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

This English version of this Guideline is a translation of the original German version; in the event of variances, the German version shall take precedence over the English translation.

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 – DGOF e. V.

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
as drug safety requires for requests, they must happen in a
transferred
acteristics of the participants must not be re
ocial research in Germany. That means in concrete that char-
scope of the professional rules of conduct of market and so-
group and methodology of the study
in public health service is perm
the same way in reporting of adverse drug events at studies

6   Information on reporting obligations

The cooperation of private market and social research agen-
cies 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 so-
research in Germany. That means in concrete that char-
acteristics of the participants must not be reported – e. g.
transferred – which might lead to their identification. As far
as drug safety requires for requests, they must happen in a
way which does 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. Dura-
tion of the storage must not exceed three months.

The cooperation of private market and social research agen-
cies and public and private research institutions working in
the same way in reporting of adverse drug events is permis-
sibly exclusively for the purpose of drug safety and if the
agency conducting the study as well as the persons or or-
organizations acting on its behalf have the professional experi-
ences and competences which are necessary for it. The cli-
ent of the study bears responsibility for training if neces-
ary.

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 guide-
line 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 gov-
ern 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 con-
ducted from abroad in order to conduct research in Ger-
many, 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 con-
duct research, together with the resulting methodological
requirements, as well as the right to obtain information on
the other. The issuers cannot guarantee indemnity. It can-
not 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 on 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)