**Template participant consent source data inserts**

These participant consent inserts can be used in source data to ensure consistent documentation of consent processes within your team. The content is designed to be adapted for use in a sticker template or as a physical page insert, depending on your local and sponsor policies. They are fully editable and can be adapted to suit different study requirements.

Consent insert for initial approach and introduction of study (edit as needed to meet your study requirements)

|  |  |
| --- | --- |
| **Date/Time .........................................................**  <Insert study logo here>  **Study name: ……………………………. Study ID:…………………………**  **Discussion with:.......................................................................................**  **Overview of study given, including *<<****insert standard study discussion items here (e.g. concept of study participation introduced, purpose of the study, eligibility for recruitment, possible risks and benefits of participation, and follow-up process.)****>>*** Any additional points or questions raised during this discussion are detailed in notes.  **PIS given: Version ............... dated ............................**  **Given on ........................................ (dd/mm/yyyy) at …………………… (hh:mm)**  **Copy of PIS entered into medical notes at ................... (hh:mm)**  **Signed ......................................................................**  **Designation ........................................................................................................** | **Date/Time .........................................................**  <Insert study logo here>  **Study name: ……………………………. Study ID:…………………………**  **Discussion with:.......................................................................................**  **Overview of study given, including *<<****insert standard study discussion items here (e.g. concept of study participation introduced, purpose of the study, eligibility for recruitment, possible risks and benefits of participation, and follow-up process.)****>>*** Any additional points or questions raised during this discussion are detailed in notes.  **PIS given: Version ............... dated ............................**  **Given on ........................................ (dd/mm/yyyy) at …………………… (hh:mm)**  **Copy of PIS entered into medical notes at ................... (hh:mm).**  **Signed ......................................................................**  **Designation ........................................................................................................** |

Consent insert for receiving consent (edit as needed to meet your study requirements)

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| **Date/Time .........................................................**  <Insert study logo here>  **Study name: …………………………. Study ID:…………………………** **Patient ID:...............**  **Discussion with ......................................................**  **They have read the study information sheet provided and have a good understanding of the purpose of the study and what participation involves.** *<<Insert any study specific points here>>*Specific points or questions raised during this discussion are detailed in notes.  **They agree to participate in the study.**  **PIS discussed: Version .............., dated ........................**  **Consent form completed: Version .............., dated ........................**  **Consent form signed at ................. (hh:mm).**  **Copies of consent form processed according to protocol …………(y/n)**  (including copy given to participant)  **Signed ......................................................................**  **Designation ........................................................................................................**  Any additional staff involved in the consent process are detailed in notes | **Date/Time .........................................................**  <Insert study logo here>  **Study name: …………………………. Study ID:…………………………** **Patient ID:...............**  **Discussion with ......................................................**  **They have read the study information sheet provided and have a good understanding of the purpose of the study and what participation involves.** *<<Insert any study specific points here>>*Specific points or questions raised during this discussion are detailed in notes.  **They agree to participate in the study.**  **PIS discussed: Version .............., dated ........................**  **Consent form completed: Version .............., dated ........................**  **Consent form signed at ................. (hh:mm).**  **Copies of consent form processed according to protocol …………(y/n)**  (Including copy given to participant)  **Signed ......................................................................**  **Designation ........................................................................................................**  Any additional staff involved in the consent process are detailed in notes |