The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

THE John Walton MUSCULAR DYSTROPHY RESEARCH CENTRE

Newcastle University

Informed consent for clinical research training

22nd May 2018

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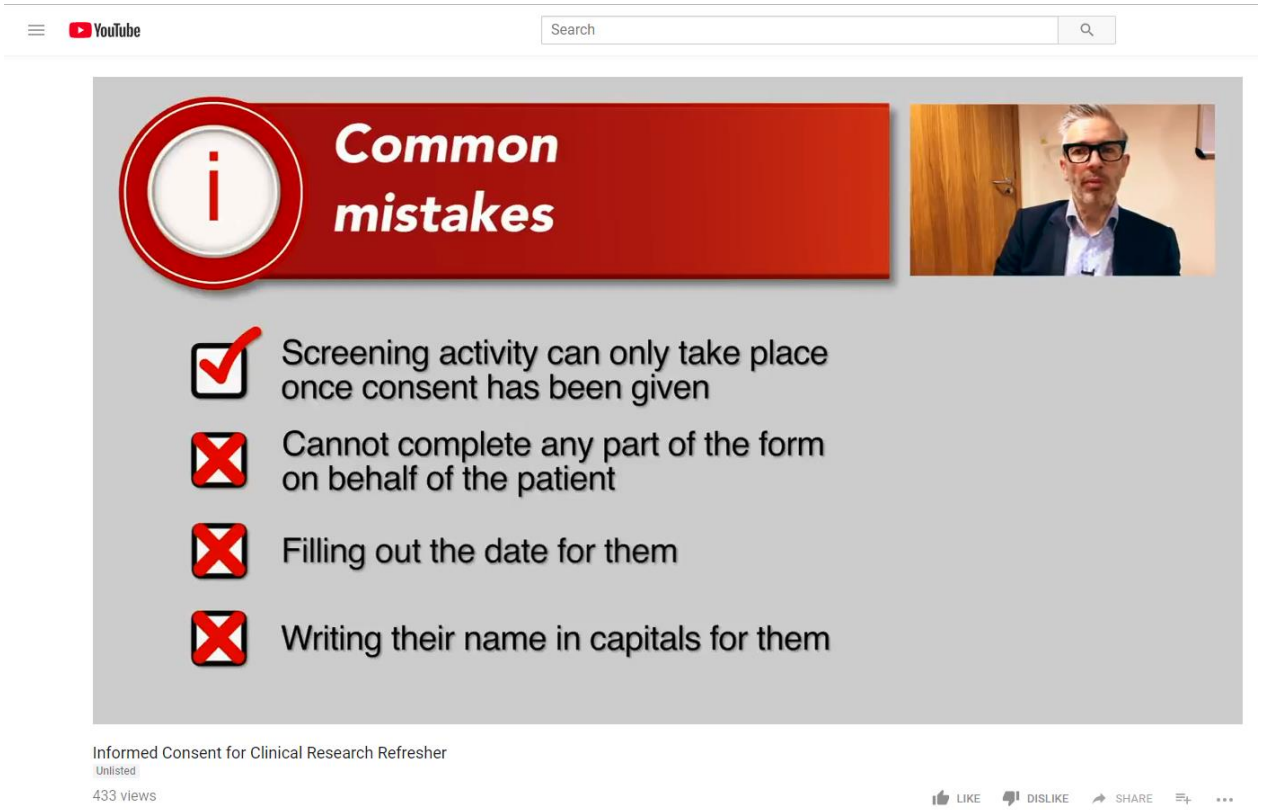
JWMDRC, Newcastle

DMD HUB
EXPANDING TRIAL CAPACITY

NHS trust you tube video

https://www.youtube.com/watch?v=Z9F7snhHoUs

Begin at 1:07



Informed consent

4.8.3 No coercion - Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.

4.8.7 Must have had time to read beforehand - Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.

4.8.8 Must sign consent before trial activity -Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.

4.8.9 Impartial witnesses - By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.

4.8.11 Family should receive consent form once signed -Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.

Informed consent

4.8.10 Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

(a) That the trial involves research.

(b) The purpose of the trial.

(c) The trial treatment(s) and the probability for random assignment to each treatment.

(d) The trial procedures to be followed, including all invasive procedures.

(e) The subject's responsibilities.

(g) The reasonably foreseeable risks or inconveniences to the subject

Informed consent

(h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

(i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.

(m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time.

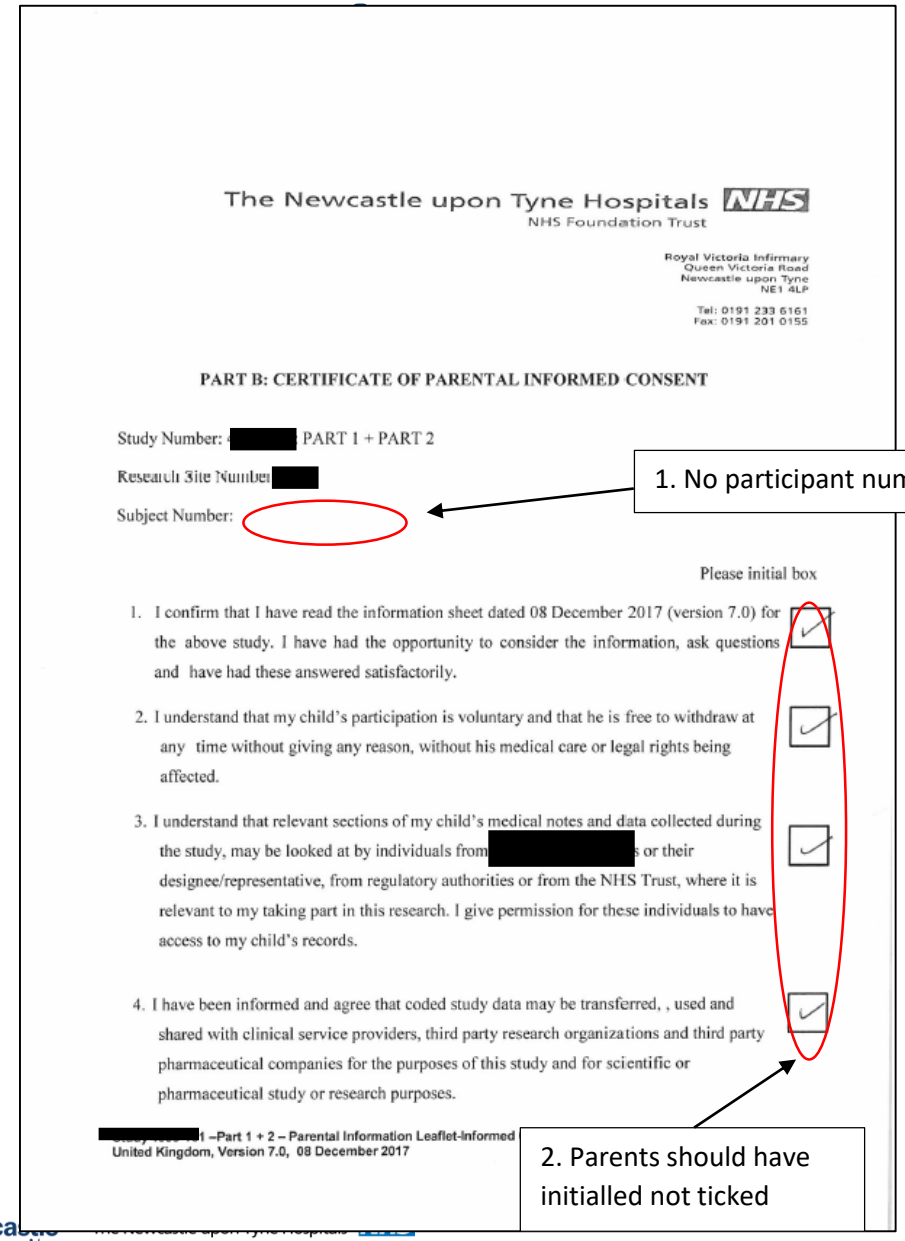
(r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

(s) The expected duration of the subject's participation in the trial.

(t) The approximate number of subjects involved in the trial.

Common mistakes from audit of studies

- All levels of doctor can make errors
- Person taking consent responsibility to provide copies and document
- Consent learning (examples)



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PART B: CERTIFICATE OF PARENTAL INFORMED CONSENT

Study Number: [redacted] PART 1 + PART 2

Research Site Number [redacted]

Subject Number:

Please initial box

1. I confirm that I have read the information sheet dated 08 December 2017 (version 7.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☑
2. I understand that my child's participation is voluntary and that he is free to withdraw at any time without giving any reason, without his medical care or legal rights being affected. ☑
3. I understand that relevant sections of my child's medical notes and data collected during the study, may be looked at by individuals from [redacted] or their designee/representative, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my child's records. ☑
4. I have been informed and agree that coded study data may be transferred, , used and shared with clinical service providers, third party research organizations and third party pharmaceutical companies for the purposes of this study and for scientific or pharmaceutical study or research purposes. ☑

[redacted] –Part 1 + 2 – Parental Information Leaflet-Informed
United Kingdom, Version 7.0, 08 December 2017

1. No participant number

2. Parents should have initialled not ticked

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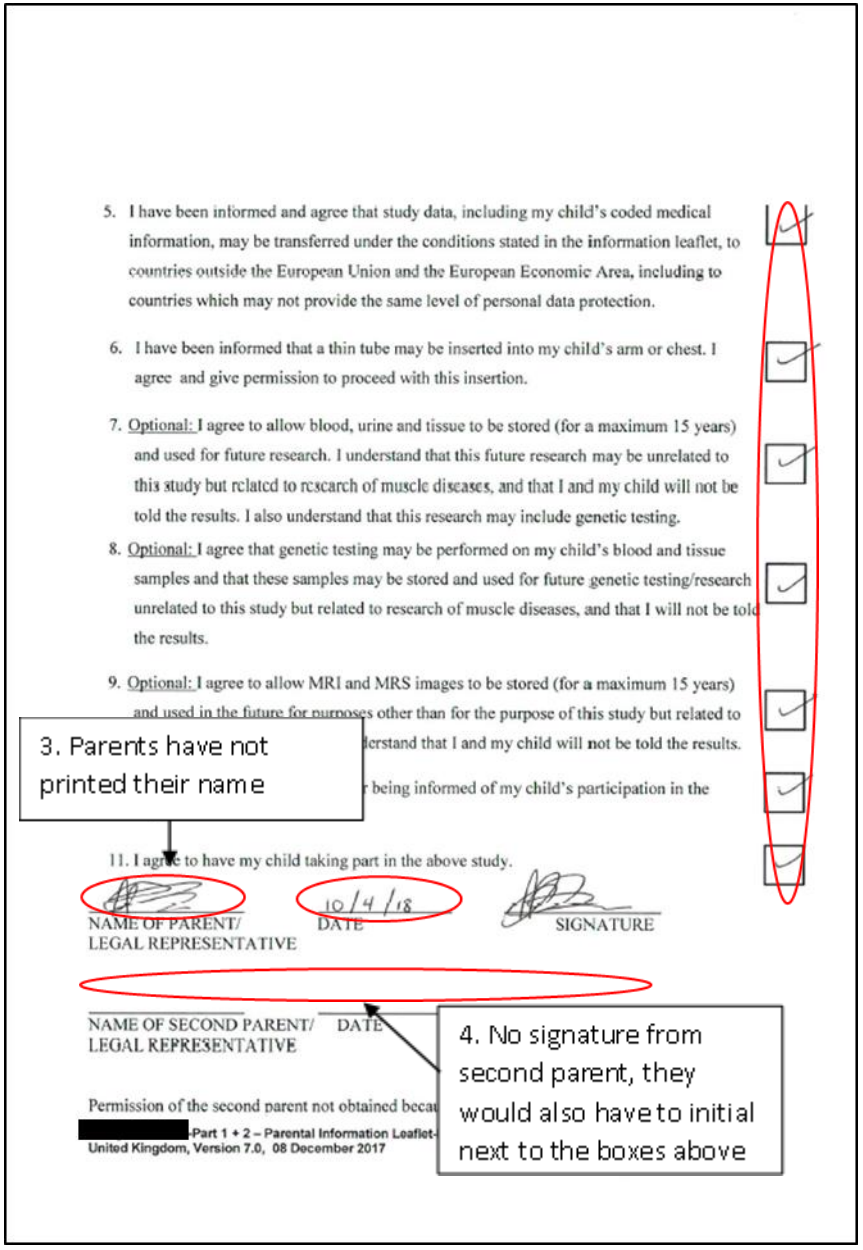
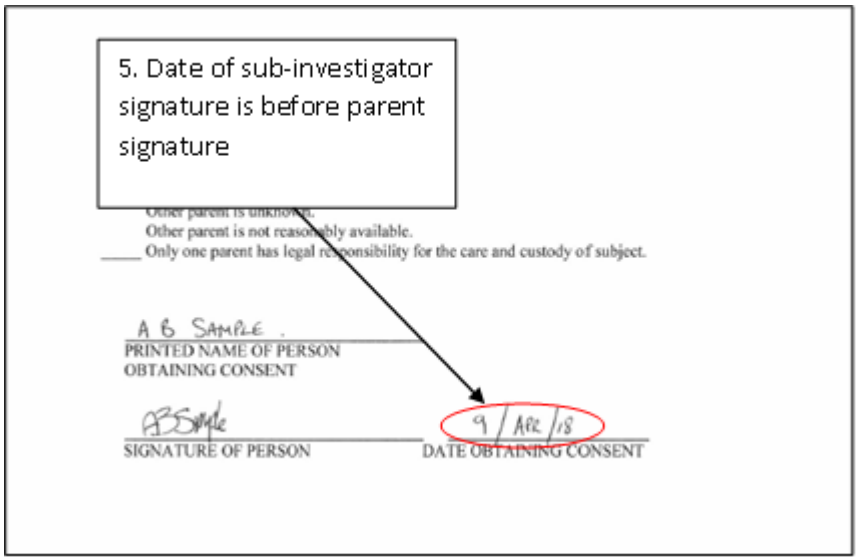

5. I have been informed and agree that study data, including my child's coded medical information, may be transferred under the conditions stated in the information leaflet, to countries outside the European Union and the European Economic Area, including to countries which may not provide the same level of personal data protection.
6. I have been informed that a thin tube may be inserted into my child's arm or chest. I agree and give permission to proceed with this insertion.
7. Optional: I agree to allow blood, urine and tissue to be stored (for a maximum 15 years) and used for future research. I understand that this future research may be unrelated to this study but related to research of muscle diseases, and that I and my child will not be told the results. I also understand that this research may include genetic testing.
8. Optional: I agree that genetic testing may be performed on my child's blood and tissue samples and that these samples may be stored and used for future genetic testing/research unrelated to this study but related to research of muscle diseases, and that I will not be told the results.
9. Optional: I agree to allow MRI and MRS images to be stored (for a maximum 15 years) and used in the future for purposes other than for the purpose of this study but related to
derstand that I and my child will not be told the results.
being informed of my child's participation in the
11. I agree to have my child taking part in the above study.
10/4/18
NAME OF PARENT/ LEGAL REPRESENTATIVE
DATE
SIGNATURE
NAME OF SECOND PARENT/ LEGAL REPRESENTATIVE
DATE
Permission of the second parent not obtained becau
[redacted]-Part 1 + 2 – Parental Information Leaflet-
United Kingdom, Version 7.0, 08 December 2017
3. Parents have not printed their name
4. No signature from second parent, they would also have to initial next to the boxes above


5. Date of sub-investigator signature is before parent signature
Other parent is unknown.
Other parent is not reasonably available.
____ Only one parent has legal responsibility for the care and custody of subject.
A B SAMPLE
PRINTED NAME OF PERSON OBTAINING CONSENT
SIGNATURE OF PERSON
9/APR/18
DATE OBTAINING CONSENT

The parent has forgotten to fill in the date (1st of February 2018) when signing a consent form and has now left the unit, what is the correct course of action?

a) Fill in the date for them.

b) Ask them to fill in the date that should have been entered at their next appointment.

c) Fill in the date for them making sure that you document the reason you have done this.

d) Do not fill in the date but instead begin a new consent form at their next appointment and ask them to start afresh.

e) Contemporaneously document that the date was missed due to human error, then at their next visit ask the parents to document that they had signed the consent form on the 1st of February, then for the parents and yourself to sign and date.

The following should be documented in prose (separately to the consent form) in the source notes when consenting.

a) The version number of the consent form
b) The name of the managing director of the drug company who signs the first page of the protocol
c) The date of issue of the consent form
d) The ethics REC number for the latest amendment
e) That the right to withdraw was discussed
f) That time was given for questions
g) That a copy of the consent form was given to parents
h) The name of the principal investigator
i) The date and time when the consent form was signed
j) The study number
k) The participant number