

**Urticaria Centers of Reference and Excellence (UCARE) Charter**

**Last updated: 06/2023**

The UCARE program is a GA²LEN initiative for the development, interaction, and accreditation of centers of reference and excellence in urticaria. Urticaria is a common and debilitating condition and can be a challenge for both patients and treating physicians, especially when chronic. UCAREs provide excellence in urticaria management, increase the knowledge of urticaria by research and education, and promote the awareness of urticaria by advocacy activities.

**UCARE Steering committee (USC)**

The UCARE network is global and interactive, and all UCAREs have the same rights and responsibilities. The UCARE network is governed by the UCARE Steering Committee (USC). The USC (1) oversees and coordinates the activities of the UCARE network and (2) reports to the GA²LEN executive committee. The USC has 5 members. Three members are delegated by the GA²LEN executive committee to ensure the long-term continuity. These are currently: The UCARE coordinators Ana Giménez-Arnau, Marcus Maurer, and Torsten Zuberbier. Two additional rotating USC members are elected by the UCARE heads and deputies for a 4-year term. Re-election is possible. Eligibility criteria to become a USC member are experience and expertise in urticaria. Geographical balance is to be considered. The USC is supported by the UCARE office, in Berlin, Germany.

*Conflicts of Interest*

The members of the USC should not undertake any other activity which could affect their independent judgment in the performance of their duties, or which conflicts with (or could reasonably give the appearance of conflicting with) the interests of UCARE. This does not preclude membership on advisory boards of pharmaceutical companies, receiving honoraria for lectures or consulting, membership on the executive boards of other disease registries or other scientific committees, but such activities should be disclosed as potential conflicts of interests.

*Confidential Information*

All USC members shall be aware that the information they receive may be of confidential nature, and that they may not make use of, or disclose, such confidential information for any other purpose than for performing their duties as USC members.

*Funding and reimbursement USC members*

USC members are not reimbursed for their USC work. They may be rewarded with honoraria or other fees for participating in UCARE events and activities. Reasonable travel expenses to attend UCARE meetings can be reimbursed, depending on the funding obtained for UCARE.

**UCARE centers**

*Application*

Centers need to apply to become a UCARE. The application is received and confirmed by the UCARE office. The UCARE office informs the applicant center about the audit procedure and provides the documents needed for the audit. The applicant must send documentation to the UCARE office by e-mail that shows in how far the center meets the 32 UCARE criteria. The office checks this documentation and decides if the center is ready to be audited and informs it accordingly. Then the UCARE office looks for an appropriate auditor – the applicant center may suggest an auditor, but the UCARE office has final say and can appoint a different auditor. The UCARE office provides the auditor with the documentation needed for the audit (documentation and audit report template). After the applicant center has provided the needed documents and the UCARE office deems them complete, an audit date is set. Applicant centers will be added to the UCARE website when the date of the audit is set. If an UCARE applicant does not respond after 3 emails sent from the UCARE office, they will be removed from the applicant list again. If the applicant wants to pick up the process again after this, a new application must be submitted. Certification should take place no later than 5 months after application.

*Audit*

UCARE audits are performed by UCARE heads and/or their deputies. Travel costs are not reimbursed unless this is cleared with the UCARE office before the audit. First UCARE audits should be performed on site. In special cases, audits by video conference are possible. For example, if the auditor has recently visited the applicant center in person or will visit at the next opportunity or the pandemic situation requires it. Videoconference audits need to be approved by the UCARE office before the audit. The auditor will receive a guideline for the online audit to be conducted.

Auditors report on their audit visit to the UCARE office, by sending the audit report and pictures taken together with a short summary (3 to 5 sentences) and their recommendation to certify the applicant center or not. The UCARE office obtains confirmation from all USC members to follow the recommendation of the auditor. In case of different opinions, USC members will seek consensus. After being successfully audited, centers receive a certificate valid for two years, after that there will be a re-audit. The second re-audit will take place after three years. After that the audit period will be every four years. Re-Audits can be conducted remotely. Providing documentation before each re-audit is mandatory for all UCAREs.

*UCARE projects -- Application and Procedure*

Scientific Projects run through the UCARE network must go through the following steps:

* The application form must be fully filled out and submitted via the UCARE office to the UCARE Steering Committee. Parameters such as scope, duration, aim, instruments, databases etc. must be fully formulated. If the application is accepted, a UCARE Steering Committee Project Advisor is assigned.
* The project must have an international Steering Committee, ideally with 3-7 members. It must be geographically diverse, and its members must have a strong interest in the project and work as project ambassadors in their region and within their scientific communities. The Steering Committee should have regular meetings at key junctures of the project.
* Project Leads must ensure that necessary ethics approvals are obtained.
* Project tools and documents must be developed.
* A pilot study (proof-of-concept) must be conducted at the UCARE centers of (some) steering Committee members.
* Depending on the project, further ethics approvals may have to be obtained from participating centers.
* If the tools and documents have been perfected (taking in learnings from the pilot study), a global rollout is the next step.
* After the deadline, data obtained should be analyzed and prepared for publication (see below for guidelines on publication).

The UCARE office will assist with the following points:

* Organizing meetings and streamlining communication
* Sending emails on behalf of the project lead
* Advertising the project via our website and social media
* Making project documents available via our website and/or member area
* Assisting with translations and scientific writing
* Giving the opportunity to present projects at UCARE events such as GUF and the UCARE conference

**Guidelines for Authorship of publications arising from UCARE projects**

Authorship is attributed according to the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals (http://www.icmje.org/). Authorship selection for each publication activity of national or international data (manuscripts, abstracts, posters) is to be agreed by all members of the USC.

All authors of UCARE publications will be required to provide full disclosures of their financial interests in line with the international Good Publications Practice 2 (GPP2) guidelines for reporting medical research.

To be listed as an author, you must meet all 3 of the following criteria:

– Substantial contributions to design, acquisition of data, or analysis and interpretation of data

– Drafting the publication or revising it critically for important intellectual content

– Final approval of the version to be published

Positions of administrative leadership, contributing patients to the study and collecting and preparing data for analysis, however important to the research, are not by themselves criteria for authorship. The USC will determine prior to the initiation of the publication which author should take the lead for writing and managing each publication or presentation (i.e. lead author). One author should take overall responsibility for the integrity of a study and its report.

**UCARE, the Urticaria Network and GA2LEN**

The UCARE program is a GA2LEN program. The UCARE network works with other partners including the urticaria network e.V. (UNEV, e.g. on CURE, the chronic urticaria registry), scientific societies and commercial partners. The UCARE network is financed by the funding its recruits. UCARE funds are managed by the UCARE office and the USC, with the help of the GA2LEN office. UCARE holds subaccounts for general UCARE business and UCARE projects. UCARE does not provide funds to the GA2LEN general account and GA2LEN does not provide funds to the UCARE subaccounts, unless approved by the USC and GA2LEN.

**UCARE meetings**

Every 2 years, the UCARE network will hold a UCARE conference. In the years between these preceptorships and conferences, the UCARE network and its members will contribute to the biannual Global Urticaria Forum (GUF) meetings. There shall be a UCARE business meeting at the UCARE conference and at GUF.