Consent for recording information in the SMA REACH UK Database in association with Neuromuscular Clinical Network & for the additional assessments

Patient Details (or pre-printed label) Responsible health professional …………………………….

Hospital Number ………………………………. Job title ……………………………………..

Patient’s Surname ………………………………

Patient’s first names ……………………………

Date of birth ……………………………………

**NHS number** …………………………………… Patient’s other requirements ………………………………

 (E.g. other language)

**Please *Initial* each statement**

**Medical Diagnosis: …………………………………………………**

**Mandatory to participate in SMA-REACH**

**I** agree that clinical information about my child will be collected, recorded and saved in the SMA REACH UK Database.

I understand that relevant sections of any of my child’s medical notes and data collected during the study may be looked at by employees from Regulatory Authorities or from Great Ormond Street Hospital/ Institute of Child Health (and other academic institutions), for monitoring and auditing purposes. Also where it is relevant to my child taking part in this research going forward, these employees will have access to relevant sections to my child’s medical notes. Furthermore, I understand that previous data about my child (from the SMARTNET database) will be collected and saved in the SMA REACH UK Database. I give permission for these individuals to have access to my child’s records

**Optional assessments**

I agree for my child to be videotaped during the physiotherapy assessments

(if you refuse, your child may still take part in the study).

I agree for my child’s GP to be informed of his/her participation in this study

I agree to be involved in a parent/patient/researcher focus group

I agree to be contacted for an interview to talk about SMA and management

I agree that the fully anonymised clinical and physiotherapy information about my child will be collected and saved in the SMA REACH UK database, will be shared with an international database and that this information can be accessed by Biogen and third parties (pharmaceuticals/academic institutes/any government bodies as required) in a strictly anoymised form. I agree that anonymised clinical information about my child can also be used for clinical audits, research, evaluation and health service planning as required.

 In addition, Pseudonymised personal data about my child will be collected and saved in the SMA REACH UK database if enrolled onto the nusinersen (SPINRAZA®) Managed Access Agreement (MAA). This will be shared with NHS England, NICE, University of Strathclyde and Biogen.

I agree to be contacted by phone for short interviews/surveys on SMA

 (only at GOSH)

……………………………………………. ……………………………………………

Signature (parent / guardian) Date

……………………………………………. ……………………………………………

NAME (BLOCK CAPITALS) Relationship to patient

**Practitioner Section:**

I have given the parent/guardian the information sheet entitled: **Recording information on the management of your child with Spinal Muscular Atrophy in the UK – SMA REACH UK Database in association with Neuromuscular Clinical Network.**

I have explained to the above parent / guardian the purpose of collecting and recording clinical information in the database.

……………………………………………. ……………………………………………

Signature Date

……………………………………………. ……………………………………………

NAME (BLOCK CAPITALS) Job title