IF THE PARTICIPANT IS UNABLE TO PROVIDE A SIGNATURE:

Thumb print of participant:

Full name (capital letters):

DECLARATION BY WITNESS

I declare that I have witnessed the careful reading of the information booklet to the potential participant and that the participant has had the opportunity to ask questions. I confirm that the participant has freely given his/her assent.
I, the undersigned, do hereby declare that I have no current or potential conflict of interest deriving from my role as a witness in this trial.

Witness's Signature:

Full name (capital letters):

STATEMENT OF PERSON RECEIVING ASSENT

I have carefully read the information booklet to the potential participant and I have made sure, to the best of my ability, that he/she has understood that the following procedures will be carried out:
1. the participant will be taken off his/her current treatment and that deferiprone or deferasirox will be administered according to the procedures set out in the protocol;
2. the participant will take part in the monitoring and examinations described in the information booklet;
3. the treatment will last 12 months, but the trial itself will last up to 14 months. During this period, the participant may not take part in another trial.
I confirm that the participant has had the opportunity to ask questions about the trial and that all of the questions he/she asked were correctly answered to the best of my ability.
I confirm that the participant was not coerced into giving assent and that this assent was obtained freely and voluntarily.
A copy of this assent document has been given to the participant.

Signature of person receiving assent:

Full name (capital letters):

Date:

DEEP

DEferiprone Evaluation in Paediatrics

DEEP-2 Clinical Trial

EudraCT number: 2012-000353-31

Study title:
Multi-centre, randomised, open label, non-inferiority active-controlled trial to evaluate the efficacy and safety of deferiprone compared to deferasirox in paediatric patients from 1 month to less than 18 years of age affected by transfusion-dependent haemoglobinopathies.

Version 2.0
Release date: 30/09/2012

SEVENTH FRAMEWORK PROGRAMME

DEFERIPRONE EVALUATION IN PAEDIATRICS

CONSORZIO PER VALUTAZIONI BIOLOGICHE E FARMACOLOGICHE

ASSENT FORM

I have been invited to participate in the DEEP-2 clinical trial.

I have read the information booklet for my age group. If I had any doubts, I had the opportunity to ask the doctor or researchers about them, and their answers were clear and comprehensive.

By participating in this clinical study, I will be discontinuing my previous treatment, and I will begin to take the drug deferiprone (syrup) or the drug deferasirox (soluble tablets) according to the trial plan. I am aware that the treatment will last 12 months, that the trial itself will last up to 14 months, during which time I will be available for the monitoring visits and examinations required, which I have read about in the information booklet.

I have been informed that I will be able to leave the trial, and that if I do I will still receive full attention from the doctors and all the necessary treatments.

Participant's Signature:

_____

Full name (capital letters):

_____

_____

Investigator's Signature:

_____

Full name (capital letters):

_____

_____

Date:

_____