

EphMRA Adverse Event Reporting Form – TEMPLATE

Market Research Agency and Project Details		
MR Agency name:		
Full Address:		
MR Agency contact telephone number:	Country Code:	
	Number:	
MR Agency contact email		
Research Interviewer's name:	Title:	
	First name:	
	Surname:	
Research Interviewer's email address:		
Date aware of Adverse Event (*)		
Agency MR Project title/reference number		
MAH (**) project number / ID		
Respondent ID or AE number		
Patient Information		
No. of patients:	Individual patient:	
<i>(Select 'multiple patients' only if individual identifying details are not available, otherwise please complete separate AE reports)</i>	Multiple patients:	
	State number of patients if known:	
Availability of patient information	YES	NO
Age	YEARS	
Gender	FEMALE	MALE
	OTHER	PREFER NOT TO STATE
Drug and Event Information		
Drug name		
Indication drug prescribed		
Description of Adverse Event:		
<i>Please describe as fully as possible</i>		
Indication/condition for which drug prescribed		
Daily Dose of drug		NOT KNOW

Lot/batch number for drug		NOT KNOW	
Frequency of dose of drug		NOT KNOW	
Route of administration/form of drug		NOT KNOW	
Reported to local regulator?	YES	NO	DON'T KNOW
Does reporter think event might have been related to the drug?	YES	NO	DON'T KNOW
MR Subject/Reporter details			
MR subject / Reporter name	Title: First name: Surname:		
Reporter type (E.g. doctor, patient / consumer)			
Does the MR subject / Reporter agree to provide their contact details (e.g. address; email/phone optional)?			
	NOT AGREE TO PROVIDE		
Does the MR subject / Report agree to be contacted for follow up	YES, AGREE	NO, DO NOT AGREE	
	SIGNATURE		
Is the MR subject / Reporter a patient / consumer?	YES	NO	

* AE/PC/SRS = Adverse Event, Product Complaint and Special Report Situations

** MAH = Marketing Authorisation Holder

Pro Forma 1 – Recruitment Agreement

Receipt of Incentive	
Project Details	
Project Title:	Project No:
Agency:	Agency Contact:
Fieldwork	
Date of receipt:	Start Time:
Location: (If online or telephone, please state this)	Duration:
Incentive	
Incentive Type: (e.g. cash)	Incentive Amount:
Declaration	
<p>I confirm that the information I have given during the course of this interview/group discussion represents my views on the subject matter.</p> <p>I confirm that I have received the incentive detailed above in appreciation for my contribution to the project.</p>	
Market Research Subject Signature	
Signature:	Name (please print)
Market Research Subject Code Number	
Code Number	

Pro Forma 2

Receipt of Incentive	
Project Details	
Project Title:	Project No:
Agency:	Agency Contact:
Fieldwork	
Date of receipt:	Start Time:
Location: (If online or telephone, please state this)	Duration:
Incentive	
Incentive Type: (e.g. cash)	Incentive Amount:
Declaration	
<p>I confirm that the information I have given during the course of this interview/group discussion represents my views on the subject matter.</p> <p>I confirm that I have received the incentive detailed above in appreciation for my contribution to the project.</p>	
Market Research Subject Signature	
Signature:	Name (please print)
Market Research Subject Code Number	
Code Number	

Pro Forma 3

Market Research Subject Consent Allowing Client Access to Market Research Fieldwork	
Project Details	
Project Title:	Project No:
Agency:	Location of Fieldwork:
Date of Fieldwork:	Start Time of Fieldwork:
Declaration	
I understand that the company that commissioned this Market Research study	
(name of recipient organisation(s) may or may not be required will: DELETE AS APPROPRIATE	
<ul style="list-style-type: none"> - Watch through a one way mirror (watching organisations do not need to be named) but type of organisation(s) should be specified - Listen to an audio recording at their offices (organisations listening in may or may not need to be named depending on whether audio information is considered personal data or not) - Watch a video recording at their offices (watching organisation(s) must be named but naming may be delayed until the end of the interview if viewing is not live) 	
I understand that the purpose(s) of the company having access is:	
The people in the company who will listen to or view the recordings will be in the following functions/roles:	
I understand that all those listening, watching or viewing the recording MUST respect the confidentiality of all information exchanged in Market Research interviews/groups and that no sales approaches will ever be made to me as a consequence of the company having this access.	
I understand that I can withdraw my consent at any stage.	
IF APPROPRIATE We would prefer not to reveal the name of the healthcare/pharmaceutical company until the end of the interview, just in case knowing this affects any responses. Is this acceptable to you or not? YES NO	
Signatures	
I have read, understand and agree to the terms above.	
Market Research Subject Signature:	Name (please print)
Agency Signature:	Name (please print)
Market Research Subject Code Number	
Code Number	

Pro Forma 4

Client Agreement to Safeguard Confidentiality of Recordings of Market Research Fieldwork	
Project Details	
Project Title:	Project No:
Agency:	Location(s) of Fieldwork:
Date(s) of Fieldwork:	Start Time(s) of Fieldwork:
Commissioning Client Company	
Declaration	
On behalf of <the commissioning client company> I can confirm that the recording(s) of Market Research fieldwork from the above study will only be used for the following purpose(s):	
The only people in the company who will listen to or view the recordings will be in the following functions/roles:	
And the recording(s) will be in the secure care of:	_____
On behalf of the commissioning client I can confirm that:	
<ul style="list-style-type: none"> - Those listening to or viewing the recording will respect the confidentiality of all information exchanged in Market Research interviews/groups - No sales approaches will ever be made to MR subjects as a consequence of having this access - No attempt will be made to reverse any anonymisation - The recordings will be stored securely, kept separate and processed in accordance with applicable data protection/privacy laws and Market Research professional codes - The recordings will be destroyed or handed back to the agency as soon as is required. - If video streaming has been used to allow remote viewing it is possible that the video transmission system used delivered a copy of the recording to the receiving computer. If this is the case any copy of the video stream saved on the observer's computer MUST be deleted. 	
Signatures	
I have read, understand and agree to the terms above	
Company Signature:	Name (please print)
Agency Signature:	Name (please print)

Pro Forma 5

Observer Agreement	
Project Details	
Project Title:	Project No:
Agency:	Agency Contact:
Location of Fieldwork:	Date of Fieldwork:
	Time of Fieldwork
Declaration	
I understand that I MUST be familiar with and adhere to the EphMRA's Observers' Guidelines.	
Observer Signature	
I have read, understand and agree to the terms	
Signature:	Name (please print)