Collaboration Agreement

for the project:

Chronic Urticaria Registry (CURE)

between

the Urticaria Network e.v.

- hereinafter „UNEV“ -

And

Mashhad University of Medical Sciences, Allergy Research Center

1. Collaboration partner / Aim of the Collaboration

1) UNEV is a non-profit organization with the aim to support research in the field of urticaria and to improve the care for affected patients.

2) The medical institution is specialized on the management of patients suffering from urticaria.

3) Both collaboration partners aim to collaborate in terms of the Chronic Urticaria Registry (hereinafter „CURE“) in accordance with the following regulations.

2. Subject of Agreement (CURE)

1) UNEV supports the development, establishment and operating of CURE, an open-ended patient registry for urticaria that collects quality, real world data on urticaria affected patients and their management. CURE will include patients who suffer from all forms of urticaria.

2) The medical institution takes part in the CURE project and will perform the required documentation in the CURE in accordance with the CURE project plan enclosed as ANNEX 1. ANNEX 1 is an integral part of this agreement. This applies as well to amendments to the project plan and, where applicable, more recent versions of the project plan.

3) The parties acknowledge that the CURE project is a non interventional, observational project. No recommendations will be given to the participating medical institutions regarding the management (e.g. regarding the diagnostic procedures and treatment strategies) of the patients. CURE is an observational registry. Therefore,

the collaboration partners agree that the CURE project does not fulfill the criteria of a clinical trial in the sense of the Pharmaceutical Products Act.

3. Conduct of the research; project managers

1) The project CURE shall be conducted in strict compliance with all applicable national regulations, Good Pharmacoepidemiology Practice, and all other applicable laws, directives, guidances and professional standards, as well as the terms and conditions of the project plan (Annex 1).

2) The medical institution shall, before the project commences, obtain all necessary approvals, e.g. obtaining an approval of the responsible review board (Ethics Committee) and competent authority for commencement of the project if applicable. Any necessary registrations/approvals are to be made/obtained in good time.

3) The medical institution may not start entering data until the responsible review board (Ethics Committee) and competent authority have issued a favourable opinion and have given approval of the project, if applicable.

4) The medical institution represent that they have the requisite and necessary experience, equipment, facilities and personnel to properly take part in the CURE project.

5) The medical institution shall appoint a project manager. The project manager shall be responsible for the orderly performance of the work pursuant to the subject of this agreement. The person appointed as project manager by the medical institution is:

Project manager: _____Maryam Khoshkhui (MD)

In the event that the project managers should leave during the term of this agreement or should be relieved of his duties as project manager for a different reason, an employee equally qualified to conduct the project may be appointed as his successor after UNEV hereto has been notified. If this is not possible or if UNEV hereto has good reasons for not agreeing to the appointed successor, the agreement may be terminated early for good cause.

6) The parties shall be in contact at regular intervals to report on the progress of the project and to clarify any issues that have arisen.

4. Enrolment of Patients

1) For the purposes of this agreement, a patient shall be deemed enrolled in the project if said patient meets all selection and registration criteria set forth in the project plan (ANNEX 1) and the informed consent form and the patient or, when the person is not able to give informed consent, his legal representative has given his written consent after being informed of the nature, significance, implications and risks of the project.

2) The decision of whether a patient is enrolled in the project is solely made by the medical institution.

5. Informed Consent

1) The medical institution shall, in accordance with the project plan and the informed consent form, duly provide opportunity for the patient or, when the person is not able to give informed consent, his legal representative, in a prior interview, to understand the objectives, risks and inconveniences of the project, and the conditions under which it is to be conducted as well as information of his right to withdraw from the project at any time.

2) The medial institution shall, in accordance with the project plan (ANNEX 1) and the informed consent form, further obtain the patients, or, when the person is not able to give informed consent, his legal representative's, informed written consent after being informed of the nature, significance, implications and risks of the project.

6. Reporting and Documentation

1) The medical institution agrees to duly complete and submit all requested data via the electronic data capture system, and in compliance with the Electronic Access Terms and Conditions.

2) The medical institution shall produce the documentation in a manner that makes it pertinent and useable for the project. In case of any ambiguity in respect of the manner of documentation, the medical institution shall immediately notify UNEV to clarify the issue. The medical institution acknowledges that the documentation as defined supra may be updated and amended from time to time by UNEV.

3) The medical institution shall correct incorrect data via the electronic data capture system as soon as the medical institution notifies incorrect data. All corrections will be documented by the "audit trail" of the electronic data capture system

4) The medical institution shall notify UNEV when a patient quits the project. The medical institution shall include in this notification the exact time of termination.

5) The medical institution will take care that the source records are maintained and stored in a secure manner (in accordance with all applicable laws and regulations).

6) UNEV will take care that the project data entered in the electronic data capture system is maintained and stored in a secure manner (in accordance with all applicable laws and regulations).

7) UNEV shall ensure that the processing of results and data is consistent with provisions of data protection laws.

8) The medical institution hereby agrees to the processing of the investigator's personal data provided to electronic data capture system by the investigator or

obtained from third parties. The Investigator has the right to have access to and correct his/her personal data.

9) The Investigator has the right to have access to and correct his/her entered data.

10) Adverse events and/or laboratory abnormalities identified in the entered data can not be followed by UNEV. The medical institutions are in charge to take care of reporting these events in accordance with all applicable laws and regulations, if applicable.

7. Intellectual property

1) All materials, documents and information supplied by UNEV to the medical institution, and all materials, documents and information prepared or developed in the course of the work to be performed under this agreement, shall be the sole and exclusive property of UNEV.

2) The medical institution shall retain the right to have access and to use its own entered data.

3) UNEV owns the CURE dataset and has the right to access, use and publish the entered data. Entered data can only be deleted with the approval of UNEV.

8. **Compensation**

1) No financial compensation is paid by UNEV to the medical institution for taking part in the CURE project and for entering patient data into the electronic data capture system.

9. Analyses and Publication

1) Analyses of the CURE dataset can be suggested to the CURE international steering committee by all medical institutions who entered a defined number of full patient data sets (basic and follow up data) in the electronic data capture system. The defined number is defined in the CURE ISC Charter and may change over time.

2) Notwithstanding the remaining provisions of this agreement, the medical institution shall have the right to publish, present or otherwise publicly disclose the results of and disseminate information pertaining to institution's activities conducted under this agreement, including own project data, for own, non-commercial purposes in research and teaching. However, the medical institution shall declare that he/she is a contract partner of UNEV whenever he/she writes or speaks in public about a matter that is the subject of this agreement or any other issue relating to UNEV.

3) Disclosure as set forth above may not impair or compromise UNEVs rights as regards patentable or copyrightable material or confidentiality obligations of the medical institution. UNEV shall have the right to require the medical institution, as applicable, to remove specifically identified confidential information (other than

research results) and/or to delay the proposed publication, presentation or other public disclosure for an additional sixty (60) days to enable UNEV to seek patent protection.

4) The medical i**nstitution** agrees that it shall not, without UNEVs prior written consent, independently publish, publicly disclose, present or discuss any results of or information pertaining to medical institutions and project managers activities conducted under this agreement until such a publication is released.

5) In particular, the medical institution agrees to submit any proposed publication, presentation or other public disclosure to UNEV for review at least sixty (60) days prior to submitting such proposed publications, presentations or other public disclosures to a publisher or other third party.

10. Confidentiality

1) The medical institution agrees to hold in confidence all materials, documents and information that UNEV disclose pursuant to this agreement, and all materials, documents and information gathered or developed pursuant to this agreement ("confidential information"). The medical institution will use such confidential information only for the purpose of fulfilling their obligations and exercising their rights hereunder and will not - without the prior written consent of UNEV - disclose it to any third party except for staff and consultants as required by law and with UNEVs knowledge, and the medical institution’s agents and employees who have a need to know such information to perform the project. The obligations of confidentiality hereunder shall survive and continue beyond the termination of this agreement.

2) No party hereto will use any other party's name in advertising, promotions, or other commercial materials without that party's prior express written permission, except that UNEV may quote from and/or reference any publications resulting from the project. The medical institution will not originate any publicity, news release or other public announcement, written or verbal, whether to the public, press or otherwise, relating to this agreement, the protocol, the project conducted hereunder, or to any amendment(s) hereto, without the prior express written consent of UNEV, except as required by law.

11. Term and Termination

1) This Agreement shall be effective as of the date it is duly signed by the parties and shall continue in effect until completion of all obligations herein or unless earlier terminated pursuant to this section.

2) Both parties may terminate this agreement upon thirty days written notice

3) In case an investigator becomes unable or unwilling to perform his obligations under this agreement, UNEV may, at his sole discretion, choose to terminate the agreement or request adequate replacement from the medical institution.

12. Obligations of Personnel

1) Where the medical institution employs personnel or any other person to perform obligations under this agreement, they will submit these persons to the terms of this agreement. The medical institution shall in particular ensure that these obligations remain in full force and effect.

13. Miscellaneous

1) This agreement constitutes the entire agreement between the parties hereto, pertaining to the subject matter hereof and supersedes all prior and contemporaneous agreements, except those contemplated hereunder or not inconsistent herewith.

2) This agreement is personal in nature and the medical institution shall not, without the prior express written consent of UNEV, assign or transfer this agreement or any rights or obligations hereunder. UNEV may assign or transfer this agreement to a successor or affiliated organization, provided that in the case of any such assignment, the assignee shall be bound by the terms and obligations provided in this agreement.

3) This agreement shall be governed by the law of Germany without regard to conflict of laws principles.

4) Any dispute arising from this agreement between the medical institution and UNEV shall be exclusively referred to the jurisdiction of Berlin, Germany.

5) The medical institution shall immediately notify UNEV if any obstacle, legal or in fact, arises, or if they become aware of such obstacle, that may affect the conduct of the project at the site. In such a case, the parties will consult with each other and amicably find a way to complete the project, or terminate this agreement.

6) This agreement is executed in two copies of which each party, i.e. UNEV and the medical institution, receives one.

14. Severability

1) In the event that individual provisions of this agreement are ineffective, this shall not affect the validity of the remaining provisions. Any such invalid provision shall be replaced by a provision which best reflects what the parties hereto intended or would have intended if they had been aware of the invalidity of the provision. The same shall hold for any omissions in the agreement.

For UNEV:

Place _____ Date _____

Name _____

For the medical institution:

Place _____Mashhad _,IRAN_____ Date ___4/_11__I__2017_

Name __
__Mashhad University Of Medical_Sciences_,Allergy Research Center

ANNEX 1 – CURE Project Plan