

Request for Board Appearance - Authorization to Practice Pharmacy Outside of a Pharmacy

Christina Madison [cmadison@roseman.edu]

Sent: Friday, August 4, 2017 2:44 PM

To: David Wuest

Cc: Pharmacy Board

Attachments: Collaborative Agreement Ro~1.pdf (2 MB) ; Off-Site Pharmacy Practice~1.pdf (82 KB)

Dave,

Please see the attached document for your consideration. I am requesting an appearance before the board in order to get an approval to practice pharmacy at a site other than a licensed pharmacy. The next schedule board meeting in Las Vegas is scheduled for **October 18th and 19th**. I would like to request to be heard in the afternoon of Wednesday October 18th if possible. Let me know if you have any questions or if you need any additional information. Thank you for your time and consideration.

Dr. Madison

Christina M. Madison, Pharm.D., BCACP, AAHIVP
Associate Professor of Pharmacy Practice
Roseman University of Health Sciences - College of Pharmacy
Clinical Pharmacy Faculty
Southern Nevada Health District
Clinical Associate Professor - Department of Internal Medicine
University of Nevada School of Medicine
702 759-1639 office
702 383-1446 fax

pm either day

Off-Site Pharmacy Practice Description

Pharmacist

Christina M. Madison, Pharm.D., BCACP, AAHIVP
Associate Professor of Pharmacy Practice
Roseman University of Health Sciences - College of Pharmacy
Clinical Pharmacy Faculty
Southern Nevada Health District
Clinical Associate Professor - Department of Internal Medicine
University of Nevada School of Medicine

Practice Site

Rob Phoenix, APRN, FNP-C
Nurse Practitioner
Huntridge Family Clinic
1830 E. Sahara Ave
Suite 201
Las Vegas, NV 89104

Description of Practice Site

The Huntridge Family Clinic is a full-service family medicine practice who works with patients to maintain and improve health. This clinic serves the entire family at all stages of life. With an emphasis on patient education and prevention. The mission of the Huntridge Family Clinics to provide patient centered, cost effective, evidence based, personalized, high quality care on an as-needed or preventive basis, regardless of their gender, race, religion, sexual orientation or sexual identification.

Days and hours of Pharmacy Services

The pharmacist would be available on site no more than 2 and ½ days per week for pharmacy practice services with the possibility of remote consultation if needed when off site.

Patient Population

Clinic services include the entire family at all stages of life with ages 6 years and older. This clinic provides services to a large LGTB, HIV positive, and transgender patient population but is all inclusive. Patients are referrals are received by private providers in the community, Clark County School District, the Southern Nevada Health Department, and the Las Vegas LGBTQ center.

Pharmacy Services to be Provided

Clinical Pharmacy Services Include

- Medication reviews (possible adverse effects, drug toxicity, or drug-drug interactions)
- Literature search (evidence based medicine)
- Laboratory review (hormone therapy monitoring for transgender patients, eligibility for PrEP therapy, routine monitoring for HIV therapy, verification of cure for sexually transmitted infections (STI), electrolyte monitoring for chronic medical conditions (including vital signs such as Blood Pressure and Blood Glucose)

- Provide treatment recommendations as requested (based on disease state – STI, HIV, PrEP, PEP, Transgender Health - gender-affirming hormones, chronic disease management (HTN, Dyslipidemia, Diabetes), Women’s Health (contraception, emergency contraception, and hormone replacement therapy), Men’s Health (BPH, erectile dysfunction, androgen deficiency), and preventative care screenings (based on age and gender)
- Participate in research projects (see included research agreement) - including data collection

List of Resources (Paper and Electronic)

Clinic is fully equipped with WiFi for access to electronic resources.

Current copies of frequently used materials (example: DHHS HIV Treatment Guidelines, PrEP Guidelines, and PEP Guidelines, STD Treatment Guidelines) are printed and readily available.

Access to Roseman University of Health Science Academic Library Resources are also available for literature research.

Policy for pharmacy services if pharmacist is unavailable

Pharmacist will be available for remote consultation during the work week (Monday thru Friday) and days unavailable due to anticipated days off, faculty obligations, professional meetings, or illness will be communicated in advance.

Policy of pharmacist regarding confidentiality and security of patient data (paper and electronic)

All patient information is housed in an electronic medical record (EMR) through Athena Health. This is a HIPPA compliant system of which I will be provided with READ ONLY access to patient profiles. Any documentation regarding pharmacy intervention will be included in the provider’s notes regarding the clinic encounter. No paper documentation is done regarding client visits.

Services will not be affiliated with an associated licensed pharmacy

Affiliation with Roseman University of Health Sciences

Funding for pharmacist salary is 100% paid by faculty appointment with Roseman University of Health Sciences – College of Pharmacy

Note: A research agreement has been established with the Huntridge Family Clinic and Roseman University of Health Sciences (agreement is included)

COLLABORATIVE RESEARCH AGREEMENT

THIS AGREEMENT is made as of 7/24/2017 by and between Roseman University of Health Sciences, a non-profit private institution of higher education having its principal place of business at 11 Sunset Way, Henderson, NV 89014 ("Roseman") and Huntridge Family Clinic, a full-service family practice, having its principal place of business at 1830 E. Sahara Avenue, Suite 201, Las Vegas, NV 89104 ("Huntridge").

WHEREAS, Roseman and Huntridge each desires to conduct the scientific research described in Exhibit A hereto; and

WHEREAS, Roseman and Huntridge, believe that collaborating with each other in the performance of such research will be of mutual benefit, will further the instructional and research objectives of Roseman and will foster the development of scientific knowledge.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, Roseman and Huntridge agree as follows:

1. DEFINITIONS

As used in this Agreement, capitalized terms have the meanings given them below or elsewhere in this Agreement:

- 1.1 Research Materials means those experimental materials and data one party may provide the other in connection with and as stated in the Research Program.
- 1.2 Research Program means the research program set forth in Exhibit A.
- 1.3 Research Program Invention will mean any invention, discovery, work of authorship, software, information or data, patentable or unpatentable, which is conceived, discovered and reduced to practice in performance of the Research Program.
- 1.4 Confidential Information means Collaborator owned confidential scientific, business or financial data or information which will be clearly marked as such in writing provided that such information:
 - 1.4.1 is not publicly known or available from other sources who are not under a confidentiality obligation to the source of the information;
 - 1.4.2 has not been made available by its owners to others without a confidentiality obligation;
 - 1.4.3 is not already known by or available to the receiving party without a confidentiality obligation;
 - 1.4.4 is not independently developed by the receiving party;
 - 1.4.5 does not relate to potential hazards or cautionary warnings associated with the performance of the Research Program of the Agreement or is not required to be disclosed under operation of law.

2. **RESEARCH PROGRAM**

- 2.1 **Research Efforts.** Provided Huntridge performs all its obligations under this Agreement, Roseman will use its reasonable efforts to conduct those activities for which it is responsible under the Research Program.
- 2.2 **Roseman Principal Investigator.** The conduct of Roseman's activities under the Research Program will be under the direction of **Christina Madison, PharmD** ("Roseman's Principal Investigator").
- 2.3 **Huntridge Principal Investigator.** The conduct of Huntridge's activities under the Research Program will be under the direction of **John Rob Phoenix, APRN, FNP-C** ("Huntridge's Principal Investigator").
- 2.4 **Use of Research Materials.** Any Research Materials of one party transferred to the other in connection with the Research Program may only be used as stated in the Research Program. Unless the parties agree otherwise, Research Materials are to be considered the "Confidential Information" of the party providing them.
- 2.5 **Reporting.** The parties will generally keep one another informed of the results of the work performed in connection with the Research Program, principally through their respective Principal Investigators. In addition, the parties' respective Principal Investigators will meet and provide reports as stated in the Research Program.
- 2.6 **Changes to the Research Program.** During the course of the Research Program, either or both of the Principal Investigators may find it advantageous to modify the Research Program. Any modifications will be documented and formalized in a written amendment to this Agreement and any such amendment will become effective only if signed by an authorized representative of both parties to this Agreement.
- 2.7 **University Purposes; No Guarantee of Results.** Huntridge acknowledges that the primary mission of Roseman is education and the advancement of knowledge; and, consequently, the Research Program will be performed in a manner best suited to carry out that mission. Specifically, Roseman's Principal Investigator will determine the manner of performance of Roseman's part in the Research Program and Roseman does not represent or warrant that the Research Program will be successful in any way or that any specific results will be obtained.
- 2.8 **Similar Research.** Nothing in this Agreement will be construed to limit the freedom of Roseman or its researchers who are participants under this Agreement, from engaging in similar research made under other grants, contracts, or research agreements with parties other than Huntridge.

3. **CONFIDENTIAL INFORMATION**

- 3.1 Either party's acceptance and use of any confidential information supplied by the other party in the course of the Research Program will be subject to the following:
- 3.1.1 To be considered Confidential Information, all written information (including Research Materials) must be marked or designated in writing as **CONFIDENTIAL** by the party providing the information, and oral communications must be reduced to writing within thirty (30) days of the initial communication of the information and such writing must be marked or designated in writing as **CONFIDENTIAL** and provided to the other party's Principal Investigator.

- 3.1.2 The Principal Investigator(s) will use reasonable efforts to limit the exchange of Confidential Information.
- 3.1.3 Where the Principal Investigator(s) does accept such information as confidential, s/he agrees to use the same degree of care to prevent the unauthorized use, dissemination, or publication of the Confidential Information, without the express written permission of the providing party.

4. **PUBLICITY**

Neither party will identify the other in any products, publicity, promotion, promotional advertising, or other promotional materials to be disseminated to the public, or use any trademark, service mark, trade name, logo, or symbol that is representative of a party or its entities, whether registered or not, or use the name, title, likeness, or statement of the other party's faculty member, employee, or student, without prior written consent. Any use of a party's name shall be limited to statements of fact and shall not imply endorsement of products or services.

5. **PUBLICATION**

- 5.1 It is contemplated that Roseman and Huntridge will publish the results. Nonetheless, each party reserves the right to publish its results separately as long as the following are met:
 - 5.1.1 Each party shall provide the other party with a copy of any manuscript disclosing results at least thirty (30) days prior to submission for publication for the purpose of enabling a review of the manuscript for potentially patentable inventions and confidential information.
 - 5.1.2 The party wishing to publish shall delete from its manuscript prior to submission all Confidential Information of the other party that the other party identifies.
 - 5.1.3 Notwithstanding anything to the contrary herein, the parties agree to abide by the policies of journals in which publications will appear as to such matters as the public release or availability of data or biological materials relating to the publication. Proper acknowledgment will be made for the contributions of each party to the results being published.

6. **INTELLECTUAL PROPERTY RIGHTS**

- 6.1 **Ownership of Research Program Inventions.** Research Program Inventions conceived, discovered and reduced to practice by Roseman, or its employees, agents or students will be owned by Roseman. Research Program Inventions conceived, discovered and reduced to practice by Huntridge, or its employees, or agents, will be owned by Huntridge (Collectively, "Sole Inventions"). Research Program Inventions conceived, discovered and reduced to practice by at least one employee, agent, or student of each of Roseman and Huntridge will be owned by Roseman and Huntridge, without any obligation to account to one another ("Joint Inventions"). Inventorship will be determined according to the principles of United States patent law. Neither party shall make any claim to the other party's Sole Inventions.
- 6.2 **Pre-Existing Rights.** Except to the limited extent required to perform a party's obligations under this Agreement, neither party receives any right, title, or interest in or to any Research Materials provided to it by the other party or any technology, works or inventions of the other party that are not Research Program Inventions, or any patent, copyright, trade secret or other proprietary rights in any of the foregoing.

- 6.3 Patents will mean those United States and foreign patents and patent applications including any continuation, reissue, or renewal thereof, or substitute therefor, and the patents that may be issued thereon, relating to any patentable Research Program Invention.
- 6.4 Patent Prosecution and Expenses. Unless the parties agree in writing otherwise, the filing, prosecution, defense and maintenance of all Patents for Joint Inventions will be conducted jointly in the name of both parties and controlled by them jointly, acting reasonably and in good faith.
- 6.5 Licensing. Each party reserves the right to license its interest in its Sole Inventions or Joint Inventions, and neither party shall have any right to compensation in connection with any such license granted by the other
- 6.6 Rights Subject to Federal Patent Policy. To the extent that any Research Program Invention has been partially funded by the Federal government, the assignment of title or the granting of any license above is subject to the rights of the Federal government and federal law set forth in 35 U.S.C. §§ 200 et. seq., as amended, and the regulations promulgated thereunder, as amended, or any successor statutes or regulations (the "Federal Patent Policy"). Any right granted in this Agreement greater than that permitted under the Federal Patent Policy will be modified as may be required to conform to the provisions of the Federal Patent Policy.

7. INDEMNIFICATION/INSURANCE

- 7.1 As used herein, "Claim" includes but is not limited to every phase of any lawsuit, loss, claim, damage or liability for death, illness or personal injury of any person (including employees of Roseman or Huntridge), for property damage, and/or for infringement of patents, trade secrets, or other rights of a third party. This indemnity shall not be deemed excess coverage to any insurance or self-insurance Roseman may have covering Claim.
- 7.2 Huntridge hereby waives any Claim against Roseman, and agrees to indemnify, defend, and hold harmless Roseman, and their trustees, directors, employees, agents or students from any Claim arising out of or connected with this Agreement or the work done under this Agreement, except to the extent such Claim is due to their negligence or willful misconduct. Roseman shall promptly notify Huntridge of any such Claim and shall cooperate with Huntridge and its insurance carrier in the defense of the Claim.
- 7.3 Roseman hereby waives any Claim against Huntridge, and agrees to indemnify, defend, and hold harmless Huntridge, and their trustees, directors, employees, agents or students from any Claim arising out of or connected with this Agreement or the work done under this Agreement, except to the extent such Claim is due to their negligence or willful misconduct. Huntridge shall promptly notify Roseman of any such Claim and shall cooperate with Roseman and its insurance carrier in the defense of the Claim.
- 7.4 During the term of this agreement, Huntridge shall maintain in full force and effect, professional and general liability insurance, for limits of not less than one million dollars (\$1,000,000) per occurrence, three million dollars (\$3,000,000) aggregate, naming Roseman University as an additional insured party for all obligations of Huntridge to Roseman. The policies shall be underwritten by an insurance company that carries an A- or better rating from A.M. Best. Each policy shall provide that such insurance will be primary insurance with respects to Roseman. If the coverage is claims-made insurance, Huntridge agrees to purchase a tail policy in the event of the termination of such insurance coverage, for the same limits, terms and conditions as listed above for a period of three (3) years after the termination of this agreement. Huntridge agrees to provide thirty (30) days' written notice to Roseman prior to the effective date of any substantial changes in coverage or cancellation of such policies.

During the term of this agreement, Roseman shall maintain in full force and effect, professional and general liability insurance, for limits of not less than one million dollars (\$1,000,000) per occurrence, three million dollars (\$3,000,000) aggregate, naming Huntridge Family Clinic as an additional insured party for all obligations of Roseman to Huntridge. The policies shall be underwritten by an insurance company that carries an A- or better rating from A.M. Best. Each policy shall provide that such insurance will be primary insurance with respects to Huntridge. If the coverage is claims-made insurance, Roseman agrees to purchase a tail policy in the event of the termination of such insurance coverage, for the same limits, terms and conditions as listed above for a period of three (3) years after the termination of this agreement. Roseman agrees to provide thirty (30) days' written notice to Huntridge prior to the effective date of any substantial changes in coverage or cancellation of such policies.

Huntridge and Roseman shall each maintain workers' compensation insurance for their own employees, as required under Nevada State law; such insurance shall include Employer's liability with a limit not less than one millions (\$1,000,000) each occurrence.

8. REPRESENTATIONS, WARRANTIES, LIABILITY LIMITS

8.1 **NO WARRANTIES.** HUNTRIDGE ACKNOWLEDGES AND AGREES THAT ROSEMAN IS AN ACADEMIC/RESEARCH INSTITUTION AND THAT THE RESEARCH PROGRAM IS OF AN EXPERIMENTAL NATURE. AS A RESULT, ANY RESULTS OF THE RESEARCH PROGRAM AND ANY RESEARCH MATERIALS ARE PROVIDED AS IS AND WITH ALL FAULTS. ROSEMAN MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THE RESULTS OF THE RESEARCH PROGRAM, WHETHER ANY RESULTS WILL OBTAIN, ANY RESEACH MATERIALS OR ANY INVENTION, PROCESS OR PRODUCT, WHETHER TANGIBLE OR INTANGIBLE, CONCEIVED, DISCOVERED, DEVELOPED OR REDUCED TO PRACTICE UNDER THIS AGREEMENT; OR THE OWNERSHIP, NONINFRINGEMENT, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH, ANY RESEARCH MATERIALS OR ANY SUCH INVENTION OR PRODUCT.

8.2 **NO DAMAGES.** ROSEMAN SHALL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL, OR OTHER DAMAGES SUFFERED BY HUNTRIDGE, ANY LICENSEE, OR ANY OTHERS INCLUDING, BUT NOT LIMITED TO, DAMAGES ARISING FROM LOSS OF DATA OR DELAY OR TERMINATION OF THE RESEARCH PROGRAM, OR FROM THE USE OF THE RESULTS OF THE RESEARCH PROGRAM, THE USE OF ANY RESEARCH MATERIALS OR ANY SUCH INVENTION OR PRODUCT. HUNTRIDGE ACKNOWLEDGES AND AGREES THAT THIS EXCLUSION AND LIMITATION IS REASONABLE CONSIDERING THE EXPERIMENTAL NATURE OF THE RESEARCH PROGRAM AND THE NATURE AND TERMS OF THE PARTIES' RELATIONSHIP.

9. TERM AND TERMINATION

9.1 **Term.** This Agreement will remain in effect for 5 (five) years from the date first written above unless terminated sooner or extended in writing signed by the parties in accordance with this Agreement.

9.2 **Termination.** Either party may terminate this Agreement upon sixty (60) days written notice.

9.3 **Survival.** The provisions of Articles 3, 4, 5, 6, 7, 8, 9 and 10 will survive any expiration or termination of this Agreement.

10. **GENERAL**

- 10.1 **Binding Effect; Assignment.** Neither party may assign or delegate its rights or obligations under this Agreement without the express written consent of the other party.
- 10.2 **Entire Agreement.** This Agreement constitutes the entire agreement between the parties relating to the Research Program, and any and all prior or contemporaneous negotiations, representations, agreements and understandings are superseded hereby. No amendment or change to this Agreement may be made except by means of a written document signed by duly authorized representatives of the parties.
- 10.3 **Notices.** Any notice or communication required or permitted to be given hereunder will be in writing and, except as otherwise expressly provided in this agreement, will be deemed given and effective (i) when delivered personally or by fax or (ii) when received if sent by email, overnight courier, or mail:

To ROSEMAN:

Roseman University of Health Sciences
Attn: Jeff Talbot
11 Sunset Way
Henderson, Nevada, 89014

To HUNTRIDGE:

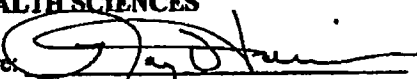
John R Phoenix, APRN, FNP-C
Huntridge Family Clinic
1830 E. Sahara Avenue, Suite 201
Las Vegas, NV 89104

- 10.4 **Applicable Law.** This Agreement will be construed and enforced in accordance with the laws of the State of Nevada without regard to any choice or conflict of laws, rule or principle that would result in the application of the laws of any other jurisdiction.
- 10.5 **Headings.** Headings included herein are for convenience only, and will not be used to construe this Agreement.
- 10.6 **Relationship of Parties.** For the purposes of this Agreement and all services to be provided hereunder, each party will be, and will be deemed to be, an independent contractor and not an agent or employee of the other party. Neither party will have authority to make any statements, representations or commitments of any kind, or to take any action that is binding on the other parties, except as explicitly provided for herein or authorized in writing.
- 10.7 **Severability.** If any provision of this Agreement will be found by a court of competent jurisdiction to be void, invalid or unenforceable, the same will either be reformed to comply with applicable law or stricken if not so conformable, so as not to affect the validity or enforceability of this Agreement.
- 10.8 **Force Majeure.** Neither party will be liable for any failure to perform as required by this Agreement, if the failure to perform is caused by circumstances reasonably beyond such party's control, such as labor disturbances or labor disputes of any kind, accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, thefts, or other such occurrences.

10.9 **Third Party Beneficiary:** Both parties agree that there is no third party beneficiary to this agreement. Nothing in this agreement, express or implied, is intended to confer any rights, remedies, claims or interests upon a person or entity other than the two parties to this agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

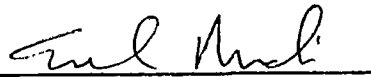
**ROSEMAN UNIVERSITY
OF HEALTH SCIENCES**

Signature: 

Name: Larry Fannin, B Pharm, PhD

Title: Interim Dean, College of Pharmacy

Date: 7/28/17

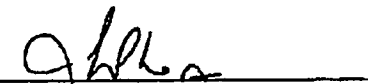
Signature: 

Name: Eucharia Nnadi, JD, PhD

Title: Chancellor, Henderson, Nevada Campus

Date: 7/25/2017

HUNTRIDGE FAMILY CLINIC

Signature: 

Name: John Phoenix

Title: Member

Date: 7-24-17

Exhibit A

Description of Research Program

Collaborative project with Roseman University of Health Sciences (Faculty Member – Christina M. Madison, Pharm.D., BCACP, AAHIVP) and Huntridge Family Clinic (Provider – John Rob Phoenix, APRN, FNP-C)

Objective: Identifying opportunities to expand an HIV prevention network to improve HIV Post Exposure Prophylaxis (PEP) and Preexposure Prophylaxis (PrEP) delivery

A retrospective chart review followed by a prospective intervention assessing the efficacy of engaging patients in a local referral network for HIV postexposure prophylaxis (PEP) and preexposure prophylaxis (PrEP) in high risk patients. With the assistance of Roseman University faculty and student pharmacists, data collection will determine challenges with access and barriers to care, HIV testing, prevention, and treatment interventions if provided and current HIV status following initial exposure warranting PEP. A description of patient characteristics for successfully engaging an HIV prevention service network as well as the network characteristics that facilitate engaging in HIV prevention services. Patient receiving PEP and transitioning to PrEP and retention on PrEP therapy are the primary endpoints for analysis. Data collected will also be used for the development of provider education to expand the knowledge of best practices for HIV prevention and public health initiatives.

Inclusion criteria:

1. Men and women over the age of 18 years.
2. Actual or perceived non-occupational exposure to HIV, self-reported, within 72 hours of enrollment and referred for care.
3. Able and willing to provide informed consent.
4. Available for 12 months of post-exposure follow-up (i.e. Las Vegas residents).

Exclusion criteria:

1. HIV+ at time of screening via 4th generation Ab/Antigen testing
2. Current PEP and/or PrEP product contraindications as listed in the package insert

Product(s):

PEP products recommended based on current treatment guidelines from DHHS; Truvada® for PrEP