Step-by-step instructions on how to complete the research credentialing process are contained in this document. The link to access the credentialing application is on page 2. PLEASE READ THESE INSTRUCTIONS

1. PURPOSE:
   To define the procedures necessary for non-University Hospitals (UH) personnel to obtain access to UH Protected Health Information (UH PHI), UH patients, or UH property for research purposes.

   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 under the supervision of a UH employee who serves as the Responsible Investigator of the research protocol and who completes all of the required steps set forth in the Research SOP GA 102: Use and Disclosure of Protected Health Information Preparatory to Research;
   3) Grants a UH-based title (Research Faculty or Research Associate);
   4) Provides the non-employee with a UH e-mail address and access to UH IT systems required to complete the research project in accordance with the standard UH policies and procedures;
   5) Provides access to UH-sponsored training as well as research education programs.

2. SCOPE:
   This SOP applies to all non-UH personnel interested in engaging in research at UH who need access to UH PHI, UH patients or UH property.

   If the individual seeking credentialing is affiliated with one of the one of the following institutions, they may proceed with the application:
   - UH Affiliated Hospitals (including Southwest General, Lake Health, and Firelands Regional Medical Center)
   - Case Western Reserve University (CWRU)
   - Kent State Nursing Students
   - Ursuline College
   - Cleveland State Nursing Students
If the individual seeking credentialing is NOT affiliated with one of the listed institutions, please fill out the form in Appendix A and send to the research credentialing office (UHResearchCredentialing@UHhospitals.org) BEFORE completing the application process. **Do NOT submit payment until you have confirmed you are eligible for Research Credentialing; fees are non-refundable.**

3. **DEFINITIONS:**
   Reference the Glossary in the SOP Manual for complete definitions of terms.

4. **POLICY STATEMENT:**
   All non-UH personnel interested in engaging in research and accessing UH patients, UH PHI or UH property, must complete the UH Research Credentialing Process. All applicants must renew their UH Research Credentials annually in order to maintain access to research studies at UH.

5. **PROCEDURES:**
   The following steps must be completed in order to be granted access to UH Patients, UH PHI (including UH IT Systems that contain PHI for the purpose of conducting research); or UH property:

5.1. Work with the Principal Investigator overseeing the research protocol(s), the UH Sponsor, or Department Administrator(s) for assistance in completing the required documentation and application process outlined below.

5.2. Identify and complete the appropriate version of the three (3) online applications:
   a. Initial Application
   b. Renewal Application
   c. CWRU Medical Student

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

5.3. **Initial Application**

5.3.1. Complete and sign ‘UH Sponsor Certification Form’ and upload electronically to application.
5.3.2. Sign ‘Authorization and Release from Liability’ form

5.3.3. Sign ‘University Hospitals Electronic Systems Agreement’ document

5.3.4. Complete UH Criminal Background Check.

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

i. Go to 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 in its entirety.

ii. Have a credit card (Visa/Mastercard/American Express/Discover) – complete with pertinent IRB study information ready in order to process payment. The cost is approximately $25.00.

iii. Click Submit button at the end of the process. 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 by clicking on the Retrieve Background button. An updated background check is required every 5 years. It is your responsibility to ensure this is kept up to date.

5.3.5. Upload a copy of MD, DO or RN license in the State of Ohio or corresponding training certificate in the State of Ohio.

a. If the applicant does not have a MD, DO or RN license in the State of Ohio, the applicant must complete the form entitled Rules for Non-Licensed Researchers in a Clinical Setting in the credentialing application.
5.3.6. Provide proof of payment of the non-refundable research Credentialing fee by attaching a copy of your receipt to the online application, or by providing the date of your email confirmation of payment. See Appendix B for payment options.

5.3.7. Complete Health Screen Requirements for Researchers in Appendix C.

5.3.8. CREC/CITI training is required for all individuals listed as study personnel. CREC/CITI certification can be obtained initially by completing CITI training or by obtaining CREC credits. For more information regarding how to obtain CREC/CITI certification, please visit https://case.edu/research/faculty-staff/education-and-training/continuingresearch-education-credit-crec or email crec@case.edu.

5.3.9. After you have completed and uploaded the required documents, click “Submit” at the bottom of the application.

5.3.10. UH Research Credentialing Notification. Once all documentation is received by the UHCRC, allow 5 to 7 business days for processing:

- The UHCRC will notify the applicant if any document is incomplete or if the request for access is satisfactory; and
- The UHCRC will notify the applicant and appropriate parties by email that all the required steps of the UH Research Credentialing Process have been completed and the date of expiration.
- You are not research credentialed until you have received an approval email with an attached certificate.
- Compliance with this policy will be monitored. Failure to adhere to this policy may result in the termination of research credentialing privileges.

5.4. **Renewal Application**

5.4.1. Complete and sign ‘UH Sponsor Certification Form’ and upload electronically to application.
5.4.2. Sign ‘Authorization and Release from Liability’ form

5.4.3. Upload a copy of MD, DO or RN license in the State of Ohio or corresponding training certificate in the State of Ohio.
   a. If the applicant does not have a MD, DO or RN license in the State of Ohio, the applicant must complete the form entitled *Rules for Non-Licensed Researchers in a Clinical Setting.*

5.4.4. Provide proof of payment of the non-refundable research Credentialing fee by attaching a copy of your receipt to the online application. See Appendix B for payment options.

5.4.5. If your background check is more than 5 years old, you must complete a new background check per the instructions above in 5.3.4.

5.4.6. After you have completed and uploaded the required documents, click “Submit” at the bottom of the application.

5.4.7. UH Research Credentialing Notification. Once all documentation is received by the UHCRC, allow 5 to 7 business days for processing;
   • The UHCRC will notify the applicant if any document is incomplete or if the request for access is satisfactory; and
   • The UHCRC will notify the applicant and appropriate parties by email that all the required steps of the UH Research Credentialing Process have been completed and the date of expiration.
   • You are not research credentialed until you have received an approval email with an attached certificate.
   • Compliance with this policy will be monitored. Failure to adhere to this policy may result in the termination of research credentialing privileges.
5.5. **CWRU Medical Student Application**

5.5.1. Complete and sign ‘UH Sponsor Certification Form’ and upload electronically to application.

5.5.2. Sign ‘Authorization and Release from Liability’ form

5.5.3. Sign ‘University Hospitals Electronic Systems Agreement’ document

5.5.4. A background verification is required with the School of Medicine. If this is your FIRST research credentialing application you must:
   - Visit [http://casemed.case.edu/registrar/forms/](http://casemed.case.edu/registrar/forms/)
   - Click the "Student Letter Request Form".
   - Select the Background Check Verification Letter" option.
   - Login with your CWRU ID and password.
   - Complete the form and select "Email" as the Delivery Method and have the letter emailed to UHResearchCredentialing@UHhospitals.org

If you have previously been UH Research Credentialed this step is not required.

5.5.5. Verify Health Screen Requirements for Researchers in Appendix C.

5.5.6. CREC/CITI training is required for all individuals listed as study personnel. CREC/CITI certification can be obtained initially by completing CITI training or by obtaining CREC credits. For more information regarding how to obtain CREC/CITI certification, please visit [https://case.edu/research/faculty-staff/education-and-training/continuingresearch-education-credit-crec](https://case.edu/research/faculty-staff/education-and-training/continuingresearch-education-credit-crec) or email crec@case.edu.

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

5.5.8. UH Research Credentialing Notification. Once all documentation is received by the UHCRC, allow 5 to 7 business days for processing;
• The UHCRC will notify the applicant if any document is incomplete or if the request for access is satisfactory; and
• The UHCRC will notify the applicant and appropriate parties by email that all the required steps of the UH Research Credentialing Process have been completed and the date of expiration.
• You are not research credentialed until you have received an approval email with an attached certificate.
• Compliance with this policy will be monitored. Failure to adhere to this policy may result in the termination of research credentialing privileges.

6. 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
   UH Policy IC-7: Corporate Health Infection Control Program
   Health Screening Requirements for Researchers Policies: EH-1, EH-2, EH-3, EH-4, EH-5, EH-6, EH-8, and EH-9
   Non-employee job aid
   Research SOP GA 102: Use and Disclosure of Protected Health Information Preparatory to Research

7. FORMS:

   UH Electronic Systems Agreement
   UH Sponsor Certification
   Certification Authorization and Release for Liability
   Rules for Non-Licensed Researchers in a Clinical Setting
   Payment Reference Form
STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH
TITLE: University Hospitals (UH) Research Credentialing

SOP NUMBER: GA-103

APPROVALS

Approved by Dr. Grace McComsey, Vice President of Research, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center - August 21, 2019
# APPENDIX A

## Name of Individual Requesting Out-of-Policy Research Credentialing:

<table>
<thead>
<tr>
<th>Date:</th>
</tr>
</thead>
</table>

## Out-of-Policy Institution Information:

<table>
<thead>
<tr>
<th>Institution Affiliation</th>
<th>☐ N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the above institution is a school, what is the department?</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>Is this research project a requirement for your course of study?</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>Will you receive course credit?</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>Is there an agreement between the institution and University Hospitals?</td>
<td>☐ Yes ☐ No</td>
</tr>
</tbody>
</table>

## University Hospitals Information:

<table>
<thead>
<tr>
<th>UH Department:</th>
</tr>
</thead>
<tbody>
<tr>
<td>UH Sponsor / Supervisor:</td>
</tr>
</tbody>
</table>

## UH Research Study Information:

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Study Number:</td>
</tr>
<tr>
<td>Time Period (MM/DD/YYYY):</td>
</tr>
<tr>
<td>Will you receive payment?</td>
</tr>
<tr>
<td>Will you have access to UH PHI?</td>
</tr>
<tr>
<td>Will you be working on UH property?</td>
</tr>
<tr>
<td>Will you have access to UH patients?</td>
</tr>
</tbody>
</table>

**Provide a brief description of your research responsibilities:**

## Additional Information, if applicable:
APPENDIX B

1. Payment Options-

A. Payment Option 1- Cash, Credit Card or Check
   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 $150.00 for new applications or $100.00 for renewals. 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.

B. Payment Option 2- General Ledger Account, PTAEO or CWRU Speedtype
   Print the “Department Payment Form” attachment provided in the payment section of the online application. The form will need to be completed and emailed to UHCRCGrantsAccounting@UHhospitals.org. After payment has been processed, you will receive an email confirmation, with UH Research Credentialing copied. This email will serve as your receipt of payment, please enter the date of the email in your REDCap application when prompted.

Payments are non-refundable, so ensure you are eligible for credentialing (i.e. you are affiliated with one of the listed institutions, or you have explicit permission from the research credentialing office) BEFORE you pay the fee.

If you are located off-site and unable to visit the UH Cashier’s Office, email UHResearchCredentialing@UHhospitals.org for the off-site payment instructions.

After you have completed and uploaded the required documents, be sure to click “Submit” at the bottom of the application.
# Health Screen Requirements for Researchers

Refer to Policies EH-1-6, EH-8, EH-9, CP-95 and IC-7

<table>
<thead>
<tr>
<th>Researcher Type</th>
<th>Proof of negative 2-step TB skin test or blood assay within 6 months of hire(^1)</th>
<th>Proof of reactive Hepatitis B surface antibody(^2). If none, vaccination offered with retest 68 weeks later. If declining vaccine after titer, must sign declination form (Policy EH-8)</th>
<th>Positive titers for MMR, Varicella and indication of receipt or declination of Tdap vaccine (Policies EH 1-5)</th>
<th>Flu Vaccination (Policy CP-95)</th>
<th>Fit Testing (Policy EH-6)</th>
<th>Location of testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>UH credentialed Medical/Allied Staff (cM/AS) and others with clinical privileges (at UH inpatient and/or ambulatory sites)</td>
<td>X</td>
<td>Must also have a negative Hepatitis B surface antigen test</td>
<td>X</td>
<td>All groups must accept or decline the influenza vaccine (typically OctMarch)</td>
<td></td>
<td>UH Employee Health</td>
</tr>
<tr>
<td>UH workforce members with potential for direct patient contact</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>UH Employee Health</td>
</tr>
<tr>
<td>Student researchers with potential for direct patient contact</td>
<td>X</td>
<td>Must show vaccination record</td>
<td>Must show vaccination record</td>
<td></td>
<td></td>
<td>Student Health</td>
</tr>
<tr>
<td>Researchers with potential for direct patient contact (Non-cM/AS, non-UH workforce member)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>PCP or their own Employee Health Office</td>
</tr>
<tr>
<td>Researchers with no direct patient contact (i.e. administrative work only) (Non-cM/AS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Will progress in the following pattern: skin test-serum test-chest film. A positive serum test will require chest film and may require additional follow up. Those with a subsequent positive serum test and/or chest film will thereafter complete yearly TB Positive History Questionnaire.

2. Practitioners who have had Hepatitis B disease must make this known on initiation of relationship with UHHS and are subject to review by Infection Control. If not immune to Hepatitis B after two full rounds of vaccine series, no further testing needed except if exposure occurs.