Guideline for Studies in Public Health Service for Purposes of Market and Social Research

This guideline is issued by the associations representing market and social research in Germany

- ADM Arbeitskreis Deutscher Markt- und Sozialforschungsinstitute e.V.
- Arbeitsgemeinschaft Sozialwissenschaftlicher Institute e.V. (ASI)
- BVM Berufsverband Deutscher Markt- und Sozialforscher e.V.
- Deutsche Gesellschaft für Online-Forschung e.V. (DGOF)

This guideline forms part of the system of self-regulation of German market and social research. The ethical and professional rules of conduct laid down in it must be interpreted and applied in this context.

This guideline is to ensure, among other things, that conducting of studies in public health service for purposes of market and social research conform to the code of the members of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V." for the collaboration between the pharmaceutical industry and physicians which in principle has to be observed as far as its rules do not contradict to the methodological, ethical and professional rules of conduct of market and social research in Germany which have priority.

1 Scope

The rules of professional conduct described below apply to all studies in public health service for purposes of market and social research, regardless of the underlying interest in their findings. They therefore apply – where appropriate – to studies among all target groups employed in public health service and to the use of all methods and techniques of data collection and analysis in market and social research.

2 Introduction

Studies in public health service for purposes of market and social research are subject to the same ethical and professional rules of conduct and methodological quality standards as all studies in market and social research. The principles and rules of professional conduct in market and social research require, among other things, that the voluntary nature of participation be clearly pointed out, the anonymity of the participants be strictly safeguarded and the market and social research be clearly differentiated from other activities.

That means in concrete that no personal data of the participants will be transferred to the client of the study or any other third parties. The research findings will be transferred only in a form which does not allow for conclusions being drawn about single participants. Moreover these rules mean in concrete that neither before, during or after conducting a study the selected participants will be specifically and individually contacted for non-research purposes of information, advertising or sales promotion nor certain attitudes in terms of the way they carry out their profession will be expected.

The rules of professional conduct in market and social research are laid down in the "ICC/ ESOMAR International Code on Market and Social Research" and in the preceding "Declaration for the Territory of the Federal Republic of Germany" as well as in the various guidelines issued by the associations representing market and social research in Germany. The scientific methodological quality standards are formulated in particular in the standard ISO 20252: 2012 "Market, opinion and social research – Vocabulary and service requirements".

In addition to the general principles and rules of professional conduct in market and social research, the following ethical and professional rules must be observed when conducting studies in public health service.

3 Arranging an appointment

When arranging an appointment for the participation the agency conducting the study or else the persons or organizations acting on its behalf – i.e. in particular interviewer and fieldwork organizations – should make appointments outside the working hours of the participants. Moreover the participation of privately or publicly employed persons should happen outside their employer's premises where they normally perform their duties. These regulations must be explicitly pointed out to the commissioned persons or organizations by the research agency. However, the concrete wishes of the participants regarding place and time of the participation must also be taken into account. In the case of privately or publicly employed participants if necessary – i.e. if a participant proposes to participate during the working hours and/or in the working rooms – the concerning duties resulting from their employment contract must be reminded. This reminder must be documented appropriately.

4 Incentives

The awarding of incentives must be conditional only to the formally correct participation in the study, not to any further requirements. Incentives are only a stimulus and a "thank you" for participation and must not be a motive for participation. The latter must be excluded by the agency as far as possible.

In studies in public health service incentives should preferably awarded as a certain

sum of money. As a stimulus and "thank you" incentives must be of neutral nature with respect to the study and the target group. Hence their value must be chosen socially adequate and staggered by professional position and time spent of the participants in a way that awarding them neither bias the sample nor influence the behavior of the participants. The professional scales of fees (e.g. the scale of fees for physicians) shall be taken as a frame of reference.

Incentives must not be awarded in form of products or services of the client of the study or in form of such connected with him.

Incentives must be awarded only by the research agency conducting the study, not by the client commissioning it. The awarding of incentives must be suitably documented.

5 Storage of addresses

In market and social research the collected data and the address data must be separated from each other and the latter deleted as soon as possible. In single studies the deletion must happen as soon as the quality checks on data collection and if necessary the data editing have been completed. In follow-up or repeated studies the address data must be stored separately from the collected data until the end of the entire project (see also "Guideline on the Treatment of Addresses in Market and Social Research").

Tax laws may make it necessary when awarding incentives to store the address data of the participants in the study along with the receipts for these incentives for a longer period of time then it would be necessary for methodological reasons. In such cases the address data must be stored for the time required by the tax laws in a way that renders the date of the participation identifiable but precludes them from being linked with the collected research data.

6 Information on reporting obligations

The cooperation of private market and social research agencies and public and private research institutions working in the same way in reporting of adverse drug events at studies in public health service is permissible – irrespective of target group and methodology of the study – exclusively within the scope of the professional rules of conduct of market and social research in Germany. That means in concrete that characteristics of the participants must not be reported – e.g. transferred – which might led to their identification. As far as drug safety requires for requests they must happen in a way which does not endanger the anonymity of the participants concerned. The agency which has conducted the study bears responsibility for the organization and realization of such requests. The participants concerned must consent to the processing of their address data necessary for it. Duration of the storage must not exceed three months.

The cooperation of private market and social research agencies and public and private research institutions working in the same way in reporting of adverse drug events is permissibly exclusively for the purpose of drug safety and if the agency conducting the study as well as the persons or organizations acting on its behalf have the professional experiences and competences which are necessary for it. The client of the study bears responsibility for training if necessary.

Moreover the private market and social research agencies and the public and private research institutions working in the same way, consider it part of their social responsibility in the interest of drug safety to take the precaution when conducting studies in public health service of pointing out to the existing obligations to report adverse drug events. For this purpose, in the case of studies conducted face-to-face, in writing or online the standard text attached to this guideline as Appendix 1 must be handed over to the participants. In the case studies conducted by telephone the standard text attached as Appendix 2 must be read out.

7 Final provisions and disclaimer of liability

This guideline forms part of the professional rules that govern German market and social research, resulting as they do from the law and the methodological standards, but also from common practice. It always applies when studies in public health service are conducted in Germany or from Germany. It therefore also applies when studies are conducted from abroad in order to conduct research in Germany, according to the precedence of national rules as laid down in the "ICC/ESOMAR International Code on Market and Social Research".

The principles and procedures described in this guideline are, inter alia, the result of weighing up the personal rights of the data subjects on the one hand, and the right to conduct research, together with the resulting methodological requirements, as well as the right to obtain information on the other. The issuers cannot guarantee indemnity. It cannot be ruled out that if the situation is weighed up at a later time or by other authorities different standards may result regarding the permissibility to conduct studies in public health service.

8 Entry into force

The professional rules of conduct described in this guideline shall enter into force at the time of their being accepted by the associations representing market and social research in Germany, on June 1st 2013.

March 2007 (revised in April 2013)

Appendix 1:
Standard text for studies conducted face-to-face, in writing or online for reminding of the obligation to report adverse drug events

(Address)

Thank you for taking part in our research project and for the information you have supplied. In the interest of drug safety we regard it as our social responsibility to take the precaution of reminding you on the existing obligations to report adverse drug events. If our research project has reminded you of such events and you have not yet reported these we would ask you to do so as soon as possible. If necessary the corresponding template is available on the internet under **www.akdae.de** as download. Thank you!

(Complimentary close)

Appendix 2:
Standard text for studies conducted by telephone for reminding of the obligation to report adverse drug events

(Address)

Thank you for your participation. In the interest of drug safety, we feel obliged to take the precaution of reminding you on the existing obligations to report adverse drug events. If your participation has reminded you of such events and you have not yet reported these we would ask you to do so as soon as possible. The corresponding template is available under **www.akdae.de**. Thank you!

(Complimentary close)