

I. DEFINITION

For purposes of this policy the term “Non-Employee” throughout this policy shall refer to anyone that participates in unpaid assignments at HHRI, including, but not limited to, Non-employee Research Collaborators, Visiting Students, Volunteers, Research/Study Monitors and Visitors/Guests. Individuals on-boarded through Hennepin Health System’s (HHS) Human Resources department are not considered non-employees for the purposes of this policy. HHRI’s policy is congruent with HHS’ volunteer policy. Only HHRI and HHS employees (or their contract personnel) are eligible to serve as a supervisor for non-employees.

A “non-employee” is defined as anyone who, without compensation or expectation of compensation beyond reimbursement, performs a task(s) at the direction of or on behalf of the HHRI. A “non-employee” should be at least 18 years of age and officially accepted and onboarded by the HHRI prior to performance of task(s). Should a “non-employee” opportunity arise for someone under age 18, the position will be reviewed for compliance with current regulations for minors in the workplace, as well as constraints on tasks that can be completed by individuals that are under age 18 outlined in HHRI policy.

“Non-employees” shall not be considered employees of the HHRI. The use of “non-employee” positions should not replace or create the impression of replacing paid staff positions.

- A. Non-employee Research Collaborator (NRC) is defined as an individual that is typically employed by another organization and is at HHRI in a coordinating capacity or to perform other compliance committee (e.g. IACUC, IRB) approved procedures. The onboarding process for an NRC is intended to establish an agency relationship with HHRI. For Human Subjects’ Research, there are a number of different roles available, and eligibility for those roles will be assessed and determined by the IRB. Medical Students and non- US trained MDs are included in this classification.
- B. Visiting Student is defined as an individual that is part of a non-HHRI/non-HCMC academic program and is at HHRI in a learning capacity.
- C. Volunteer is defined as an individual that is at HHRI performing tasks under the supervision of an HHRI/HCMC employee and is not being paid for the tasks they complete.
- D. Research/Study Monitor – is defined as an individual that is typically employed by another organization and is at HHRI in a monitoring/verification capacity.
- E. Visitor is defined as anyone who is at HHRI as an observer with no interaction with the work of HHRI (e.g., observing experiments and/or touring labs)

II. POLICY:

HHRI believes that all “non-employees” should be treated equally in all practices and conditions of the assignment. Therefore, it is the policy that HHRI will not discriminate against any “non-employee” because of race, creed, color, religion, sex, disability, handicap, age, national origin, marital status, status with regard to public assistance, affectional preference, member or activity in a public commission, or protected veteran status.

This policy serves to provide overall guidance and direction in the use of “non-employees” at the HHRI. It is intended for internal management guidance only and does not constitute, either implicitly or explicitly, a binding contractual or personnel agreement.

III. PROCESS

- A. HHRI Human Resources is notified by the requesting party of the need for a non-employee.
- B. Requesting party is provided a Non-Employee Requisition form for completion. Information required from the non-employee includes:
 - 1. First & Last Name
 - 2. Email Address
 - 3. Anticipated Start Date
 - 4. End Date (if unknown, a maximum of one year will be used and extensions made as needed).
 - 5. Name of School/Business, if applicable
 - 6. Principal Investigator’s First & Last Name
 - 7. Department Visiting
 - 8. HHRI Department Contact Name & Phone Number
 - 9. Type of Access needed (doors, systems, emails, etc.)
- C. Once the Non-Employee Requisition is received, Human Resources will work with the relevant administrative and compliance departments to complete the onboarding process.

IV. PRACTICE & PROCEDURES:

A. For Non-employee Research Collaborator (NRC) Positions:

- 1) HHRI requires that all NRCs provide verification of their immunization health record (TB, MMR, and Varicella; and Tetanus if working with animal subjects) or complete these immunizations at their local health care provider prior to starting their activities at HHRI. The Hepatitis B immunization series is strongly encouraged for roles with direct patient contact. NRCs must also successfully complete all other required health testing prior to starting their activities. NRCs working with animal subjects must sign an Animal Facility Health Waiver. Additional health testing may be required for those NRCs having direct contact with patients or animals, or those working in an HHRI laboratory. Scope of additional testing is determined in collaboration with and according to and in compliance with both HHRI and applicable regulatory agency standards.

The results of such a screen will not be used to screen out individuals with disabilities. Information obtained in response to such inquiries or screening will be kept confidential except that (a) the supervising authority may be informed regarding restrictions on the duties of individuals with disabilities and regarding accommodations, (b) first aid and safety personnel may be informed, where and to the extent appropriate, if the condition might require emergency treatment, and (c) officials, employees, representatives, or agents of the MN Department of Human Rights or local human rights agencies

investigating compliance with the act or local human rights ordinances will be informed, if they request such information.

- 2) The Human Resources Department will initiate applicable background checks, including but not limited to MN DHS, MBI/Fingerprinting and OIG/SAM checks as appropriate.
- 3) It is the responsibility of the host HHRI Research Personnel to ensure that the NRC completes appropriate health screening, required HHRI training, maintains confidentiality, abides by HHRI Policies and Procedures, and follows workplace protocols.
- 4) Training Requirements are determined by HHRI's Office for Education and Quality in Clinical Research and must be satisfied before commencing activities with the Institute.

Failure to maintain training requirements may result in the discontinuation of the NRC's relationship with the Institute.

- 5) Access is at the discretion of the HHRI - The HHRI accepts the involvement of all NRCs with the understanding that such activity is at the sole discretion of the Institute. NRCs agree that the Institute may at any time, for whatever reason, decide to terminate the NRC's relationship with the HHRI.

The NRC may at any time, for whatever reason, decide to sever the relationship with the Institute. Notice of such a decision should be communicated to the HHRI host as soon as possible.

Remote Epic access may be granted on a case by case basis when acting in a research capacity as opposed to clinical care. NRCs must be listed as personnel on an active approved IRB protocol before they will be given Epic access for research purposes.

- 6) Conflict of Interest - No person who has a conflict of interest with any activity or program of the Institute, whether personal, philosophical, or financial will be allowed to serve as an NRC at HHRI unless the conflict can be reasonably mitigated to the satisfaction of the HHRI Conflict of Interest Committee.
- 7) Confidentiality – NRCs are responsible for maintaining the confidentiality of all proprietary or privileged information to which they are exposed while serving as an NRC.

Failure to maintain confidentiality may result in discontinuation of the NRC's relationship with the Institute.

- 8) Maintenance of Records - Records will be maintained on each NRC with the Institute, including dates of access and activities performed. NRC records will be accorded the same confidentiality as staff records.

B. For Visiting Student and Volunteer Positions:

- 1) For Volunteer Assignments – In addition to the information needed for all non-employees (see Section III), the supervising authority shall provide the following information for a Volunteer Assignment:
 - a. Purpose of the assignment;
 - b. Responsibilities the volunteer *will and will not* have; and
 - c. Potential workplace hazards.
 - d. For Professional volunteers - Physician, Veterinarian, PhD Scientist, Lawyer, etc.
 - The value per hour that the **professional** volunteer will add to the program and to the organization if contributing value to the Institute.
 - Determine what existing position best describes the type of work the volunteer will perform.
 - Use the minimum hourly wage from that position's salary range as the value.
 - e. The Non-Employee Requisition is then forwarded to Human Resources for review and processing.

- 2) For Volunteer Assignments - It is the responsibility of the supervising authority to conduct reference checks. No reference checks are done on Visiting Student Assignments.

- 3) HHRI requires that all Volunteers and Visiting Students, after a conditional offer of assignment is made, provide verification of their immunization health record (TB, MMR, and Varicella; and Tetanus if working with animal subjects) or complete these immunizations at their local health care provider prior to starting their activities at HHRI. The Hepatitis B immunization series is strongly encouraged for roles with direct patient contact. Volunteers and Visiting Students must also successfully complete all other required health testing prior to starting their assignment. Visiting Students and Volunteers working with animal subjects must sign an Animal Facility Health Waiver. Additional health testing may be required for those Visiting Students and Volunteers having direct contact with patients or animals, or those working in an HHRI laboratory. The scope of additional testing is determined by the supervising authority according to and in compliance with both HHRI and applicable regulatory agency standards.

The results of such a screen will not be used to screen out individuals with disabilities. Information obtained in response to such inquiries or screening will be kept confidential except that (a) the supervising authority may be informed regarding restrictions on the duties of individuals with disabilities and regarding accommodations, (b) first aid and safety personnel may be informed, where and to the extent appropriate, if the condition might require emergency treatment, and (c) officials, employees, representatives, or agents of the MN Department of Human Rights or local human rights agencies investigating compliance with the act or local human rights ordinances will be informed, if they request such information.

- 4) The Human Resources Department will initiate applicable background checks, including but not limited to MN DHS, MBI/Fingerprinting and OIG/SAM checks as appropriate.

- 5) It is the responsibility of the supervising authority to ensure that the Visiting Student/Volunteer completes appropriate health screening, required HHRI training, maintains confidentiality, abides by HHRI Policies and Procedures, and follows workplace protocols.
- 6) Training Requirements are determined by HHRI's Office for Education and Quality in Clinical Research and must be satisfied before commencing activities with the Institute. Failure to maintain training requirements may result in the discontinuation of the Visiting Student/Volunteer relationship with the Institute.
- 7) Access is at the discretion of the HHRI - The HHRI accepts the involvement of all Visiting Student and Volunteer positions with the understanding that such activity is at the sole discretion of the Institute. Visiting Students and Volunteers agree that the Institute may at any time, for whatever reason, decide to restrict access or terminate the Visiting Student or Volunteer's relationship with the HHRI.
- 8) Employees as Visiting Students and Volunteers - The HHRI does allow current staff to spend time in student capacities and/or provide services as Volunteers. This service is accepted provided the Student/Volunteer service is provided totally without coercion, involves duties which are outside the scope of normal staff duties, and are provided outside of usual working hours.
- 9) Family Members as Visiting Students and Volunteers - The HHRI does allow family members to volunteer and/or spend time in student capacities with the Institute. Family members enrolled as Visiting Students/Volunteers are not to be placed under the direct supervision of other members of their family employed by the Institute.
- 10) Medical Students and Non-U.S. Trained MDs – The HHRI does allow Medical Students and Non U.S. Trained MDs to volunteer and/or spend time in a learning capacity at the Institute. Depending on the activities of the Medical Student or Non-U.S. Trained MD, they may be deemed a Non-employee Research Collaborator. Upon assessment of the individual's competency by the Office for Education and Quality in Clinical Research, those deemed appropriately trained may conduct activities that involve potentially infectious substances including blood borne pathogens and phlebotomy. Remote Epic access may be granted on a case by case basis when acting in a research capacity as opposed to clinical care.
- 11) Minors – The HHRI only allows minors (individuals under the age of 18) to volunteer in low risk roles. The position will be reviewed for compliance with current regulations for minors in the workplace to ensure they are not exposed to anything hazardous or detrimental to their well-being, which includes an assessment of the duties to be assigned and when during the day the activities will be conducted.

Prohibited Activities as a Minor Visiting Student/Volunteer include the following:

- Operating heavy equipment including vehicles
- Working with infectious or potentially infectious agents, including human blood, bodily fluid or performing phlebotomy
- Handling, packing or transporting of biohazardous materials
- Access to Epic
- No IRB application

These limitations are consistent with the volunteer policy of HCMC.

- 12) Service at the Discretion of the HHRI - The HHRI accepts the service of all Visiting Students/Volunteers with the understanding that such service is at the sole discretion of the Institute. Visiting Students/Volunteers agree that the Institute may at any time, for whatever reason, decide to terminate the student/volunteer relationship with the HHRI.

The Visiting Student/Volunteer may at any time, for whatever reason, decide to sever the relationship with the Institute. Notice of such a decision should be communicated to the supervising authority as soon as possible.

- 13) Confidentiality – Visiting Students/Volunteers are responsible for maintaining the confidentiality of all proprietary or privileged information to which they are exposed while serving as a student/volunteer.

Failure to maintain confidentiality may result in termination of the Visiting Student/Volunteer's relationship with the Institute.

- 14) **Professional** Volunteer Timesheets – **Professional** volunteers are required to accurately complete an HHRI Professional Volunteer Timesheet on a semi-monthly basis if they are contributing value to the organization. Timesheets must be approved by the volunteer's supervising authority and submitted to the HHRI Payroll Allocation Accountant. Visiting Students do not need to complete timesheets.

- 15) Maintenance of Records - Records will be maintained on each Volunteer/Visiting Student with the Institute, including dates of service and position(s) held. Volunteer/Visiting Student records will be accorded the same confidentiality as staff records.

C. For Research/Study Monitors:

- 1) It is the responsibility of the supervising authority to ensure that the Monitor is escorted while on campus, maintains confidentiality, abides by HHRI Policies and Procedures, and follows workplace protocols.
- 2) Service at the discretion of the HHRI - The HHRI accepts the service of all Monitors with the understanding that such service is at the sole discretion of the Institute. Monitors agree that the Institute may at any time, for whatever reason, decide to terminate the Monitor's relationship with the HHRI.

3) The Monitor may at any time, for whatever reason, decide to sever the relationship with the Institute. Notice of such a decision should be communicated to the supervising authority as soon as possible.

4) Confidentiality – Monitors are responsible for maintaining the confidentiality of all proprietary or privileged information to which they are exposed while serving as a Monitor.

Failure to maintain confidentiality may result in discontinuation of the Monitor's relationship with the Institute.

5) Maintenance of Records – Monitor's records are maintained by the Office for Education and Quality in Clinical Research.

D. For Visitor Positions:

1) The "host" of a Visitor to the animal facilities is required to inform the Director of Veterinary Services in advance of the Visitor's arrival.

2) It is the responsibility of the supervising authority to ensure that the Visitor maintains confidentiality, abides by HHRI Policies and Procedures, and follows workplace protocols.

3) Entry at the Discretion of the HHRI - The HHRI accepts the entry of all Visitors with the understanding that such entry is at the sole discretion of the Institute. Visitors agree that the Institute may at any time, for whatever reason, decide to terminate the Visitor's relationship with the HHRI.

4) The Visitor may at any time, for whatever reason, decide to sever the relationship with the Institute. Notice of such a decision should be communicated to the supervising authority as soon as possible.

5) Confidentiality – Visitors are responsible for maintaining the confidentiality of all proprietary or privileged information to which they are exposed while serving as a Visitor.

Failure to maintain confidentiality may result in discontinuation of the Visitor's relationship with the Institute.

6) Visitor records will be maintained for 12 – 24 months. Visitor records will be accorded the same confidentiality as staff records.



SUBJECT: Non-Employee Utilization
POLICY NO: VII:08
APPLICABLE TO: Individuals who participate in unpaid assignments at HHRI
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E. Non-Employee Site Access Grid

Requirements for HHRI Non-Employee Site Access				
<u>Steps to Access</u>	<u>Non-employee Research Collaborators</u>	<u>Visiting Students and/or Volunteers</u>	Research/Study Monitors	Visitors
Hazard Awareness/General Release for Animal Facility	If AS	If AS		If AS
Must have a campus escort			x	x
General Confidentiality/HIPAA Agreement	x	x	x	x
Peoplesoft #	x	x	x	
Indemnification Agreement	x	x		
HCMC Picture ID/Bldg. Access Badge	x	x		
Epic Access	IF HS		x	
Health Screening (TB, MMR and Varicella; and Tetanus if AS)	x (verify)	X (verify)		
Human Subjects Research Training (includes CITI, EQ orientation, Seminar video, COI)	IF HS			
IACUC Training (includes COI)	IF AS	IF AS		
Professional Volunteer Time & Effort (if work financially benefits HHRI)	x	x		
Excluded Parties checking	x	x		
MN DHS Background Check	IF PC	IF PC		
MBI & Fingerprinting	AA	AA		
Blood Borne and Hazardous Materials Training	AA	AA		
Lab Safety Training (including radiation)	AA	AA		
Animal Facilities Health Waiver	AS	AS		AS
KEY:				
AA= As Applicable				
HS = Human Subjects				
AS = Animal Subjects				
PC = Patient Contact				