10/2012</b>
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**This SOP begins with important definitions. Step by step instructions on how to complete the research credentialing process are contained in this document.**

## **1. PURPOSE:**

To define the procedures necessary for non-University Hospitals (UH) personnel to properly obtain access to UH Protected Health Information (UH PHI) and to UH Information Technology (IT) Systems. This procedure follows compliance with Subtitle D of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) enacted by the United States government in 2009.

## **2. SCOPE:**

This SOP applies to all non-UH personnel interested in engaging in research at UH and provides a step-by-step instruction on how to obtain UH Research Credentials and how to renew them annually.

Non-UH personnel must be affiliated with one of the following:

1. UH Affiliated Hospitals
2. Case Western Reserve University (CWRU)
3. The MetroHealth System
4. Ursuline College
5. Louis Stokes Cleveland VA Medical Center
6. Cleveland State University
7. Ohio State University

The benefits of the UH Research Credentialing Process

- 1) Allows access to UH PHI for Institutional Review Board (IRB)-approved research protocols;
- 2) Permits the use and disclosure of UH PHI preparatory to research only under the supervision of a UH employee who serves as the Responsible Investigator of the proposed research protocol and who completes all of the required steps set forth in the SOP for Clinical Research "Use and Disclosure of Protected Health Information Preparatory to Research";

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- 3) Grants a UH-based title (Research Faculty for MD's and/or PhD's or Research Associate for all others);
- 4) Obtains a UH e-mail address and UH IT access as allowed by the IRB; and
- 5) Offers free access to UH-sponsored research training programs.

### **3. RESPONSIBLE INDIVIDUALS:**

- 3.1. Non-UH personnel interested in engaging in research at UH are responsible for completing all the required steps necessary for obtaining UH Research Credentials and must comply with the following:
  - 3.1.1. Comply with the laws prior to using and/or disclosing UH PHI for research purposes;
  - 3.1.2. Contact/work with the Principal Investigator (PI) or Responsible Investigator who oversees the research protocol(s);
  - 3.1.3. Non-UH employees who are Principal Investigators must be UH Research Credentialed and must have a Responsible Investigator who is a UH employee in order to use and/or disclose UH PHI preparatory to research;
  - 3.1.4. Complete a new UH Department Chairman Certification if added to new/additional UH IRB-approved protocol(s) after the initial approval and to notify the UH Clinical Research Center (UHCRC) at [UHResearchCredentialing@uhhospitals.org](mailto:UHResearchCredentialing@uhhospitals.org) of the updated list of UH IRB-approved research protocol(s) the non-UH personnel is engage with;
  - 3.1.5. Acknowledge when the UH Research Credentials expire and to renew them annually;
  - 3.1.6. Non-UH employees that are Research Scholars, Fellows, Coordinators, and other research personnel who do not hold a valid clinical license (e.g. M.D., D.O., R.N.) or corresponding training certificate in the State of Ohio who require access to the electronic medical record (EMR) must complete the form, Rules for Non-Licensed Researchers in a Clinical Setting; and

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- 3.1.7. Notify the [Nursing Research Council](#) for a scientific review of nursing research projects.
- 3.2. Department Administrators (DA) are responsible for facilitating the process by working with non-UH personnel to ensure they are UH Research Credentialed and must complete the following:
  - 3.2.1. Fill out a Non-Employee Request Form found on Oracle and submit electronically to Human Resources;
  - 3.2.2. Submit an eSecurity Access Request Form to UH Information Technology for a UH e-mail address and IT access as allowed by the IRB; form can be found on the UH Intranet under forms;
  - 3.2.3. Inform non-UH personnel the importance of using a UH e-mail address by following the [UH Policy: IS-14 – Acceptable Use of UH Electronic Assets](#); and
  - 3.2.4. Ensures non-UH personnel are renewing their UH Research Credentials annually if engaged in research protocols longer than their expiration.
- 3.3. Principal Investigators or Responsible Investigators overseeing the research study must ensure that all non-UH personnel are UH Research Credentialed prior to engaging in research that uses or discloses UH PHI for research purposes and comply with the following:
  - 3.3.1. Only add non-UH personnel to IRB-approved research protocol(s) if they have been UH Research Credentialed;
  - 3.3.2. Investigators that are UH employees who desire to use and/or disclose UH PHI preparatory to research must complete and submit the Use and Disclosure of Protected Health Information Preparatory to Research Investigator's Certification to the UH Privacy Officer, [Compliance@UHhospitals.org](mailto:Compliance@UHhospitals.org); and
  - 3.3.3. Comply with the UH Policy: [R-3 – Uses and Disclosures of Protected Health Information \(PHI\) for Research](#).

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- 3.4. Department Chairpersons are responsible for certifying all non-UH personnel that will be engaging in specifically identified research protocol(s) within their respective department and granting approval for a UH-based title.
- 3.5. The UH Clinical Research Center (UHCRC) is responsible for processing and confirming that all required documentation is complete prior to releasing approval and will perform the following:
  - 3.5.1. Notify appropriate parties of denials and approvals associated with any UH Research Credentialing application; and
  - 3.5.2. Run audits by randomly selecting UH e-mail addresses to ensure the process has been completed. Departments causing most infractions will be notified to ensure compliance as required by this SOP.
- 3.6. UH Information Technology (IT) is responsible for granting system access once an eSecurity Access Request Form has been received and has verified with the UHCRC that the non-UH personnel has been UH Research Credentialed. UH IT will revoke access upon the expiration of the UH Research Credentials.

#### **4. DEFINITIONS:**

Please reference the Glossary for complete definitions of terms.

#### **5. POLICY STATEMENT:**

All non-UH personnel interested in engaging in research must complete the UH Research Credentialing Process, and renew their UH Research Credentials annually in order to be granted proper access to UH PHI and UH IT Systems as allowed by the IRB.

#### **6. PROCEDURES:**

Please reference the UH Research Credentialing Flow Chart (Attachment A) for a graphic representation of this process. The steps described below must be completed by all non-UH personnel in order to obtain proper access to UH PHI and UH IT Systems.

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In addition, the research protocol must include the following:

- a) Descriptions of systems needed to complete the research;
- b) A list of all individuals who will be engaged in the research protocol;
- c) How the data will be protected during the conduct of the research protocol; and
- d) How long the data will be kept after study closure of the research protocol.

Individual(s) completing the UH Research Credentialing Process must be added to the research protocol(s) prior to engaging in any research at UHCMC.

**UH Research Credentialing Procedure:** This procedure applies to individuals from the institutions:

1. UH Affiliated Hospitals employees
2. Case Western Reserve University (CWRU) employees and students, including:  
dental, nursing, graduate, undergraduates and medical students
3. The MetroHealth System employees
4. Ursuline College employees and students
5. Louis Stokes Cleveland VA Medical Center employees
6. Cleveland State University students
7. Ohio State University undergraduate students

\*If your institution is not listed above please contact  
[UHResearchCredentialing@UHhospitals.org](mailto:UHResearchCredentialing@UHhospitals.org) before submitting an application.

The following steps must be completed in order to be granted proper access to UH PHI and UH IT Systems for the purpose of conducting research:

1. Contact the Principal Investigator or Responsible Investigator overseeing the research protocol(s) and work with the Department Administrator(s) for assistance in completing the required documentation.
2. Complete an online application:

- A. Initial Application**
- B. Renewal Application**
- C. CWRU Medical Student**

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[Click here to begin an online application](#)

**A. Initial Application Steps**

1. Upload a completed and signed 'UH Department Chairman Certification' document\*
2. Read and upload a signed 'Authorization and Release from Liability' form\*
3. Read and upload a signed 'University Hospitals Electronic Systems Agreement' document\*
4. Obtain a UH Criminal Background Check.

The following describes the process for obtaining a UH Criminal Background Check:

- Go to [www.CorporateScreening.com/vendor](http://www.CorporateScreening.com/vendor) and click on **Vendors/Contractors** button.
- Enter the special promotional code: **uhresearcher** and then hit the **GO!** button.
- Complete the online application section in its entirety.
- Have credit card (Visa/Mastercard/American Express/Discover) – complete with pertinent IRB study information ready in order to process payment. (Cost: \$45) and appropriate Department Chair signature
- Click **Submit** button at the end of the process and you're done. You will be provided with an electronic receipt and confirmation code at the time of completion.
- A unique login that can be used to view your results will be e-mailed to your e-mail address. Reports can be retrieved at [www.CorporateScreening.com/vendor](http://www.CorporateScreening.com/vendor) by clicking on the **Retrieve Background** button.

5. If Applicable: Non-UH employees that are Research Scholars, Fellows, Coordinators, and other research personnel who do not hold a valid clinical license (e.g. M.D., D.O., R.N.) or corresponding training certificate in the State of Ohio who require access to the EMR must complete the form: Rules for Non-Licensed Researchers in a Clinical Setting\*
6. Please print the "Payment Reference Form" attachment provided in the Payment section of the online application.\* This form will need to be completed and taken to

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the UH Cashier's Office with your payment of \$150.00. Please note that this payment is non-refundable. You must save the receipt from the UH Cashiers Office to upload on to your research credentialing application. Applications without receipts will not be processed and any lost receipts will not be replaced. The Cashier's Office is located in the Humphrey Building, first floor, room 1629, near Pre-Admission Testing. Hours: 9:00 a.m. - 4:00 p.m. Monday – Friday.

If you are located off-site and unable to visit the UH Cashier's Office, please email [UHResearchCredentialing@UHhospitals.org](mailto:UHResearchCredentialing@UHhospitals.org) for the off-site payment instructions.

7. After you have completed and uploaded the required documents, be sure to click "Submit" at the bottom of the application.

\*All documents required for the online application can be downloaded and uploaded through the online application.

Notification of approval will occur as described in the below section: "UH Research Credentialing Notification"

### **B. Renewal Application Steps**

1. Upload a completed and signed 'UH Department Chairman Certification' document\*
2. Read and upload a signed 'Authorization and Release from Liability' form\*
3. If Applicable: Non-UH employees that are Research Scholars, Fellows, Coordinators, and other research personnel who do not hold a valid clinical license (e.g. M.D., D.O., R.N.) or corresponding training certificate in the State of Ohio who require access to the EMR must complete the form: Rules for Non-Licensed Researchers in a Clinical Setting\*
4. Please print the "Payment Reference Form" attachment provided in the Payment section of the online application.\* This form will need to be completed and taken to the UH Cashier's Office with your payment of \$100.00. You must save the receipt from the UH Cashiers Office to upload on to your research credentialing application.



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Applications without receipts will not be processed and any lost receipts will not be replaced. The Cashier's Office is located in the Humphrey Building, first floor, room 1629, near Pre-Admission Testing. Hours: 9:00 a.m. - 4:00 p.m. Monday – Friday.

If you are located off-site and unable to visit the UH Cashier's Office, please email [UHResearchCredentialing@UHhospitals.org](mailto:UHResearchCredentialing@UHhospitals.org) for the off-site payment instructions.

5. After you have completed and uploaded the required documents, be sure to click "Submit" at the bottom of the application

\*All documents required for the online application can be downloaded and uploaded through the online application.

Notification of approval will occur as described in the below section: "UH Research Credentialing Notification"

### **C. CWRU Medical Student Application Steps**

1. Upload a completed and signed 'UH Department Chairman Certification' document\*
2. Read and upload a signed 'Authorization and Release from Liability' form\*
3. Read and upload a signed 'University Hospitals Electronic Systems Agreement' document\*
4. After you have completed and uploaded the required documents, be sure to click "Submit" at the bottom of the application

\*All documents required for the online application can be downloaded and uploaded through the online application.

Notification of approval will occur as described in the below section: "UH Research Credentialing Notification"



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## **UH Research Credentialing Notification**

- 1) Once all documentation is received by the UHCRC, please allow 5 to 7 business days for processing;
- 2) The UHCRC will notify the applicant if any document is incomplete or if the request for access is satisfactory; and
- 3) Upon completion, the UHCRC will notify the applicant and appropriate parties by e-mail that all the required steps of the UH Research Credentialing Process have been completed and the date of expiration.

## **UH Research Credentialing Audits**

In order to ensure that the UH Research Credentialing Process and corresponding documentation has been completed, the UHCRC will perform random sample audits of five (5) UH e-mail addresses. After three (3) consecutive monthly reviews with no deficiencies have occurred, the audit will occur quarterly. The UHCRC will notify the Department causing most infractions to ensure Departments are compliant as required by this SOP.

## **7. REFERENCES:**

[UH Research Credentialing Website](#)

[Corporate Screening](#)

[UH Policy IS – 14: Acceptable Use of Electronic Assets](#)

[UH Policy R – 3: Uses and Disclosures of Protected Health Information \(PHI\) for Research](#)

[UHCMC Nursing Research Council Website](#)

## **8. FORMS OR ATTACHMENTS:**

University Hospitals Research Credentialing Process Flow Chart (Attachment A)

UH Electronic Systems Agreement

UH Department Chairman Certification

Authorization and Release for Liability

Rules for Non-Licensed Researchers in a Clinical Setting

Payment Reference Form

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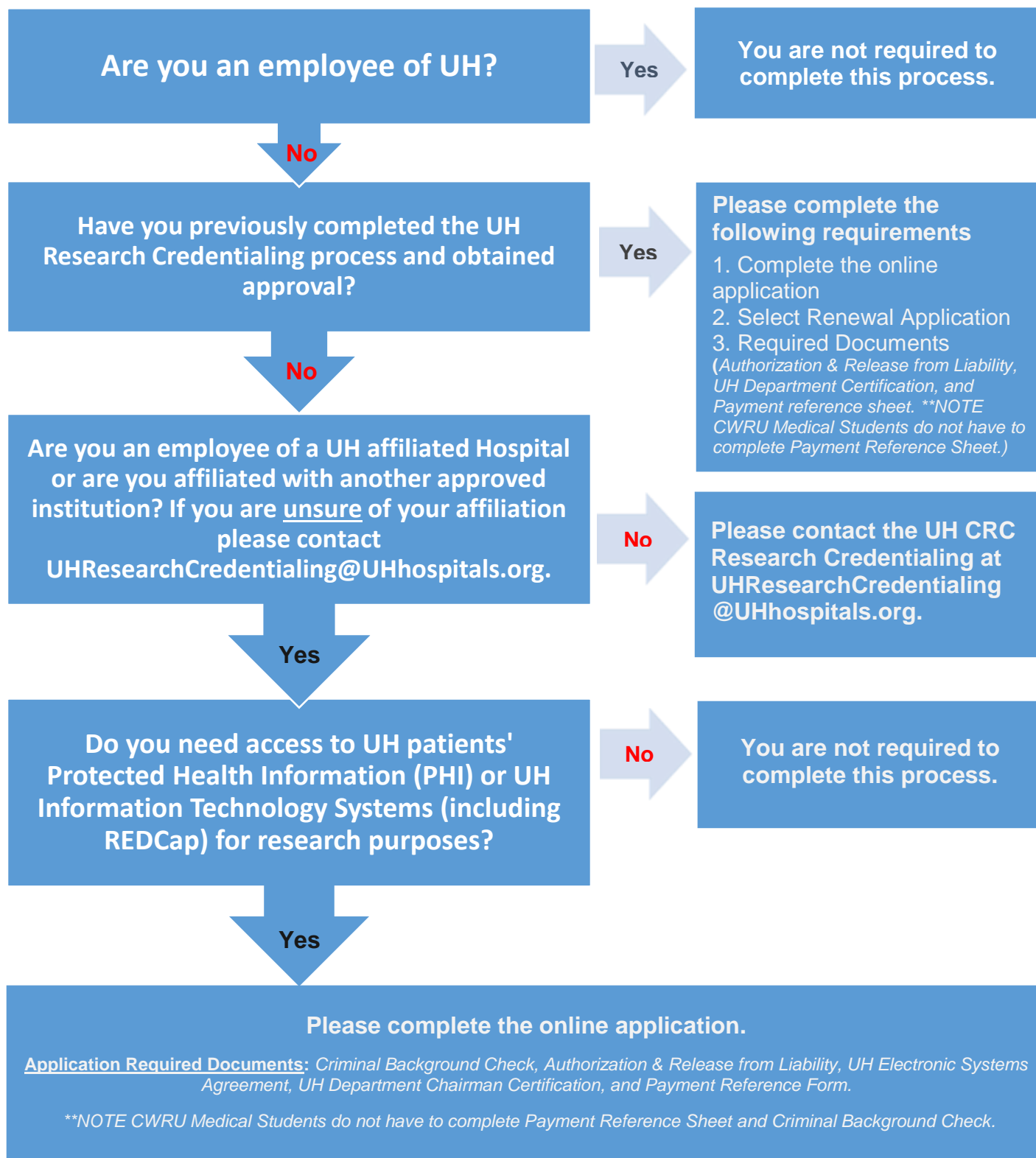
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Use and Disclosure of Protected Health Information Preparatory to Research Investigator's Certification

**APPROVALS**

Approved by Dr. Grace McComsey, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center– August 31, 2017





## **University Hospitals Electronic Systems Agreement**

### **SUMMARY OF TERMS**

The summary below is a short and informal description of the terms of this contract. It is not a complete description. You are requested to review the entire contract.

- This contract will allow you to access University Hospitals Electronic Systems. Please note that use of data may require separate agreement(s). You may not share your username, password or access rights with anyone else.
- With respect to all patient medical information obtained through the University Hospitals Electronic Systems, you must abide by University Hospitals policies and applicable law relating to the confidentiality of this information. Your access to University Hospitals Electronic Systems is monitored and recorded by University Hospitals. Violations may result in notifications to law enforcement, disciplinary action for employees, and revocation of University Hospitals Electronic Systems access rights.
- University Hospitals Electronic Systems are additional tools for you to use, but University Hospitals cannot guarantee the accuracy of data obtained through the Electronic Systems, and cannot guarantee that the Electronic Systems will always be accessible to you.



This Electronic Systems Agreement (this “Agreement”) is made by you in consideration of University Hospitals Health System, Inc. (“University Hospitals”) allowing you to access University Hospitals Electronic Systems and Data (“Systems”). The Systems include any information system in which University Hospitals data is stored or through which such data is accessible, including without limitation the University Hospitals Physician Portal, and the University Hospitals Electronic Medical Record. **Please read this Agreement carefully**, and then sign and initial where indicated to evidence your agreement with the terms of this Agreement.

In addition to the general terms outlined below, **you must individually initial each of the following three paragraphs (A, B & C)**, to indicate your specific agreement:

A. \_\_\_\_\_ I acknowledge that I am not permitted to share my personal user name or password with other people or with members of my organization. I understand that each person (including members of my organization who act on my behalf) must be given their own user name and password to access the Systems. **I acknowledge that if I share my user name and password in violation of this provision, then (1) I am personally liable for any misuse of the Systems resources by other persons who are using my user name and password, even if I did not know about or authorize such misuse; (2) University Hospitals shall have the right to immediately terminate this Agreement and my access to the Systems; and (3) if I am employed by a University Hospitals entity, I may be subject to disciplinary action up to and including termination.** I acknowledge that any other members of my organization who require access to the Systems must personally execute an Electronic Systems and Data Use Agreement with University Hospitals: this Agreement only pertains to me.

B. \_\_\_\_\_ **Neither I nor members of my organization will use information obtained through the Systems for any purpose other than the approved purpose(s) for which I accessed the Systems.** When accessing patient medical information, I acknowledge that accessing patient medical information for reasons unrelated to the provision of care to patients or other purpose specifically approved by UH may constitute a violation of federal or state law, and may carry civil or criminal penalties. I acknowledge that in the event of unauthorized access of patient information constituting a violation of law, University Hospitals may be obligated to report such violation to patients, appropriate law enforcement authorities, the media, or other parties. I acknowledge that any misuse of patient medical information will be cause for University Hospitals to immediately terminate this Agreement and my access to the Systems. I acknowledge that if I am employed by a University Hospitals entity, any misuse of patient medical information is grounds for disciplinary action up to and including termination. **I acknowledge that University Hospitals monitors and records identifying information about each access and attempted access to patient medical information through the Systems. I understand that in the event of a security breach, this information will be used by University Hospitals to identify the person(s) responsible for the breach. I agree that, in the event of a security breach, I will indemnify University Hospitals against all liabilities, costs and expenses arising from my violation of this Agreement or negligent acts, errors or omissions.**

C. \_\_\_\_\_ UNIVERSITY HOSPITALS (AND ITS SUBSIDIARIES, AFFILIATES, THIRD PARTY SUPPLIERS AND LICENSORS) PROVIDE THE SYSTEMS ON AN "AS IS," AS-AVAILABLE, BASIS, WITH ALL FAULTS, AND HEREBY DISCLAIM ALL OTHER WARRANTIES AND CONDITIONS, EITHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OR CONDITIONS OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, ACCURACY,



AUTHENTICITY, COMPLETENESS, RESPONSIVENESS, NON-INFRINGEMENT, NON-INTERFERENCE, COMPATIBILITY OF SOFTWARE PROGRAMS, INTEGRATION, OR THOSE WARRANTIES WHICH MAY ARISE BY COURSE OF DEALING, OR COURSE OF TRADE. ALSO, THERE IS NO WARRANTY OF LACK OF VIRUSES OR OTHER DISABLING CODE OR CONDITION, LACK OF NEGLIGENCE OR OF WORKMANLIKE EFFORT. YOU ARE RESPONSIBLE FOR VERIFYING ANY IMPORTANT INFORMATION THROUGH SOURCES OTHER THAN THE SYSTEMS. IN ADDITION, UNIVERSITY HOSPITALS DOES NOT WARRANT THE SECURITY OF THE SYSTEMS OR, THAT INFORMATION, SOFTWARE, CONTENT, AND FEATURES AVAILABLE THROUGH IT WILL BE UNINTERRUPTED, ERROR-FREE, PROVIDED PROPERLY OR COMPLETELY, OR BE AVAILABLE 24 HOURS PER DAY, 7 DAYS PER WEEK. UNIVERSITY HOSPITALS IN ITS SOLE DISCRETION MAY PROVIDE SUPPORT FOR THE SYSTEMS.

IN NO EVENT WILL UNIVERSITY HOSPITALS (OR ITS SUBSIDIARIES, AFFILIATES, THIRD PARTY SUPPLIERS AND LICENSORS) BE LIABLE TO YOU, YOUR ORGANIZATION, YOUR PATIENTS OR ANY OTHER PARTY FOR (I) ANY SPECIAL, DIRECT, INDIRECT, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR OR ARISING FROM PERSONAL INJURY, MEDICAL MALPRACTICE CLAIMS, LOSS OF BUSINESS PROFITS, BUSINESS INTERRUPTION, LOSS OF PROGRAMS OR INFORMATION, AND THE LIKE) OR ANY OTHER DAMAGES ARISING IN ANY WAY FROM OR IN CONNECTION WITH THE AVAILABILITY, USE, RELIANCE ON, PERFORMANCE OF THE SYSTEMS, PROVISION OF OR FAILURE TO PROVIDE THE SYSTEMS, LOSS OF DATA, YOUR ACCESS OR INABILITY TO ACCESS OR USE THE SYSTEMS OR YOUR USE AND RELIANCE ON INFORMATION OR CONTENT AVAILABLE ON OR THROUGH THE SYSTEMS, INCLUDING VIRUSES ALLEGED TO HAVE BEEN OBTAINED, OR INVASION OF PRIVACY FROM OR THROUGH THE SYSTEMS, EVEN IF UNIVERSITY HOSPITALS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT OR OTHERWISE; OR (II) ANY CLAIM ATTRIBUTABLE TO ERRORS, OMISSIONS, OR OTHER DYSFUNCTION IN, OR DESTRUCTIVE PROPERTIES OF, ARISING OUT OF OR IN CONNECTION WITH THE USE OR PERFORMANCE OF THE SYSTEMS. TO THE EXTENT THAT APPLICABLE LAW PROHIBITS THE VALIDITY OR EFFECTIVENESS OF ANY PART OF THIS OR THE PRECEDING PARAGRAPH, THE LIABILITY OF UNIVERSITY HOSPITALS AND ITS SUBSIDIARIES, AFFILIATES, THIRD PARTY SUPPLIERS AND LICENSORS SHALL BE LIMITED TO THE MAXIMUM EXTENT PERMITTED BY LAW.



## **General Terms**

1. **General.** This Agreement sets forth the terms and conditions under which you use the Systems and under which University Hospitals agrees to your use of the Systems. By using the Systems, you agree to be bound by the terms of this Agreement. This Agreement expressly incorporates all applicable University Hospitals policies and procedures, including without limitation the University Hospitals policies and procedures governing information services, patient rights and protection of patient medical information. University Hospitals' policies and procedures may be found on the University Hospitals intranet by clicking on the appropriate policy link(s) under the *Policies and Procedures* section of the Physician Portal left menu. For administrative policies, click *UHCMC Policies Volume 1*. For clinical policies, click *UHCMC Policies Volume 2*. For University Hospitals system-wide policies, click the *UH Policies and Procedures* link. University Hospitals policies and procedures concerning information services begin with the prefix "IS-." University Hospitals policies and procedures concerning patient rights begin with the prefix "PR-." University Hospitals policies and procedures concerning the protection of patient medical information begin with the prefix "PH-." You further agree to abide by any policies specific to the use of the Systems which are communicated to you or posted within the Systems under the Policies and Procedures section of the Physician Portal left menu. Please refer to the *Physician Portal Policies and Procedures* link to access these portal specific policies.

Your agreement to the terms of this Agreement is required for you to be granted access to the Systems. If you do not agree to the terms of this Agreement, you may not access the Systems.

2. **No Commercial or Private Use; No Discrimination; Legal Compliance.** University Hospitals makes the Systems available to authorized users at no charge, in order to fulfill University Hospitals' charitable mission to improve the health of persons in the University Hospitals service area and to conduct authorized and approved research. Access to the Systems is intended solely for these purposes. Any other use or any attempt to use the Systems for commercial purposes or other purposes is strictly prohibited.

If you are using the Systems to access patient medical information, note that the Systems are limited to information concerning treatment rendered at University Hospitals facilities. The Systems are not intended to be used, and may not be used, to store or process any information relating to the treatment of patients in the private physician office setting, or any other setting not entirely owned and controlled by University Hospitals. You are expressly prohibited from using the Systems in an attempt to store or process information generated by your own medical practice or medical office, or other non-University Hospitals health care provider.

You are further expressly prohibited from using the Systems in any manner that discriminates against persons on the basis of their race, color, religion, age, national origin, ancestry, gender, sexual orientation, disability, veteran status, financial status or ability to pay, or participation in government-funded health care programs (including without limitation Medicare and Ohio Medicaid).

You and University Hospitals agree that nothing in this Agreement constitutes, or is intended to constitute, an inducement by University Hospitals for you to refer patients to University Hospitals facilities or personnel, or to recommend or arrange for patients to receive items or services from University Hospitals facilities or personnel. You and University Hospitals agree to comply with all applicable laws and regulations relative to this Agreement, including without limitation Federal Anti-Kickback Statute (42 U.S.C. Sec. 1320a-7(b) (the "Anti-Kickback Statute") and the Physician Self





Referral Law (42 U.S.C. Sec. 1395nn) (also referred to as the “Stark Law”). You and University Hospitals agree that your access to the Systems does not constitute the provision of remuneration or any other thing of value to you, and that you have no legally cognizable interest in this Agreement or continued access to the Systems. You agree to notify University Hospitals immediately in the event that you are excluded from participation in any health care payment program funded in whole or part by the federal or a state government, including without limitation Medicare and Ohio Medicaid. In the event of such exclusion, this Agreement shall terminate automatically and you agree to cease all access to or use of the Systems. In the event that you believe that University Hospitals, any subsidiary of University Hospitals, or any person acting on behalf of University Hospitals or a subsidiary of University Hospitals, has engaged in a violation of law or of University Hospitals policy, you agree to immediately report such belief to either: (1) the University Hospitals Compliance Officer, at (216) 767-8223; or (2) the University Hospitals Compliance Hotline, at (800) 227-6934 (reports to the University Hospitals Compliance Hotline may be made anonymously).

3. Right to Change or Modify the Systems. Without prejudice to any other rights that University Hospitals may have, University Hospitals reserves the right and sole discretion to change, limit, terminate or modify the Systems at any time with or without notice. University Hospitals may temporarily or permanently cease to provide the Systems or any part thereof to any user or group of users (including you), without prior notice and for any reason or no reason. In the event you or University Hospitals terminates this Agreement, you must immediately stop using the Systems.

4. Changes to or Termination of Agreement. University Hospitals reserves the right, from time to time, to amend or change this Agreement (including any of the University Hospitals policies which may be applicable to your use of the Systems) on the University Hospitals intranet. You agree to visit this site periodically to be aware of and review any such revisions. Changes to this Agreement shall be effective upon posting. By continuing to use the Systems after revisions are posted, you accept the revisions and agree to abide by them.

Either you or University Hospitals may terminate this Agreement at any time and for any reason or no reason. Notice of such termination must be in writing and must be sent by email; provided, however, that University Hospitals may notify you of the termination of this Agreement by discontinuing your access to the Systems. If you determine to terminate this Agreement, you must email notice of such termination to: [portalsupport@uhhospitals.org](mailto:portalsupport@uhhospitals.org). Upon termination of this Agreement, your access to the Systems will be discontinued. Upon any termination of this Agreement, your obligations and agreements contained in Sections A, B, C, 5, 6 and 8 of this Agreement shall survive such termination.

5. Intellectual Property Rights; Research. As between you and University Hospitals, all title and intellectual property rights (including without limitation, copyrights, patents, trademarks and trade secrets) in and to the Systems (including but not limited to, related software and including but not limited to any images, photographs, animations, video, audio, music, text, content and "applets," incorporated into the Systems or the software used to provide the Systems), and any derivative works therefrom, are owned by University Hospitals. All title and intellectual property rights in and to the information and content which may be accessed through use of the Systems are the property of University Hospitals and/or the particular patient to whom medical information applies, and is protected by federal and state laws governing the confidentiality of patient medical information, as well as applicable copyright or other intellectual property laws and treaties. Neither this Agreement, nor your use of the Systems, provides you with any ownership in such information. This Agreement does not



grant you any rights to use such content other than as expressly permitted in this Agreement, nor does it grant any rights to the Systems other than the right to use the Systems according to the terms of the Agreement. You may not disseminate information contained on, or concerning, the Systems to any person or entity, except as expressly permitted in this Agreement.

You acknowledge that this Agreement does not, by itself, allow you to access or review any information or patient data through the Systems for purposes of conducting research, preparing a research protocol, performing statistical analysis or epidemiological reviews, writing scholarly reviews or journal articles or other related uses. All such uses must be separately approved through applicable University Hospitals policies concerning research activities, including receipt of Institutional Review Board and/or Research Privacy Board approval when required by University Hospitals policy. If such approvals are obtained, each person conducting such research who accesses the Systems must execute this Agreement. Your right to use the Systems ends when your need, with respect to the specific research/protocol approved by University Hospitals, ends.

6. Indemnification. You agree to defend, indemnify and hold harmless University Hospitals, its subsidiaries and affiliates, and their respective officers, directors, employees, agents and suppliers from and against all liabilities, costs and expenses, including reasonable attorney's fees, related to or arising from: (a) any violation of this Agreement by you (or any parties who use your computer and/or your user name or password, with or without your permission, to access the Systems); (b) the unauthorized release of confidential patient medical information caused by you (or any parties who use your computer and/or your user name or password, with or without your permission, to access the Systems); (c) negligent acts, errors, or omissions by you (or any parties who use your computer and/or your user name or password, with or without your permission, to access the Systems), relating to the use of the Systems; and (d) claims for infringement of any intellectual property rights arising from the misuse of the Systems or violation of this Agreement by you (or any parties who use your computer and/or your user name or password, with or without your permission, to access the Systems).

7. Your Equipment. You are solely responsible for obtaining, installing, and maintaining suitable equipment and software, including any necessary system or software upgrades, patches or other fixes, which are or may become necessary to access the Systems. Minimum systems requirements may apply to the use of the Systems and it is your responsibility to ensure your computer system complies with these requirements. You are responsible for management of your information, including but not limited to back-up and restoration of data, erasing data from disk space you control and managing your own network. You are also responsible for development and maintenance of any security procedures you deem appropriate to control access to your own equipment and systems, such as logon security and encryption of data, user ID and password on your router and firewalls, to protect your information. You acknowledge that if you are a "covered entity" or "business associate" under the privacy and security provisions of the Health Insurance Portability And Accountability Act of 1996 and all regulations and guidance promulgated thereunder ("HIPAA"), you are responsible for implementing such policies, practices and safeguards as are required under HIPAA, with respect to your own operations and your own information systems. You will implement encryption or data destruction methods in order to be compliant with HIPAA and University Hospitals policies and procedures, and guard the privacy and security of protected health information in the event your equipment is lost or stolen.



8. Miscellaneous Provisions.

a. If any part of this document is held invalid or unenforceable, that portion shall be construed in a manner consistent with applicable law to reflect, as nearly as possible, the original intentions of the parties, and the remaining portions shall remain in full force and effect.

b. The Systems may contain third party web site links, and if so then such links are provided by University Hospitals only as a convenience to its users. Any web sites linked to or from the Systems are not reviewed, controlled, or examined by University Hospitals and University Hospitals is not responsible for the contents of any linked site or any link contained in a linked site. The inclusion of any linked sites or content from the Systems does not imply endorsement of the linked site or content by University Hospitals. In no event shall University Hospitals be liable to anyone for any damage arising from or caused, directly or indirectly, by the creation or use of a third party's web site, or the information or material accessed through such web sites.

c. You and University Hospitals agree that the laws of the State of Ohio, without reference to its principles of conflicts of laws, will be applied to govern, construe and enforce all of the rights and duties of the parties arising from or relating in any way to the subject matter of this Agreement. YOU AND UNIVERSITY HOSPITALS CONSENT TO THE EXCLUSIVE PERSONAL JURISDICTION OF AND VENUE IN A COURT LOCATED IN THE CITY OF CLEVELAND, OHIO, FOR ANY SUITS OR CAUSES OF ACTION CONNECTED IN ANY WAY, DIRECTLY OR INDIRECTLY, TO THE SUBJECT MATTER OF THIS AGREEMENT OR TO THE SYSTEMS. Except as otherwise required by law, any cause of action or claim you may have with respect to the Systems must be commenced within one (1) year after the claim or cause of action arises or such claim or cause of action is barred.

d. This Agreement, including all policies and notices incorporated into this Agreement by reference, constitutes the entire agreement between you and University Hospitals with respect to the subject matter hereto and supersedes any and all prior or contemporaneous agreements whether written or oral. You agree not to assign or otherwise transfer this Agreement in whole or in part; any attempt to do so shall be void. Except as provided in Section 4, this Agreement may only be amended in a written instrument signed by you and University Hospitals, and approved as to form by an attorney in the University Hospitals Law Department.

e. You agree to furnish to University Hospitals any documents, records or other information that is reasonably requested by University Hospitals in order to determine your compliance with the terms of this Agreement.

f. If you discover a security breach involving protected health information accessed through the Systems, you will provide written notice to University Hospitals within three (3) business days by faxing the notice to (216) 767-8272 and sending the original to the address below:

University Hospitals Privacy Officer  
Compliance and Ethics Department  
University Hospitals Management Service Center  
3605 Warrensville Center Road  
Mail Stop # MSC 9105  
Shaker Heights, OH 44122



The undersigned individual agrees to the terms of this Agreement in his or her individual capacity:

Signature: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

Email: \_\_\_\_\_

## AUTHORIZATION AND RELEASE FROM LIABILITY

I am an applicant for appointment to the University Hospitals Research Staff (hereinafter "Participation") at  
University Hospitals Cleveland Medical Center (hereinafter "Entity").

I understand and acknowledge that it is my responsibility to provide all information requested by Entity upon which a proper evaluation can be undertaken, including but not limited to education level, current employment, health status, character, ethics, and any other criteria adopted by the Entity for Participation, and for resolving any discrepancies or doubts about such information. I further acknowledge that I am responsible for knowing the contents of the applicable bylaws, rules, policies, corporate code of conduct, and requirements of the Entity and its professional staff or network, and agree to be bound by them in the application process and if granted Participation.

I understand and acknowledge that Participation is a privilege, and that I am not automatically entitled to Participation simply by virtue of my academic background, professional training, or membership in a particular institution or professional organization. I understand and agree that I have no right to Participation, that Entity may terminate or alter the terms of my Participation at any time for any reason or no reason, and that neither my appointment to the staff nor my execution of this agreement creates any contractual right, whether express or implied. I further understand that Participation does not constitute approval of clinical privileges, and that my Participation does not permit me to provide clinical treatment of patients in any manner.

By submitting this Application, I agree to such investigation and to the disciplinary reporting and information exchange activities of the Entity and its Agents as follows:

1. **Authorization of Investigation and Release of Information Concerning Application for Participation.** I authorize Entity and its Agents to consult with any third party who may have information bearing on my professional qualifications, credentials, competence, character, health status, ethics, behavior, or any other matter reasonably having a bearing on my qualifications for Participation and authorize such third parties to release such information to the Entity and its Agents.
2. **Release from Liability.** I hereby further release from liability the Entity and its Agents, state licensing boards, health care organizations, academic institutions, consultants, any staff thereof, and all individuals, institutions, and entities providing information in accordance with this authorization, for their acts performed in good faith and without malice in connection with the gathering, evaluating, and release and exchange of information as consented to above. This release shall be in addition to any other applicable immunities provided by law for peer review activities.

I understand and agree that this Authorization and Release is irrevocable for any period during which I am an applicant for Participation at the Entity, or I am a member of Entity's Research Staff. I agree to execute another consent as required by law, regulation, or Entity accreditation standards.

All information submitted by me in this application is complete and true to my best knowledge and belief. I understand and agree that any material misstatements in, or omissions from this application constitute cause for denial of or revocation of Participation. I understand and acknowledge that the Entity shall be solely responsible for all decisions concerning the granting of Participation.

I further acknowledge that I have read and understand the foregoing Authorization and Release. I further acknowledge that I have received the UH Code of Conduct (<http://www.uhhospitals.org/aboutuh/missionvision/tabid/1806/codeofconduct.aspx>). I have read, understood and agree to abide by the UH Code of Conduct.

A copy of this original document as signed by me shall have all the same force and effect as the signed original.

\_\_\_\_\_  
Date Signed  
(MM/DD/YYYY)

\_\_\_\_\_  
Applicant's Printed Name

\_\_\_\_\_  
Applicant's Signature

# RULES FOR NON-LICENSED RESEARCHERS IN A CLINICAL SETTING

*Non-employees of University Hospitals must be credentialed by the UH Clinical Research Center (UHCRC) prior to gaining access to the electronic medical record (EMR). As part of that process, this form is to be completed by Research Scholars, Fellows, Coordinators, and other research personnel who do not hold a valid clinical license (e.g. M.D., D.O., R.N.) or corresponding training certificate in the State of Ohio. Access to the EMR will not be granted until this form is reviewed and signed by both the applicant and the applicant's supervising physician.*

I, \_\_\_\_\_ [name], as a [**select one**][Research Scholar][Research Coordinator][Research Fellow] [Other (fill in here) \_\_\_\_\_], acknowledge, understand, and agree to the following:

- I am applying to be credentialed for purposes of conducting research or educational activities. I will not be granted any clinical privileges
- I do not hold a license to practice medicine, nursing, or any other clinical field in the State of Ohio
- The law prohibits me from providing care or treatment to patients, even if I graduated from medical school or trained as a physician in another country
- My job duties do not require me to perform clinical duties or provide patient care or treatment
- When in a clinical setting, **I am allowed to:**
  - Observe and interact with patients, ask them questions, and record their answers
  - Review the patient's chart, imaging studies, lab results, and other diagnostic reports for research and educational purposes only
  - Prepare documentation for research and educational purposes, including clinical trials
  - Perform laboratory work for research or educational purposes, including clinical trials
  - Participate in grand rounds, morbidity and mortality conferences, and evaluations of adverse patient events
- When in a clinical setting, **I am NOT allowed to:**
  - Hold myself out as a physician or other licensed medical personnel
  - Treat a patient or obtain a patient's consent for treatment
  - Conduct a physical examination of a patient
  - Make a diagnosis or give medical advice
  - Perform histories and physicals (H&P) for treatment purposes, even if attested to by an attending physician or principal investigator
  - Interpret imaging studies, lab results, or other diagnostic data for treatment purposes, even if attested to by an attending physician or principal investigator
  - Make decisions as to a patient's inclusion/exclusion criteria
  - Give orders or make entries in the patient's medical record for clinical purposes
  - Administer anesthesia, controlled substances, intravenous drugs, or other medications
  - Charge money, or anything else of value, for treatment or clinical services
  - Perform any other task that requires a medical, nursing, or other clinical license
- If I fail to follow these rules, my position may be terminated. I may also be guilty of engaging in the unauthorized practice of medicine, a felony crime punishable by jail and monetary fines
- If I ever have questions or do not understand what I am allowed and not allowed to do, I can always receive guidance from my principal investigator, department chairman, UHCRC office, or the UH Compliance office

By signing below, I certify that I have read, understood, and agree to the above:

As the UH employee primarily responsible for supervising this applicant, I certify that I have read and agree to the foregoing:

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Title

Chairman/Division Chief approval:

\_\_\_\_\_

## Payment Reference Form

Please print this information sheet and take it to the UH Cashier's Office with your payment. You must save the receipt from the UH Cashiers Office to upload on to your research credentialing application. Applications without receipts will not be processed and any lost receipts will not be replaced. Please note that this fee is non-refundable.

For any questions regarding the Payment Reference Sheet, please contact  
[UHresearchcredentialing@uhhospitals.org](mailto:UHresearchcredentialing@uhhospitals.org).

### Cashier's Office

The Cashier's Office is located in the Humphrey Building, first floor, room 1629, near Pre-Admission Testing.  
Hours: 9:00 a.m. – 4:00 p.m. Monday – Friday

### Applicant Information

*Please fill in the information below.*

Last Name:

Date:

First Name:

Phone Number:

Initial Application (\$150.00): ☐

Renewal Application: (\$100.00) ☐

### Payment Reference

*Please fill in the information below.*

**Research Credentialing - \_\_\_\_\_ 100 00000 10069 000 00000 0000 000 000 0000**  
(Applicant's Last Name)



**UH Department Chairman and UH Investigator Certification**

I, \_\_\_\_\_ (Research Applicant) am applying to work on the following Research Projects (list up to 3)

UH IRB Protocol Number	Position Description (Roles & Responsibilities)	Does Applicant require access to any UH IT Systems*	Will Applicant be present at any UH Facility**	Principal Investigator Signature***

**\*NOTE:** Each Department is responsible for requesting any UH IT Systems Access and will be held accountable for each Applicant's system use.

**\*\*NOTE:** All Applicants that will be present at a UH Facility must be cleared by Employee Health prior to his/her start date

**\*\*\*NOTE:** If the Principal Investigator is not a UH employee, then a UH employed co-investigator or designated sponsor must sign this form

**ATTENTION:** UH Research Credentials expire one (1) year from the date of approval. You will not receive a notification so please mark your calendar with a renewal reminder. If your credentialing expires, your UH IT Access will be shut off automatically and will not be restored until the UH Research Credentialing Annual Renewal Procedure is completed and approved.

I hereby certify that I am the UH Investigator or designated UH sponsor named to oversee the above-named Research Applicant, and I will personally approve and oversee (i) the individual's access to any UH IT systems, (ii) the individual's interaction with any UH patients and (iii) any changes that occur related to the Research Applicant's roles and responsibilities as listed above.

**UH Sponsor Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

I hereby certify that I am the Chair of the Department of \_\_\_\_\_ and I approve the above-named Research Applicant to engage in the listed research project(s) within my Department.

**UH Chairman Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**UH Chairman Name (Printed):** \_\_\_\_\_