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

Common Informed Consent Problems and Solutions

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Frederick W. Luthardt, MA, CCRP

June 12, 2007 (JHBMC – Carroll Auditorium)
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"

Date: June 1, 2007
Principal Investigator: Marcus Welby, M.D.
Application Number: 01-02-03-04

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

NOT VALID WITHOUT THE IRB STAMP OF CERTIFICATION
APPROVED
SEP 2 9 2005
JHM IRB

Do not sign after the expiration date of: 09/28/2006

FOR ADULTS AND CHILDREN CAPABLE OF GIVING CONSENT:
Participant's Signature — Date 6/12/07

FOR ADULTS NOT CAPABLE OF GIVING CONSENT:
Signature of Surrogate/Guardian/Health Care Agent for Participant — Date
Relationship of Surrogate to Participant: _____

FOR CHILDREN NOT CAPABLE OF GIVING CONSENT:
Signature of Parent — Date
Signature of Parent # 2 (45 CFR 406 and 407 studies) — Date
Signature of Legal Guardian (when applicable) — Date

SIGNATURE(S):
Signature of Person Obtaining Consent (Investigator or IRB Approved Designee) — Date 6/12/07
Witness to Consent Procedures (Optional unless 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.

FOR OFFICE USE ONLY:
STUDY APPROVED FOR ENROLLMENT OF: _X_ Adults Only ___ Adults and Children ___ Children Only

eIRB Application

JOHNS HOPKINS
Approval Expires *09/26/2006*

Date: June 1, 2007
Principal Investigator: Marcus Welby, M.D.
Application Number: NA_0000xxxx

15. What does your signature on this consent form mean?
Your signature on this form means that:
- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

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

This consent form is approved from 09/27/2005 to 09/26/2006.

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

FOR ADULTS AND CHILDREN CAPABLE OF GIVING CONSENT:
Participant's Signature — Date 6/12/07

FOR ADULTS NOT CAPABLE OF GIVING CONSENT:
Signature of Surrogate/Guardian/Health Care Agent for Participant — Date
Relationship of Surrogate to Participant: _____

FOR CHILDREN NOT CAPABLE OF GIVING CONSENT:
Signature of Parent — Date
Signature of Legal Guardian (when applicable) — Date
Signature of Child (over 12 years old) for Assent — Date

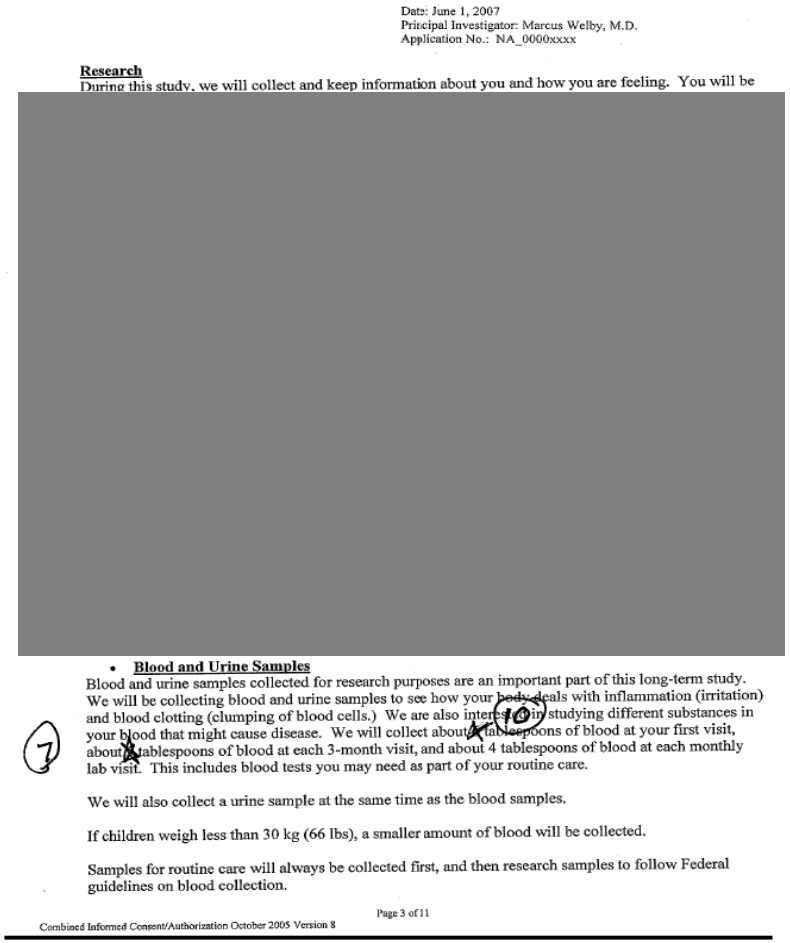
SIGNATURE(S):
Signature of Person Obtaining Consent (Investigator or IRB Approved Designee) — Date 6/12/2007
Witness to Consent Procedures (Optional unless IRB or Sponsor required) — Date

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.

FOR OFFICE USE ONLY:
STUDY APPROVED FOR ENROLLMENT OF: ___ Adults Only _X_ Adults and Children ___ Children Only

Informed Consent Form Problems… Alterations to the Form

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



Date: June 1, 2007
Principal Investigator: Marcus Welby, M.D.
Application No.: NA_0000xxxx

Research
During this study, we will collect and keep information about you and how you are feeling. You will be

- **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 4 tablespoons of blood at your first visit, about 4 tablespoons 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 samples.

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.

Page 3 of 11
Combined Informed Consent/Authorization October 2005 Version 8

Date: June 1, 2007
Principal Investigator: Marcus Welby, M.D.
Application No.: NA_0000xxxx

you try your best on each one. You do not have to answer any question that you do not wish to, and you may stop at any time.

The tests may require up to five hours to complete, but we will take breaks for rest, lunch, etc. If the testing cannot be completed in one day, we would ask that you return for one additional visit within two weeks.

In some cases, portions of some of the tests will be audio- or videotaped or otherwise recorded. Your identity will not be disclosed on any recording. The recording will be used only for research and teaching purposes.

Two years later, we will contact you and ask you to return to have the same tests and interviews performed again. Thereafter, if funding for the study permits, we would like to ask you to return for periodic follow-up visits, not more often than once a year.

In order to make sense out of your test results, we need to access information in your medical record and other research records. By agreeing to participate in this study, you are authorizing us to obtain your medical records from your health care providers, and your research records from other JHU research studies that we are conducting.

NOT FOR CANCER GROUP

mcw 6/1/07

What are the risks or discomforts of the study?
You may become tired and frustrated with some of the testing. Every effort will be made to make your research visit 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.

5.
6.
7.
8.
9.

Combin

Informed Consent Form Problems… Incorrect or Invalid Form

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

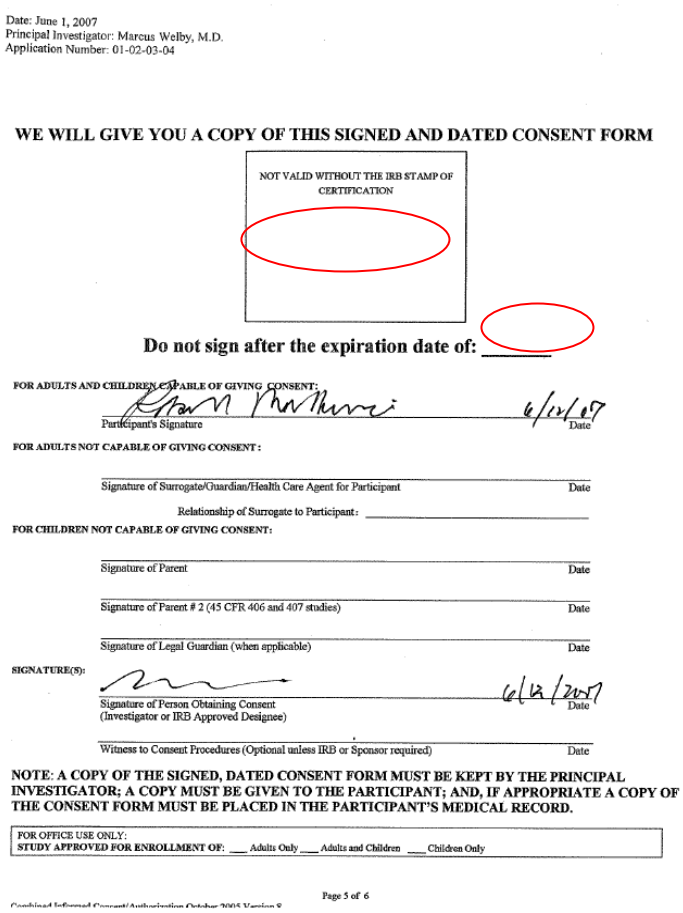
- *Unstamped* Consents are emailed to the site.
  - The form is occasionally utilized without heeding the accompanying IRB instruction:

"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)



Date: June 1, 2007
Principal Investigator: Marcus Welby, M.D.
Application Number: 01-02-03-04

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

NOT VALID WITHOUT THE IRB STAMP OF CERTIFICATION

Do not sign after the expiration date of: _____

FOR ADULTS AND CHILDREN CAPABLE OF GIVING CONSENT:

Participant's Signature — Date 6/12/07

FOR ADULTS NOT CAPABLE OF GIVING CONSENT:

Signature of Surrogate/Guardian/Health Care Agent for Participant — Date

Relationship of Surrogate to Participant: _____

FOR CHILDREN NOT CAPABLE OF GIVING CONSENT:

Signature of Parent — Date

Signature of Parent # 2 (45 CFR 406 and 407 studies) — Date

Signature of Legal Guardian (when applicable) — Date

SIGNATURE(S):

Signature of Person Obtaining Consent (Investigator or IRB Approved Designee) — Date 6/12/2007

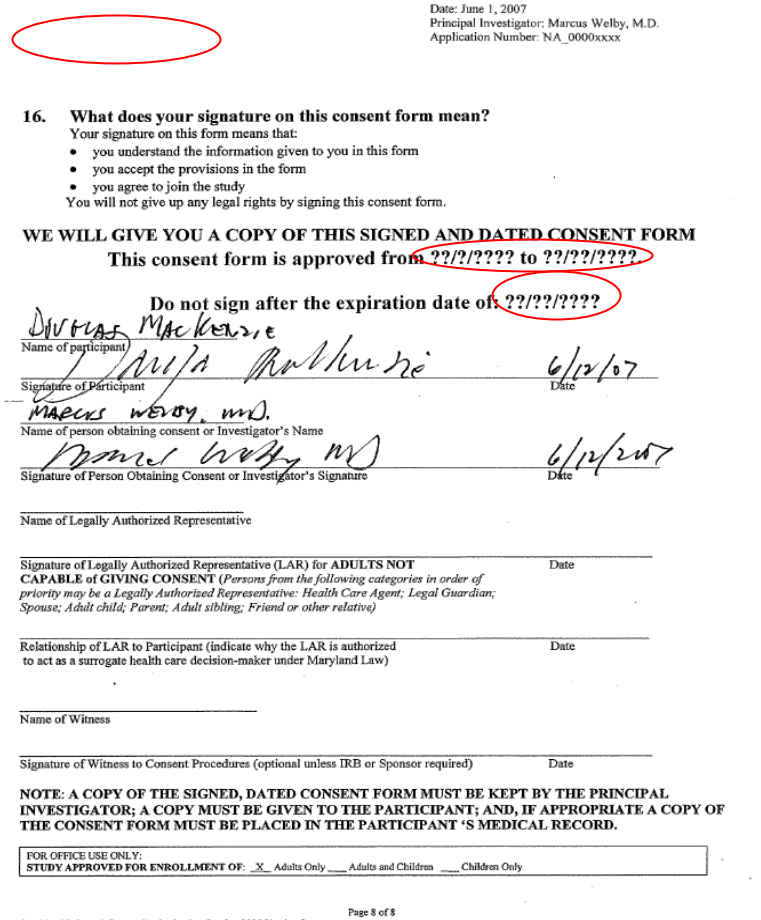
Witness to Consent Procedures (Optional unless IRB or Sponsor required) — Date

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.

FOR OFFICE USE ONLY:
STUDY APPROVED FOR ENROLLMENT OF: ___ Adults Only ___ Adults and Children ___ Children Only

Page 5 of 6

Combined Informed Consent/Authorization October 2005 Version 8



Date: June 1, 2007
Principal Investigator: Marcus Welby, M.D.
Application Number: NA_0000xxxx

16. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

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

This consent form is approved from ??/?/???? to ??/??/????

Do not sign after the expiration date of: ??/??/????

Name of participant: DOUGLAS MACKENZIE

Signature of Participant — Date 6/12/07

Name of person obtaining consent or Investigator's Name: MARCUS WELBY, M.D.

Signature of Person Obtaining Consent or Investigator's Signature — Date 6/12/2007

Name of Legally Authorized Representative

Signature of Legally Authorized Representative (LAR) for **ADULTS NOT CAPABLE of GIVING CONSENT** (*Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)* — Date

Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under Maryland Law) — Date

Name of Witness

Signature of Witness to Consent Procedures (optional unless 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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Page 8 of 8

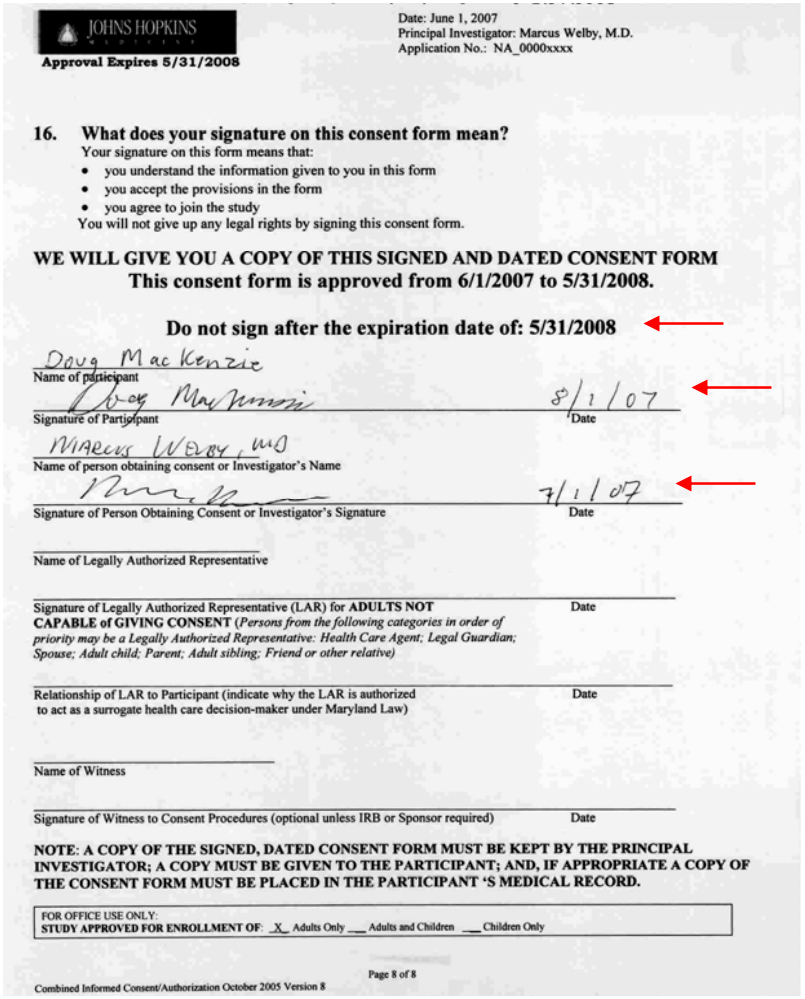
Combined Informed Consent/Authorization October 2005 Version 8

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



JOHNS HOPKINS MEDICINE

Approval Expires 5/31/2008

Date: June 1, 2007
Principal Investigator: Marcus Welby, M.D.
Application No.: NA_0000xxxx

16. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM
This consent form is approved from 6/1/2007 to 5/31/2008.

Do not sign after the expiration date of: 5/31/2008

Doug MacKenzie
Name of participant

Doug MacKenzie — 8/1/07
Signature of Participant — Date

Marcus Welby, MD
Name of person obtaining consent or Investigator's Name

7/1/07
Signature of Person Obtaining Consent or Investigator's Signature — Date

Name of Legally Authorized Representative

Signature of Legally Authorized Representative (LAR) for **ADULTS NOT CAPABLE of GIVING CONSENT** *(Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)* — Date

Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under Maryland Law) — Date

Name of Witness

Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required) — Date

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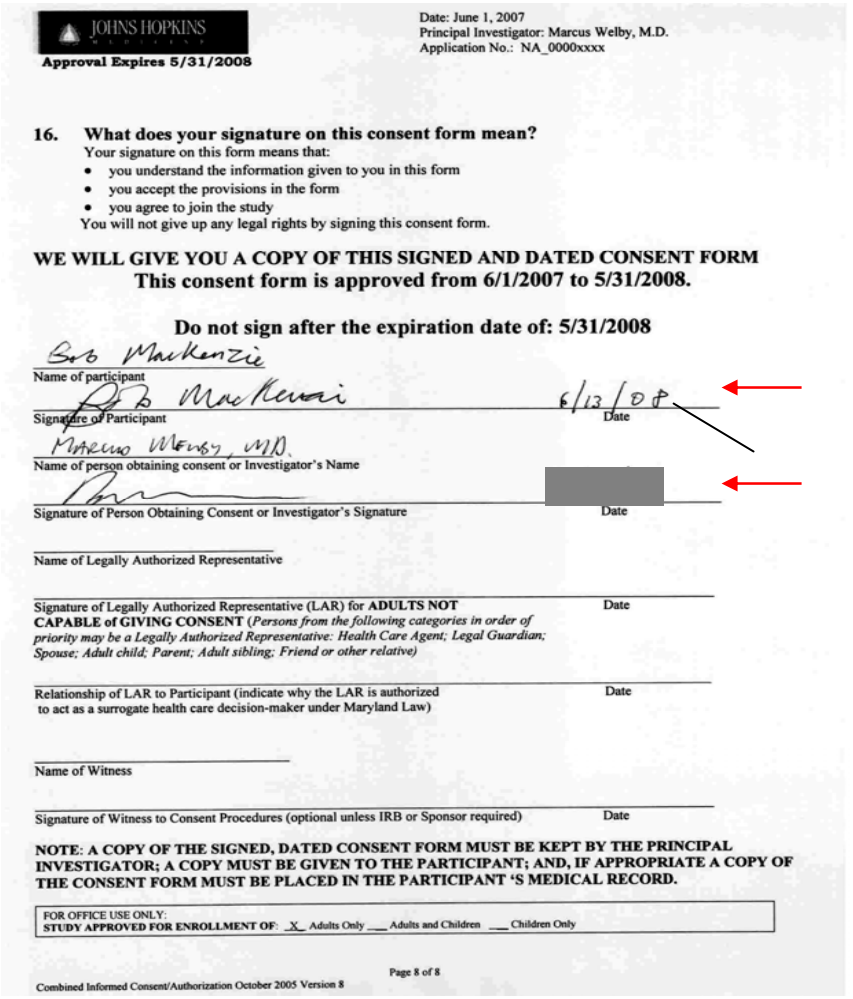
Page 8 of 8
Combined Informed Consent/Authorization October 2005 Version 8



JOHNS HOPKINS MEDICINE

Approval Expires 5/31/2008

Date: June 1, 2007
Principal Investigator: Marcus Welby, M.D.
Application No.: NA_0000xxxx

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- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM
This consent form is approved from 6/1/2007 to 5/31/2008.

Do not sign after the expiration date of: 5/31/2008

Bob MacKenzie
Name of participant

Bob MacKenzie — 6/13/08
Signature of Participant — Date

Marcus Welby, MD
Name of person obtaining consent or Investigator's Name

Signature of Person Obtaining Consent or Investigator's Signature — Date

Name of Legally Authorized Representative

Signature of Legally Authorized Representative (LAR) for **ADULTS NOT CAPABLE of GIVING CONSENT** *(Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)* — Date

Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under Maryland Law) — Date

Name of Witness

Signature of Witness to Consent Procedures (optional unless 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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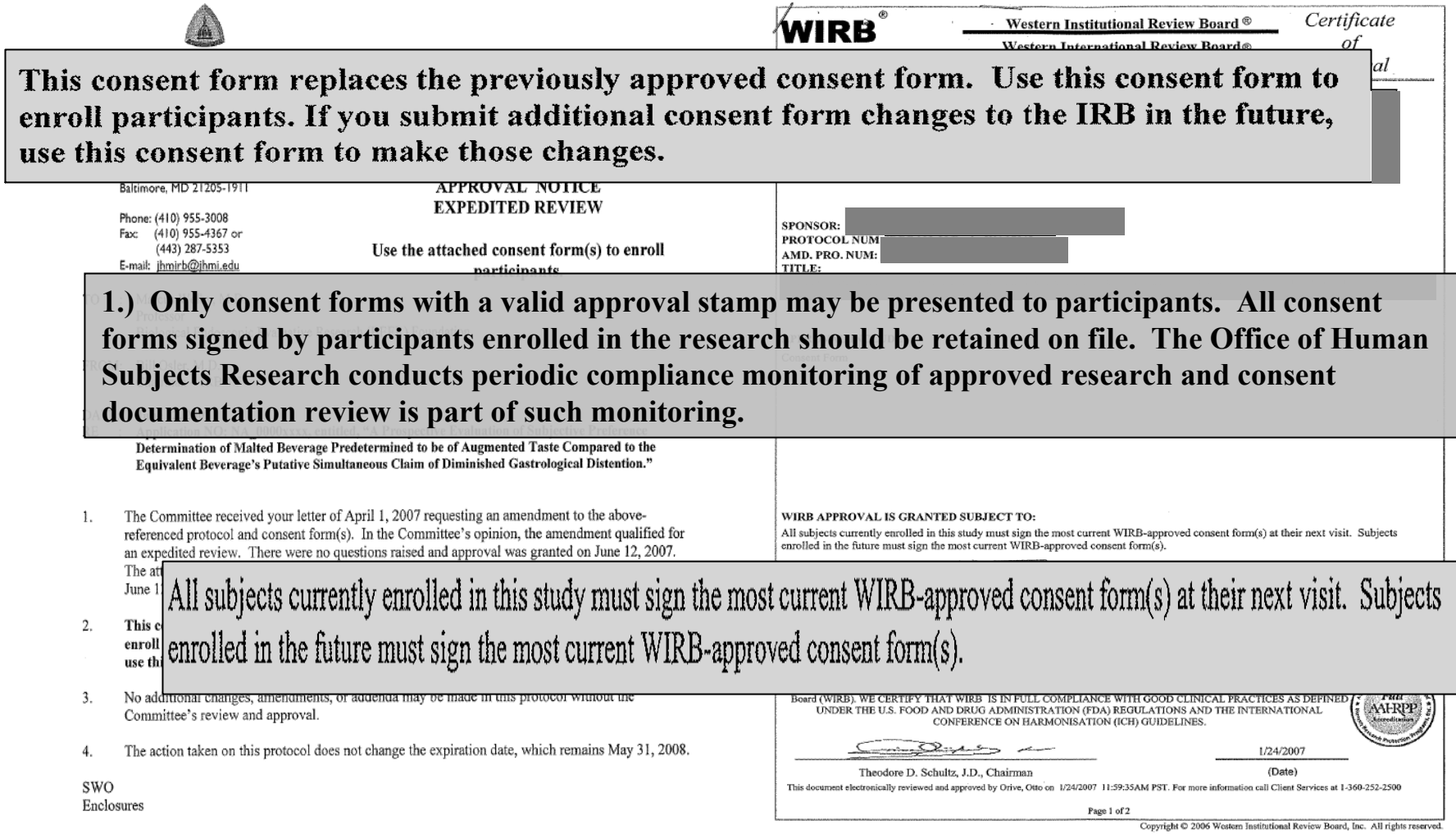
Page 8 of 8
Combined Informed Consent/Authorization October 2005 Version 8

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.

WIRB® Western Institutional Review Board ® Certificate of

Baltimore, MD 21205-1911

Phone: (410) 955-3008
Fax: (410) 955-4367 or (443) 287-5353
E-mail: jhmirb@jhmi.edu

APPROVAL NOTICE
EXPEDITED REVIEW

Use the attached consent form(s) to enroll participants

SPONSOR:
PROTOCOL NUM:
AMD. PRO. NUM:
TITLE:

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.

Determination of Malted Beverage Predetermined to be of Augmented Taste Compared to the Equivalent Beverage's Putative Simultaneous Claim of Diminished Gastrological Distention."

1. The Committee received your letter of April 1, 2007 requesting an amendment to the above-referenced protocol and consent form(s). In the Committee's opinion, the amendment qualified for an expedited review. There were no questions raised and approval was granted on June 12, 2007. The at
June 1

2. **This c**
enroll
use th

3. No additional changes, amendments, or addenda may be made in this protocol without the Committee's review and approval.

4. The action taken on this protocol does not change the expiration date, which remains May 31, 2008.

SWO
Enclosures

WIRB APPROVAL IS GRANTED SUBJECT TO:
All subjects currently enrolled in this study must sign the most current WIRB-approved consent form(s) at their next visit. Subjects enrolled in the future must sign the most current WIRB-approved consent form(s).

All subjects currently enrolled in this study must sign the most current WIRB-approved consent form(s) at their next visit. Subjects enrolled in the future must sign the most current WIRB-approved consent form(s).

Board (WIRB). WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Theodore D. Schultz, J.D., Chairman

1/24/2007
(Date)

This document electronically reviewed and approved by Orive, Otto on 1/24/2007 11:59:35AM PST. For more information call Client Services at 1-360-252-2500

Page 1 of 2

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

Checklist Examples…

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

Protocol:
Subject ID:
Date of Visit:
Time of Visit:

Informed Consent Source Documentation

	Yes	No*
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)*

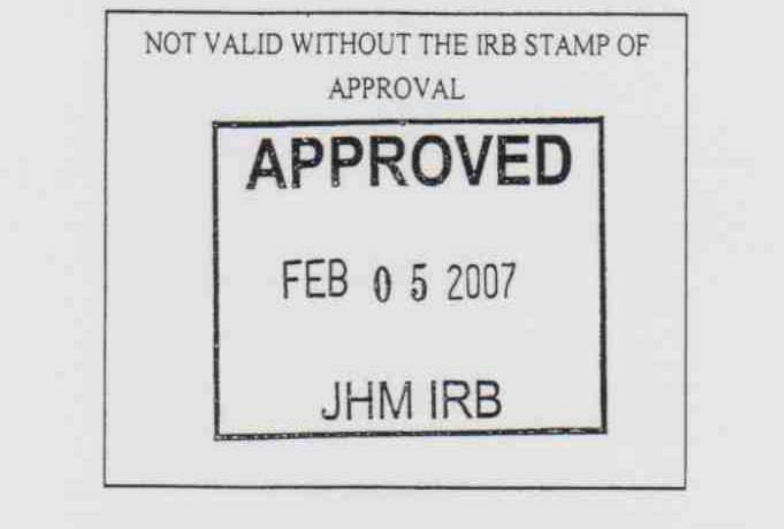
_____
_____
_____
_____

Consenter signature and date

Approved Consent Forms…
What to look for

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

"Paper Applications"



eIRB Applications

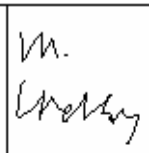
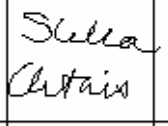
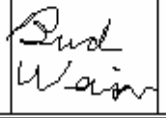
Approval Expires 10/09/2007

"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

Staff Name/Role	Responsibilities	Signature	IRB Appr. Date	PI Initials
Marcus Welby, M.D. **Principal Investigator**	1, 2, 3, 4, 6, 7,8,9		6/1/2007	
Stella Artois, CRA , **Study Coordinator**	2, 3, 4, 5,9		6/1/2007	
Bud Weiser, M.D. **Co-Investigator**	1, 2, 7,8		6/1/2007	

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

eIRB Study Team List

9.0 Study Team members

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

	Last	First	Degrees	Primary Dept	Role	Consenting Hopkins participants	Agree to participate
[View]	Weiser	Bud	Ph.D.	SOM	Co-Investigator	No	yes
[View]	Artois	Stella	n/a	SOM	Consent Designee	yes	yes
[View]	Adams	Samuel	MA	SOM	Other Staff	no	yes

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 joined 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:

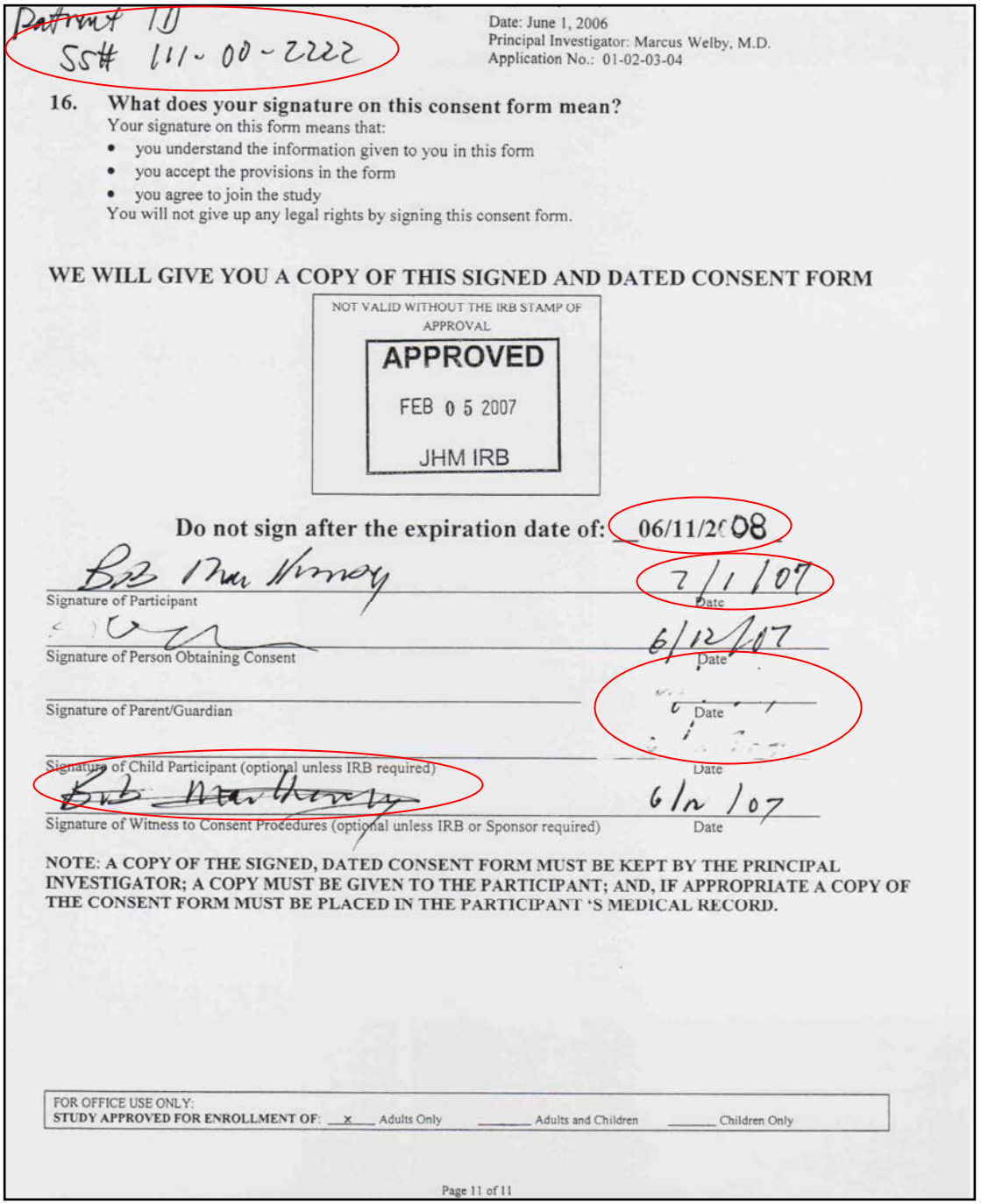
- Who...
  - Signs
  - Gets copies
- How…
  - The “sit-down,” “send-home,” “spontaneous”
  - Verification of comprehensions/Q&A
- When…
  - Information only versions/take-home
  - ICF signed/dated on or before study procedures begin
- Where…
  - Location of consent process/Q&A
  - Location of original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



Patient ID
SS# 111-00-2222

Date: June 1, 2006
Principal Investigator: Marcus Welby, M.D.
Application No.: 01-02-03-04

16. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

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

NOT VALID WITHOUT THE IRB STAMP OF APPROVAL

APPROVED
FEB 0 5 2007
JHM IRB

Do not sign after the expiration date of: 06/11/2008

Signature of Participant — Date: 7/1/07

Signature of Person Obtaining Consent — Date: 6/12/07

Signature of Parent/Guardian — Date

Signature of Child Participant (optional unless IRB required) — Date

Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required) — Date: 6/12/07

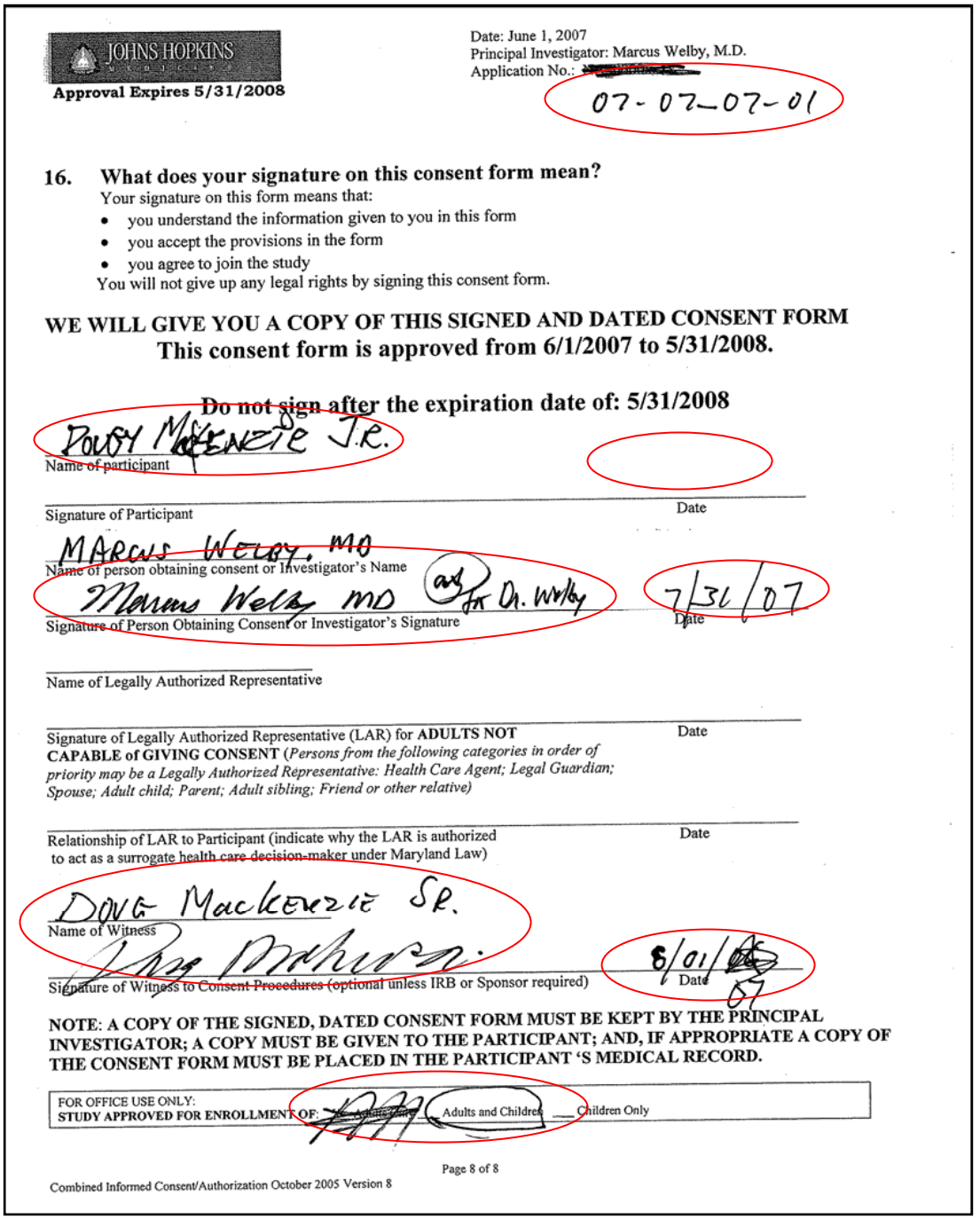
NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT 'S MEDICAL RECORD.

FOR OFFICE USE ONLY:
STUDY APPROVED FOR ENROLLMENT OF: __x__ Adults Only _____ Adults and Children _____ Children Only

Page 11 of 11

Interactive Exercise: eIRB Consent Form

"Spot the Errors":



JOHNS HOPKINS MEDICINE

Approval Expires 5/31/2008

Date: June 1, 2007
Principal Investigator: Marcus Welby, M.D.
Application No.: [redacted]
07-07-07-01

16. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

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

This consent form is approved from 6/1/2007 to 5/31/2008.

Do not sign after the expiration date of: 5/31/2008

Doug MacKenzie J.R.
Name of participant

Signature of Participant — Date

Marcus Welby, MD
Name of person obtaining consent or Investigator's Name

Marcus Welby MD for Dr. Welby
Signature of Person Obtaining Consent or Investigator's Signature — Date 7/31/07

Name of Legally Authorized Representative

Signature of Legally Authorized Representative (LAR) for **ADULTS NOT CAPABLE of GIVING CONSENT** (*Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)* — Date

Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under Maryland Law) — Date

Doug MacKenzie SR.
Name of Witness

Signature of Witness to ~~Consent Procedures~~ (optional unless IRB or Sponsor required) — Date 8/01/07

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.

FOR OFFICE USE ONLY:
STUDY APPROVED FOR ENROLLMENT OF: ~~Adults Only~~ Adults and Children ___ Children Only

Page 8 of 8

Combined Informed Consent/Authorization October 2005 Version 8

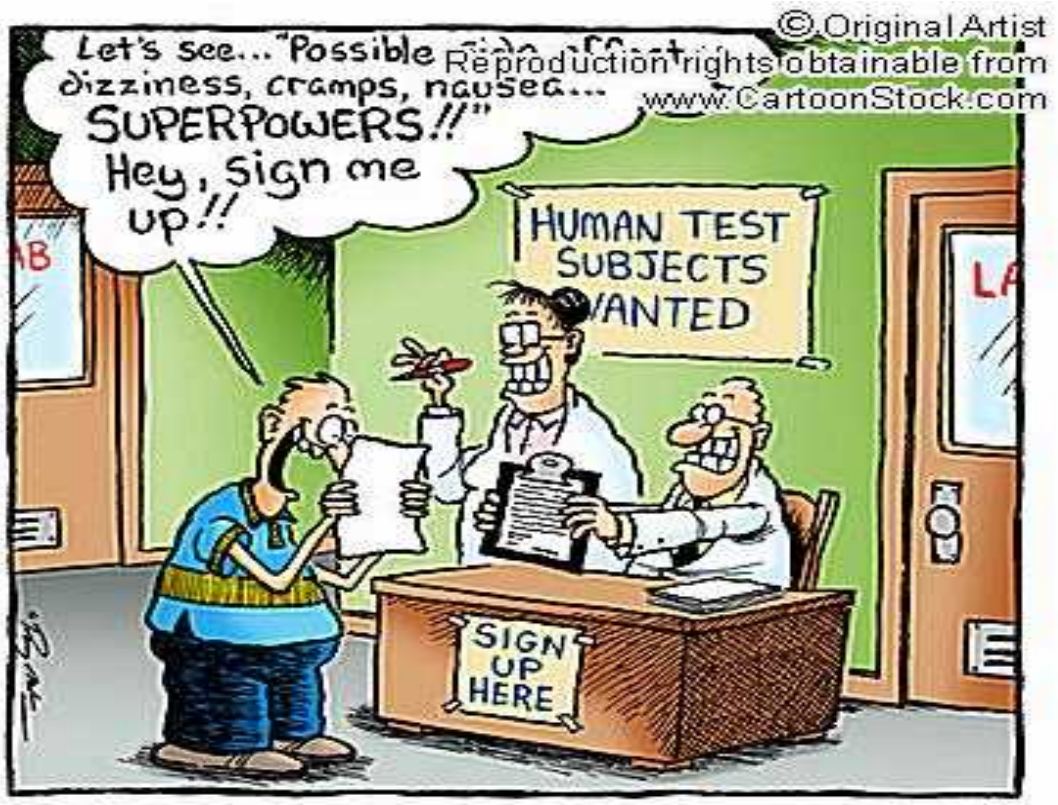
Conclusion…

- 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?



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

References

- FDA Consent Guidance: 21CFR50: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50
- ICH E6: http://www.fda.gov/cder/guidance/959fnl.pdf
- DHHS: “Common Rule” - http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
- JHU Guidance: http://irb.jhmi.edu/Guidelines/informedconsentguidance.html