### 6.1 Recruiting an HCP to participate in market research

**PLEASE NOTE: This is not a fully formed consent agreement and you will need to add further specific detail e.g. the name of the recipient company. For more information about consent agreements please see the BHBIA’s GDPR Update on Consent for market research or section E4.2 of the BHBIA’s Legal and Ethical Guidelines.**

Example Wording

Interviewer says:

*This research has been commissioned by a company that manufactures medicines/medical devices. It is a legal requirement that the company keep records of any side effects or complaints that people may have about their medicines/medical devices. We must assist the company in meeting its legal obligations.*

*Therefore, if, during the interview, you make any reference to a side effect or complaint about a medicine or device, we will let the company know about this even if it has already been reported by you directly to the company or the regulatory authorities. You can decide whether or not to give the company your name and contact details.*

*Please confirm the following statement:*

*“I agree that if I discuss any side effect or complaint about a medicine/medical device during the market research, this information will be passed to the company.”*

Next Steps

1. Interviewer should i) obtain confirmation from the HCP market research participant that they are happy to proceed on this basis and ii) keep a record of the confirmation.

1. If the HCP does not provide confirmation, they should not be recruited to participate in the market research. Interviewer should thank them and end the recruitment process.
2. If the HCP provides confirmation and raises an AE/PC/SRS during the interview, the MRA should seek confirmation from them that they can forward their contact details to the MAH/Certificate Holder. See Annex 6.3 for an example of the wording for this.

### 6.2 Before an HCP participates in market research

Use this after recruiting the HCP and before they participate in the market research.

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Example Wording

Interviewer says:

*This research has been commissioned by a company that manufactures medicines/medical devices. It is a legal requirement that the company keep records of any side effects or complaints that people may have about their medicines/medical devices. We must assist the company in meeting its legal obligations.*

*Therefore, if, during the interview, you make any reference to a side effect or complaint about a medicine/medical device, we will let the company know about this even if it has already been reported by you directly to the company or the regulatory authorities. You can decide whether or not to give the company your name and contact details.*

*If you do provide your name and details with the AE, please rest assured everything else you say during the course of the survey will remain confidential.*

*Are you happy to proceed with the survey on this basis?*

1. *Yes*
2. *No*

Next Steps

1. Interviewer should obtain confirmation (1. Yes) from the HCP market research participant that they are happy to proceed on this basis.
2. If the HCP does not provide confirmation, they cannot participate in the market research. Interviewer should thank them and end the participation.
3. If the HCP provides confirmation, the market researcher carrying out the interview should obtain a signed statement from them to that effect. Here is an example of the wording for this:

*DATE:*

*NAME:*

*STATEMENT:* *I understand that if I raise any AE/PC/SRS during the research interview, this information will be passed to the pharmaceutical company that commissioned the research. I confirm that this was explained to me before participating in this market research and that I was given the option not to take part in the research but that I decided to participate on this basis.*

*SIGNATURE:*

1. If the HCP provides confirmation and raises an AE/PC/SRS during the interview, the MRA should seek confirmation from the HCP that they can forward their contact details to the MAH/Certificate Holder. Please see Annex 6.3 for an example of the wording for this.

### 6.3 When an HCP raises an AE/PC/SRS during market research

Use this at the end of the market research interview and not during it.

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Example Wording

Interviewer says:

*You previously confirmed that you agreed to information about AEs, PCs and SRSs that you may raise during participation in the market research, being provided to the company that has commissioned this research.*

*During this interview you described a situation that would be categorised as an AE, PC or SRS. I would therefore like to confirm to you that we will now pass this information to the company.*

*In order to further assist with medicines/medical devices safety monitoring, [NAME OF COMPANY] may want to contact you directly to ask some follow-up questions. Please could you confirm that you consent to [NAME OF AGENCY] giving [NAME OF COMPANY] your contact details for any further follow-up.*

*Please confirm the following statement:*

*“I confirm that I consent to my name and contact details being passed to [NAME OF COMPANY] in the case that there is a need to follow up on the AE, PC or SRS raised during this interview.”*

 Next Steps

1. If the HCP confirms their agreement, the interviewer should obtain a written record of this.
2. If the HCP confirms that contact details cannot be given to the MRA, the interviewer should say:

*Thank you. I confirm that I will not pass your contact details to the company.*

### 6.4 Recruiting a patient/caregiver to participate in market research

**PLEASE NOTE: This is not a fully formed consent agreement and you will need to add further specific detail e.g. the name of the recipient company. For more information about consent agreements please see the BHBIA’s GDPR Update on Consent for market research or section E4.2 of the BHBIA’s Legal and Ethical Guidelines.**

Example Wording

Interviewer says:

*This research has been commissioned by a company that manufactures medicines/medical devices. It is a legal requirement that the company keep records of any side effects or complaints that people may have about their medicines/medical device. We must assist the company in meeting its legal obligations.*

*Therefore, if, during the interview, you make any reference to a side effect or complaint about a medicine/medical device, we will let the company know about this even if it has already been reported by you directly to the company or the regulatory authorities. You can decide whether or not to give the company your name and contact details.*

Please confirm:

*“I agree that if I discuss any side effect or complaint about a medicine/medical device during the market research, this information will be passed to the company.”*

Next Steps

1. Interviewer should i) obtain confirmation from the market research participant that they are happy to proceed on this basis and ii) keep a record of the confirmation.

1. If the market research participant does not provide confirmation, they should not be recruited to participate in the market research. Interviewer should thank them and end the recruitment process.
2. If the market research participant provides confirmation and raises an AE/PC/SRS during the interview, the MRA should seek confirmation from them that they can forward their contact details to the MAH/Certificate Holder. See Annex 6.6 for an example of the wording for this.

### 6.5 Before a patient/caregiver participates in market research

Use this after recruiting the patient/caregiver and before they participate in the market research.

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Example Wording

Interviewer says:

*As we previously discussed, it is a legal requirement that the company keep records of any side effects or complaints that people may have about their medicines/medical devices. Please confirm that you agree that if you discuss any side effect or complaint about a medicine/medical device with us during the research, we will give this information to the company.*

Next Steps

1. Interviewer should obtain confirmation from the market research participant that they are happy to proceed on this basis.
2. If the market research participant does not confirm, they cannot participate in the market research. Interviewer should thank them and end the participation.
3. If the patient/caregiver provides confirmation, the market researcher carrying out the interview should obtain a signed statement from them to that effect. Here is an example of the wording for this:

*DATE:*

*NAME:*

*STATEMENT:**I understand that if I mention any side effect or complaint about a medicine/medical device, this information will be provided to the medicines/medical devices manufacturer. I confirm that this was explained to me before participating in this market research and that I was given the option not to take part in the research but that I decided to participate on this basis.*

*SIGNATURE:*

1. If the patient/caregiver provides confirmation and raises an AE/PC/SRS during the interview, the MRA should seek confirmation from the patient/caregiver that they can forward their contact details to the MAH/Certificate Holder. Please see Annex 6.6 for an example of the wording for this.

### 6.6 When a patient/caregiver raises an AE/PC/SRS during market research

Use this at the end of the market research interview and not during it.

**PLEASE NOTE: This is not a fully formed consent agreement and you will need to add further specific detail e.g. the name of the recipient company. For more information about consent agreements please see the BHBIA’s GDPR Update on Consent for market research or section E4.2 of the BHBIA’s Legal and Ethical Guidelines.**

Example Wording

Interviewer says:

*We previously discussed the obligations that a medicines/medical devices manufacturer has to keep records of any side effects or complaints that people may have about their medicines/medical devices.*

*When you were answering the research questions, you mentioned that [INSERT BRIEF DESCRIPTION OF WHAT WAS SAID].*

*In order to find out more about the side effect or product complaint that you described, the medicines/medical devices manufacturer might want to contact you directly to ask some follow-up questions.*

*Please could you confirm that you consent to us giving the medicines/medical devices manufacturer, [INSERT NAME], your contact details for any further follow-up. This is an information notice that gives you more information about how your contact details will be used.*

Next Steps

1. If the patient/caregiver confirms their agreement, the interviewer should obtain a written record of this.
2. If the patient/caregiver confirms that contact details cannot be given to the MAH/Certificate Holder, the interviewer should say:

*Thank you. I confirm that I will not pass your contact details to the company.*

### 6.7 The start of a market research internet study where HCP respondents can enter free text

Example Wording

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Interviewer says:

*This study is sponsored by a pharmaceutical company and for this reason we are required to pass on any possible AEs, PCs and SRSs. The details of these will be reported anonymously unless you agree to disclose your personal details, only and exclusively for the purpose of follow-up by the client’s medicine/device safety team. Please select one of the options below:*

* *I would like to proceed and agree to be contacted by the medicine/device safety team for follow- up (PROCEED)*
* *I would like to proceed but do not wish to be contacted by the medicine/device safety team for follow-up (PROCEED)*
* *I don’t want to proceed and wish to end the interview here (THANK AND CLOSE)*