### 6.2 Before an HCP participates in market research

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

**PLEASE NOTE: This is not a fully formed consent agreement and you will need to add further specific detail eg. 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. It is a legal requirement that the company keep records of any side effects or complaints that people may have about their medicines. 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, 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. Please see Annex 6.3 for an example of the wording for this.