The Office of Human Subjects Research’s Compliance Monitoring Program Educational Seminars:

Common Informed Consent Problems and Solutions

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June 13, 2007 (EBMC – BRB G01,03)
Presentation Content

• Awareness of common Informed Consent Form problems
• Understanding common Informed Consent Process problems
• Offer strategies to improve Informed Consent compliance
• Interactive examination of consent problems
Informed Consent Problems…
Main Findings from Monitoring and Audits:

• The Consent Form:
  – expired
  – altered
  – non-IRB approved (no stamp or logo)
  – incorrect (e.g., e-mailed version or for another study)

• The Consent Process:
  – missing or incorrect or unauthorized signatures
  – missing or incorrect dates
  – no verification of the consent process or indication that the subject received a copy of the consent
  – missing forms/document retention
  – not re-consenting (WIRB)
  – not following the IRB approved consent process
Informed Consent Form Problems...
Expired Forms

"Paper Application"

eIRB Application

13. What does your signature on this consent form mean?
By signing this consent form, you are not giving up any legal rights. Your signature means that you understand the information given to you in this form, you accept the provisions in the form, and you agree to join the study.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Do not sign after the expiration date of 09/26/2006.

For adults and children capable of giving consent:

Signature Date

Relationship of Signatory to Participant

For children not capable of giving consent:

Signature Date

Signature of Parent

Date

Signature of Legal Guardian (when applicable)

Date

Signature of Person Nominating Consent (investigator or IRB-approved designee)

Date

Witness to Consent Procedure (optional) name (IRB or Sponsor required)

Date

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD.

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Combined Informed Consent Form

February 2003 Version 1
Informed Consent Form Problems...

Alterations to the Form

- Changes made to the form itself reflecting exceptions or deviations to the approved protocol...

Blood and Urine Samples

Blood and urine samples collected for research purposes are an important part of this long-term study. We will be collecting blood and urine samples to see how your body deals with inflammation (irritation) and blood clotting (clumping of blood cells). We are also interested in studying different substances in your blood that might cause disease. We will collect about 1 tablespoon of blood at each 3-month visit, and about 4 tablespoons of blood at each monthly lab visit. This includes blood tests you may need as part of your routine care.

We will also collect a urine sample at the same time as the blood sample.

If children weigh less than 30 kg (66 lbs), a smaller amount of blood will be collected.

Samples for routine care will always be collected first, and then research samples to follow Federal guidelines on blood collection.

What are the risks or discomforts of the study?

You may become tired and fatigued with some of the testing. Every effort will be made to make your research visits as comfortable and convenient as possible. Breaks for lunch and rest will be scheduled; other may be taken if needed.

There is the possible risk of loss of confidentiality.
Informed Consent Form Problems… Incorrect or Invalid Form

• Occurs when related studies are being conducted simultaneously or have similar application numbers.

• *Unstamped* Consents are emailed to the site.
  – The form is occasionally utilized without heeding the accompanying IRB instruction:

  “Dear Dr. Welby,
  Attached is the IRB approval memo for the continuing review, for your protocol number 01-02-03-04. The attached electronic consent form *cannot be used to enroll subjects*; it is only for your files. The hard copy of the approval memo and stamped consent form, that can be used to enroll subjects, have been sent to your office. Contact the IRB office at 5-3008 if you have any questions about this information.”
Informed Consent Form Problems...

Forms Not IRB approved

- Site uses unstamped ICF email-version upon approval/re-approval (no stamp)
- Site uses eIRB submitted version (no logo)
Informed Consent Process Problems...
Signatures Irregularities

• **Missing Signatures**
  – Either: PI, Consent Designee, Parent, Legally Authorized Representative, and/or witness (if required)

• **Form signed by unapproved signatories**
  – Personnel not added to the study
    • Post-docs
    • Research Fellows
    • Research Assistants
    • Nurses
    • Study Coordinators
    • Administrative assistants
    • Other clinical or office staff

• **Signatures in the wrong place**
Informed Consent Process Problems...

Improper Signature Dates

• Form dated after commencement of study procedures or missing
Informed Consent Process Problems…

• Failure to re-consent or use most up-to-date approved ICF per IRB/WIRB instruction…

This consent form replaces the previously approved consent form. Use this consent form to enroll participants. If you submit additional consent form changes to the IRB in the future, use this consent form to make those changes.

1.) Only consent forms with a valid approval stamp may be presented to participants. All consent forms signed by participants enrolled in the research should be retained on file. The Office of Human Subjects Research conducts periodic compliance monitoring of approved research and consent documentation review is part of such monitoring.
Informed Consent Process Problems…

Document Organization

• Lost, missing, or misfiled…
• Keeping only the signature page of the consent
• No instruction of where forms will be stored
• No verification that subject received a copy of the consent form
• Documents not maintained in a secure location

*Be Advised: Data for subjects without consents may be disqualified!*
Informed Consent Process Problems
Not Following IRB Approved Procedure

• Examples:
  – Sending consent home to be signed/dated
  – Employing an unapproved consent summary (e.g., “short form”) in place of the form
  – Utilizing an oral consent for a study requiring a written consent

• Specific Event:
  – A protocol has an IRB Approved Consent Process:
    “A written Informed Consent Form and [HIPAA Authorization] will be […] signed by each subject or guardian prior to enrollment into the study. The consent form, approved by the Johns Hopkins Institutional Review Board, will be supplied by the investigator. The investigator will keep the original signed copies of all consent forms in the files.”

• Monitoring Finding: Consent was obtained over the phone, even though oral consent was not approved for the protocol.
Non-Compliance Don’ts

- Don’t change dates (e.g., “back-dating”)
- Don’t correct mistakes (e.g., “striking out” and re-entering “correct” date or signature)
- Don’t add or delete text
- Don’t use correction fluid (white out)
- Don’t “re-consent” in response to errors
- Don’t be hasty
Compliance Do’s

• Do get IRB approval for all changes to the consent form in response to
  – Changes/corrections to the form
  – Changes to the protocol procedures
  – Changes to Risks/Benefit

• Do utilize consent process checklist

• Do use the most recent, approved consent (check for the stamp or logo!)

• Do generate a Note-To-File explaining consent form errors, immediate response, and corrective action
Informed Consent Form checks…

- The correct, IRB approved form (stamp or logo)
- The required signatures on the proper lines
- The correct dates, written by the person signing the form
- Use a checklist to confirm the proper form is being used and the approved consent process is being followed…
- Be sure anyone who signs the ICF is IRB approved (and trained) to do so
- That copies are appropriately distributed
- That the process is documented
INFORMED CONSENT CHECKLIST

Subject initials: ________________

Date of Birth: ________________

Subject study identifier: _________

Consent Version #:Expiration Date: ________________

Consent signed and dated by subject: YES ☐ NO ☐
Date: ____________

Was a copy of the consent given to the subject: YES ☐ NO ☐

Consent signed and dated by parent: YES ☐ NO ☐ N/A ☐
Date: ____________

Assent signed by minor: YES ☐ NO ☐ N/A ☐

Assent NOT signed by minor; reason not obtained: ____________________________________________________________________________

Verbal assent obtained and assent signed by parent, documenting this assent
YES ☐ NO ☐ N/A ☐

Consent/assent obtained by:
Print name ____________________________ Signature ____________________________ Date ____________

Informed Consent Source Documentation

Consent form is verified IRB approved and current
Date IRB Approved: ________________ Expiration Date: ________________

Patient reviewed consent

Patient understands the purpose, risks and benefits of study participation

The initial consent process was completed prior to any study related procedures being performed

Patient was provided a copy of the signed informed consent

Patient was given contact information to call with any questions regarding the study

Comment(s)*

Consenter signature and date

Protocol:
Subject ID:
Date of Visit:
Time of Visit:
Approved Consent Forms…

What to look for

• Examine the consent form you are about to use verify its validity:

   "Don’t sign a consent form without one…"
Personnel Authorized to Obtain Consent

Making sure those who get consent and sign the form are IRB approved to do so…

Responsibilities Delegation Log

<table>
<thead>
<tr>
<th>Staff Name/Role</th>
<th>Responsibilities</th>
<th>Signature</th>
<th>IRB Appr. Date</th>
<th>PI Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marcus Welby, M.D. Principal Investigator</td>
<td>1, 2, 3, 4, 6, 7, 8, 9</td>
<td>M. Welby</td>
<td>5/1/2007</td>
<td>W</td>
</tr>
<tr>
<td>Stella Artois, CRA, Study Coordinator</td>
<td>2, 3, 4, 5, 9</td>
<td>Stella Artois</td>
<td>6/1/2007</td>
<td>W</td>
</tr>
<tr>
<td>Bud Weiser, M.D. Co-Investigator</td>
<td>1, 2, 7, 8</td>
<td>Bud Weiser</td>
<td>5/1/2007</td>
<td>W</td>
</tr>
</tbody>
</table>

Responsibility Key

1. Obtains Consent
2. Evaluates Subject Inclusion/Exclusion criteria
3. Maintains Source Documents
4. Completes Case Report Forms
5. Dispenses Study Drug
6. Administrative
7. Obtains Laboratory Values (sample collection)
8. Interprets Medical Reports and Laboratory Results (i.e. ECGs, MRIs, etc.)
9. Adverse Event Documenting and Reporting

el RB Study Team List

9.0 Study Team members

Click Add to add Study Team members or Edit to update Study Team member information:

<table>
<thead>
<tr>
<th>Last</th>
<th>First</th>
<th>Degrees</th>
<th>Primary Dept</th>
<th>Role</th>
<th>Consenting Hopkins participants</th>
<th>Agree to participate</th>
</tr>
</thead>
<tbody>
<tr>
<td>[View] Weiser</td>
<td>Bud</td>
<td>Ph.D.</td>
<td>SOM</td>
<td>Co-Investigator</td>
<td>No</td>
<td>yes</td>
</tr>
<tr>
<td>[View] Artois</td>
<td>Stella</td>
<td>n/a</td>
<td>SOM</td>
<td>Consent Designee</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>[View] Adams</td>
<td>Samuel</td>
<td>MA</td>
<td>SOM</td>
<td>Other Staff</td>
<td>no</td>
<td>yes</td>
</tr>
</tbody>
</table>
Example of Consent Documentation

• May be entered and filed as part of the clinic note or EPR or,

• May be filed in research record as narrative confirmation of the consent process

• Example Statement:

  Mrs. Tobe Namedlater agreed to join our study today. I introduced the protocol to her and gave her the informed consent form. She read it, and we went over the form and details of the protocol. She had no questions and exhibited comprehension of the study’s procedures, risks, benefits, and that she could withdraw her consent at any time. She and I signed and dated the form. She was given a copy of the Informed Consent Form and encouraged to contact me with any questions. Additional copies are filed in the study record and her clinic chart. The consent was signed prior to any study specific procedures being undertaken.
Informed Consent Process Compliance...

Consider the following when describing the consent process in your protocol and follow the process consistently:

• Who...
  – Signs
  – Gets copies
• How…
  – The “sit-down,” “send-home,” “spontaneous”
  – Verification of comprehensions/Q&A
• When…
  – Information only versions/take-home
  – ICF signed/dated on or before study procedures begin
• Where…
  – Location of consent process/Q&A
  – Location of original and other copies
Interactive Exercise: “Spot the Errors”

• Givens:
  – Only the PI and a consent designee are IRB approved to obtain consent
  – Protocol Approval Period is 6/1/07-5/31/08
  – Subject begins study on 6/12/07
  – No new revisions from the previous consent
  – The Study is approved for adult enrollment
  – No witness is required
Interactive Exercise: IRB Stamped Consent Form

“Spot the Errors”: 
Interactive Exercise: eIRB Consent Form

“Spot the Errors”:
Conclusion…

• Consent is not just the static form, it’s a dynamic process by which the subject and investigator embark on a collaborative relationship optimized via
  – Conscientious Consent Planning
  – Consistent Implementation
  – Complete Verification

• Why follow the rules?
  – To be in compliance with Regulations
  – To maximize the safety of the research subject
  – To demonstrate study conduct integrity
How to Get in Touch with the Compliance Monitoring Team

• Please contact the JHM IRB office at 410-955-3008 if you have questions regarding regulatory guidance.

• For general questions and assistance, the monitors may be contacted at the JHM-IRB office. Please ask for “Compliance.”

• The Monitors may also be contacted directly by email:
  – jschulc1@jhmi.edu
  – fluthard@jhmi.edu
Questions?

Let's see... "Possible... dizziness, cramps, nausea... SUPERPOWERS!!"

Hey, sign me up!!

HUMAN TEST SUBJECTS WANTED

Another successful recruitment drive for the Collins University Medical Research Center.
References


• JHU Guidance: http://irb.jhmi.edu/Guidelines/informedconsentguidance.html