1. PURPOSE

UCB, Inc. ("UCB") is subject to federal and state health care Anti-Kickback Statutes that prohibit giving or offering anything of value to healthcare professionals ("HCPs") or health care institutions ("HCIs") to influence prescribing or purchasing decisions. A violation of these laws can lead to penalties including criminal and/or civil fines for the company or individuals, imprisonment of individuals, and exclusion of UCB products from eligibility for reimbursement from Medicare and Medicaid. UCB is also subject to laws and regulations prohibiting promotion of investigational drugs or the off-label promotion of approved drugs.

It is the goal of UCB to ensure that its activities comply with all applicable state and federal laws. In addition UCB endeavors to conform to pertinent industry guidelines, including the American Medical Association ("AMA") guidelines regarding healthcare providers' acceptance of gifts from industry, the Pharmaceutical Research and Manufacturers of America ("PhRMA") Code on Interactions with Healthcare Professionals, the U.S. Department of Health and Human Services' Office of the Inspector General ("OIG") guidance to the pharmaceutical industry, the Accreditation Council for Continuing Medical Education ("ACCME") standards for industry support of continuing medical education.

The purpose of this Policy is to ensure that all Market Research conducted by UCB complies with applicable federal and state laws and regulations.

This Policy does not apply to the development or conduct of advisory boards. Refer to SOP *Advisory Boards*.

2. SCOPE

This Policy is applicable to all functional areas and all employees and agents of UCB, including consultants, contractors, and vendors involved in conducting Market Research for or on behalf of UCB or involving U.S. HCPs, HCIs, or Patients / Consumers.

3. ABBREVIATIONS AND DEFINITIONS

Abbreviations and definitions are used in accordance with the UCB GxP Glossary. To the extent that these definitions differ from those contained in the UCB Glossary, these definitions will take precedence for the purpose of this policy / procedure.

3.1 Abbreviations

N/A

Uncontrolled copy – for information purposes only.

3.2 Definitions

Market Research	Market research is the systematic and objective identification, collection, analysis, and dissemination of information for the purposes of assisting management in decision making related to the identification and solution of problems and opportunities in the marketplace. Market research encompasses primary data, secondary data, qualitative information, and quantitative data. Market research is distinct from advisory boards, which are generally conducted by UCB in person, using paid consultants and not on an anonymous basis.
Primary Data	Information or data originated by the researcher or vendor specifically to address the project or business issue at hand.
Secondary Data	Information or data collected by the researcher or vendor for broad usage or for some purpose other than the specific project or business issue to which it will be applied; sometimes referred to as "syndicated data" or "syndicated reports."

4. POLICY

From time to time, UCB may commission Market Research to collect data or information from HCPs, HCIs, patients / consumers or others regarding its marketed and/or investigational products, or other relevant topics. Regardless of the design of the project, Market Research should be conducted only if there is a legitimate and compelling business need. Duplicative studies should be avoided unless necessary to collect additional, important information.

Market research will be managed through the Market Research function or another appropriate Operational Excellence function as appropriate to the specifics of the study goals, and in accordance with applicable policies. Market Research may be managed through other functions, teams, or organizations only with the written consent of the Director Market Research (or designate) or the VP of Operational Excellence or some other appropriate member of senior line management. Other functions, teams, organizations conducting market research on UCB's behalf must comply with all UCB policies and procedures for market research.

Market Research sometimes requires that product information and claims (approved or potential) are presented to respondents to accurately understand their response. However, Market Research should never be used to promote products, nor should Market Research ever be used to directly or indirectly influence or encourage HCPs, HCIs or others to purchase, prescribe, or recommend UCB products or as a reward for previously doing so.

Adverse event or product complaint information collected or learned of during Market Research activities must be reported in accordance with applicable procedures.

Uncontrolled copy – for information purposes only.

4.1 Study Design

The study design for a Market Research project should reflect the goals of the study and should not involve subjects that do not meaningfully contribute to those goals. For example, a study intended to explore issues facing a specific geographic region may include a random sample of HCPs, HCIs or others from that particular area but generally should not include HCPs, HCIs or others from outside that area. The sample size should not be larger than what is required to obtain the information sought. Similarly, decisions on research fielding approach (for example, telephone versus in-person interviews, focus groups versus mini-groups, etc.) should be based on study goals.

On occasion, it may be necessary to present information or other stimuli to respondents about UCB products and/or competitor products in order to answer the questions posed by the Market Research. This may include findings from scientific studies. Stimuli presented should be appropriate to the research study goals and should be presented to research respondents for the minimum amount of time necessary to accomplish research goals. UCB Legal may review market research stimuli and results on an as needed basis.

Market research is generally conducted in an anonymous (double blind) fashion and interaction with respondents is usually managed through a third party market research firm. Market research occasionally conducts unblinded research to collect information from customers; in these cases, the use or disclosure of the company's name or the name of any product should be consistent with UCB review procedures to ensure compliance with applicable laws and regulations.

The Market Research function will be responsible for the development of an annual Market Research plan; such plan will be submitted, reviewed, and approved consistent with other UCB policies and procedures. Activity Notification Forms (ANF's) will be created and approved for each market research study covered by this policy. Market Research studies not included in the approved plan, and other deviations from the approved plan will be documented in the Activity Notification Form.

4.2 Third-Party Vendor

Third-party vendors are required to comply with this Policy as well as all other relevant UCB compliance policies.

4.3 Documentation, Record Maintenance and Retention

All records, information and deliverables related to this procedure will be retained for a period of six (6) years or longer if required by applicable law, contract or regulatory requirement. Records related to this procedure will be maintained by the activity owner unless otherwise specifically directed by the Legal Department. For GxP records retention refer to Corporate SOP *Retention Periods for GxP Records*.

Uncontrolled copy – for information purposes only.

Such documentation should include, at a minimum, documentation regarding Market Research requests, executed contracts with third-party vendors, and reports of the findings from the Market Research.

5. REFERENCES

- sop-009342, Retention Periods for GxP Records
- sop-009645, Advisory Boards
- sop-010837, Collecting and Reporting Adverse Events and Product Quality Complaints from Market Research Programs and Databases

6. DOCUMENT HISTORY

Supersedes Document(s) (Document Number and Version)	**Changes**
q-002053 v1.0	Upgrade in MIKADO CD changed prefix from “q” to “gov”.
gov-000548 v1.0	Modifications to the Policy (4.0) and Documentation (4.3) sections to reflect improved practices for the management of market research projects.
gov-000548 v2.0	Modifications to the Policy to reflect improved practices for the management of market research projects.

Uncontrolled copy – for information purposes only.

DOCUMENT APPROVAL ELECTRONIC SIGNATURES

Signed by	Meaning of Signature	Server Date (dd-MMM-yyyy HH:mm:ss TZ)
CRASSWELLER Ian	Author Approval	14-Aug-2014 23:45:30 CEST
HELLING Douglas	Legal Approval	20-Aug-2014 17:03:55 CEST
DAVIS Clive	Management Approval	22-Aug-2014 19:51:15 CEST
DHALLA Anisa	Subject Matter Expert Approval	09-Sep-2014 12:09:26 CEST

Uncontrolled copy – for information purposes only.