### 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.

**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:

*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. Please confirm that you agree that if you discuss any side effect or complaint about a medicine 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, this information will be provided to the medicines 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. Please see Annex 6.6 for an example of the wording for this.