INFORMED CONSENT

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Objectives
- Background
- Definition
- Why do we need it?
- The process of obtaining informed consent
- A brief overview of special situations
- Conclusion

Background

Definition of Informed Consent

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written signed and dated consent form.

IGC GCP 1.28

Why do we need it?

Ethical and legal considerations

Essentially......

- Ethical and legal frameworks.
- Independently scrutinised and approved.
You can expect the following to review 100% of informed consent forms:

- Monitor/auditors from the sponsors, local R & D and Ethics and inspectors from the MHRA

Guidelines
- Nuremberg code
- Declaration of Helsinki
- ICH GCP

Common & Statute Law
- EU Clinical Trials Directive
- Regulatory
  - Medicines for Human Use (Clinical Trials) Regulations 2004
  - Statutory Instruments (LOI) 1928 and 2984
- Data Protection Act
- Human Tissue (Scotland) Act 2006
- Adults with incapacity (Scotland Act) 2000
- Common Law

Who can take informed consent for clinical studies?
- When should it be taken?
- Is it appropriate?
- Are you well prepared?
- Documentation

The screening visit for a heart failure study requires an echocardiogram to assess left ventricular function to confirm that the participant is eligible. Should consent to the study be taken before or after the patient is confirmed eligible?

1. Before
2. After the echocardiogram
3. After the echocardiogram and a coffee
Consent must be obtained prior to participation in the trial e.g., before initiation of any screening procedures.

- Must be signed and personally dated by the participant/legal representative and the person taking the consent.
- The original goes in the Trial Master File and
  - 1 copy to the participant/legal rep.
  - 1 copy in the participant’s notes.

**The discussion**

- Comfortable, relaxed, no interruptions.
- The participant can bring a close friend or relative.
- Repeat, explain and reinforce information.
- Ask questions to ascertain level of understanding.
- Let them ask questions.
- Timing.

**The assessment**

- Is ongoing.
- The way in which the information is conveyed is as important as the information itself.
- It’s important to acknowledge diversity.

**The process of informed consent should include...**

1. The discussion.
2. Assessment.
3. Reinforce the discussion.
4. The consent form.

**What is ‘enough time’?**

- IRAS gives guidance on this – at least 24 hours unless you can ethically and scientifically justify a shorter time.
  - In an acute trial when treatment has to be given in <24 hrs to fulfill protocol requirements.
  - This is an ethics requirement but not a regulatory requirement.
Commonly through the use of the patient information sheet.

Potential participants can take this away with them, show it to friends and family.

According to ICH GCP 4.8.10 there are 20 essential elements of the PIS......

1. Involves research
2. Purpose of the trial
3. Trial treatments and probability for random allocation
4. Procedures to be followed
5. Subjects responsibilities
6. Experimental aspects of the trial
7. Risks or inconveniences to the subject
8. Expected benefits (if none, ensure awareness)

9. Alternative treatments / procedures
10. Compensation arrangements
11. Prorated payment
12. Anticipated expenses
13. That participation is voluntary. The subject may refuse or withdraw at any time without penalty or loss of benefits.
14. Direct access to medical records for monitors, auditors, IEC, regulatory authorities to verify data / procedures.
15. Confidentiality of records, anonymity if results are published
16. Informed of any new info, relevant to willingness to continue
17. Person to contact for more information and in event of trial related injury
18. Foreseeable circumstances under which subjects participation may be terminated
19. Expected duration of participation
20. Approximate numbers in trial.

Points to note about PIS

- One size will not fit all
- Location of further information and independent guidance
- Presentation—consider colour, pictures and diagrams
- Landscape and vertical style

PIS Review

It’s a worthwhile exercise to have a ‘dry run’ of your patient information sheet on a similar patient group so that you can:

- Work out any wrinkles and potential misunderstandings
- Familiarise yourself with it
- Prepare yourself for the sort of questions you’re likely to get asked
The consent form

- Is a record of the informed consent discussion.
- Re-consenting may be required

Why do patients withdraw?

- Fed up with arduous visits
  - Too time consuming
  - Too many invasive investigations
  - Too many questionnaires
- Adverse events
- Concomitant medication
- Lack of effect or cured
- Long follow-up and lose interest

Withdrawal Process

- Withdrawal of the consent to participate that was previously given
- If they do decide to withdraw then ascertain what they are withdrawing from!
- Give them choices:
  - Taking study drug
  - Follow-up clinics
  - Seeing a particular clinic staff member
  - Everything

Think

A 12 year old child attends a routine asthma outpatient appointment with his grandparents (his parents are out of town). The child is potentially suitable for screening for a trial involving a new inhaler. How would you proceed?

1. Ask the grandparents to sign the consent.
2. Ask the nurse to sign the consent.
3. As this is not an emergency, wait for parents to return home.

When it all gets a bit difficult....

Some special considerations
**Minors - Hierarchy**

- A parent or person with parental responsibility should always be approached first.
- If a parent is unavailable or unable to consent, then a professional legal representative may be appointed.
- If a professional legal representative is also unavailable, then an experienced staff member or doctor may be approached.

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**Minors (cont)**

- In the UK, there are two legal systems running in parallel:
  - Studies involving CTIMP s – a minor is defined as under 16 years of age and consent from a parent or legal representative is required as stipulated in the Medicines for Human Use (Clinical Trials) Regs.
  - Studies not involving CTIMPs – Statute law applies | Age of Legal Capacity (Scotland) Act 1995 or Children (Scotland) Act 1995.
- Consent must represent assumed will of the child.
- Explicit wishes of child capable of forming opinion are considered.
- Information to child according to capacity for understanding, given by experienced staff (separate info sheets for children).
- MRC Ethics Guide.

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**AWI (cont)**

- Always remember:
  - A suitably qualified and experienced member of the research team must assess that the potential participant is unable to give consent for themselves.
  - This assessment must be fully documented in the relevant paperwork.
  - Consider: Incapacity may be transient and assessment is an ongoing process.

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**Consent in Emergency Situations**

- Statutory Instrument 2004 No. 2984
- Now possible to enter an incapacitated person into a clinical trial involving emergency medicine without prior consent.
- Previously, such patients could not be enrolled into clinical trials involving emergency medicine without the consent of their legal representative.
- According to the amended Regulations, an incapacitated person can be enrolled without prior consent provided that the following conditions are met:
  - Treatment is required urgently.
  - The nature of the trial also requires urgent action.
  - It is not reasonably practicable to meet the conditions stated in the Regulations without respect to obtaining consent.
  - An ethical committee has given prior approval to the procedure under which the action is taken.
- The Adults with Incapacity (Scotland) Act 2000 has undergone similar amendment to provide for incapacitated persons in Scotland to be entered into clinical trials involving emergency medicine without prior consent.

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**Harmonised...?**

An unconscious stroke patient is eligible for a trial involving a new anti-clothing drug. A personal legal representative cannot be identified in time. How would you proceed with consent?

1. Find a legal representative.
2. Carry on regardless and give the drug.
3. Do nothing. Forget the whole thing.

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**Adults with Incapacity (cont)**

- Part 5, Section 51 of the Adults with Incapacity (Scotland) Act 2000.
- Legal representative
  - Personal: Guardian or welfare attorney who has power to consent.
  - The adult’s nearest relative.
- Professional: Doctor primarily responsible for the patient’s medical treatment (not connected with the conduct of the trial) or
  - person nominated by healthcare provider.
- Consent by legal rep represents assumed will of participant.

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Summary

- All clinical trial subjects must sign informed consent prior to the recording of any information on study-specific forms.
- If vulnerable subjects are to be included then they must be identified as such and specific arrangements must be made for their participation.
- Only authorised personnel should complete study-specific tasks.
- If you don't comply with legal requirements regarding informed consent than you break the law.

Some links.....

- NRES
- RCN
  - http://www.rcn.org.uk/development/researchanddevelopment/ris/publications_and_position_statements/informed_consent
- MRC
  - 2004, MRC Ethics Guide “Medical Research Involving Children”
    http://www.mrc.ac.uk/Utilities/DocumentRecord/index.htm?Id=MRC002430
  - 2007, MRC Ethics Guide “Medical research involving adults who cannot consent”
    http://www.mrc.ac.uk/Utilities/DocumentRecord/index.htm?Id=MRC004444

So remember – It’s a process not like this.....

Thank-you

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