Consent Forms
Wendy Doggett, doggettw@ohsu.edu
June 28, 2012
Today’s topics

• Tips for consent form writing
• New consent form templates
Consent Process, Consent Discussion
http://www.hhs.gov/ohrp/policy/consent/

• Information sharing, two way street
• Begins with recruitment
• Continues throughout the study
Consent Forms

Three main components:

1. Provides information about the study
2. Promotes understanding
3. Promotes voluntariness
Before you begin . . .

• *Read the protocol.*
  - Hours saved
    - Analyst
    - Reviewers
    - Chair
  - Days saved
    - Rescheduling studies with poor consents
  - Weeks saved
    - Deferrals due to poor consents
Begin with the required OHSU template.
http://www.ohsu.edu/xd/about/services/integrity/policies/irb-forms.cfm#results

• Don’t submit the sponsor’s template.
• Don’t cut and paste from the sponsor’s template.
• The more closely the current OHSU template is followed, using only the protocol for reference, the faster and easier the review.
Reading Level

• 6\textsuperscript{th} - 8\textsuperscript{th} grade reading level is the standard goal.
• OHSU clinical consent template, when completed = 7.9 - 8.4 grade level on Flesch-Kincaid readability scale.
• Flesch-Kincaid has limitations
  ▪ “Information” vs “data”
  ▪ “Immunization” vs “shot”
Flesch-Kincaid

Under “Review” tab in Word
You will have an x-ray done of your wrist and this will show us your bone density but you will not have this x-ray done of your wrist and this will show us your bone density for the next three months.
A code number will be assigned to you, your cells and genetic information, as well as to information about you. Only the investigators named on this consent form will be authorized to link the code number to you. Other investigators who may receive samples of your medical information for research will be given only the code number which will not identify you. Research records may be reviewed and copied by the sponsor, the OHSU Institutional Review Board, the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and the Oregon Clinical & Translational Research (OCTRI). All other parties including employers, insurance companies, and relatives will be refused access to your information unless you provide written permission or unless we are required by law to release it.

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All other parties including employers, insurance companies, and relatives will be refused access to your information unless you provide written permission or unless we are required by law to release it.
Avoid including clinical care information.

• You have been invited to be in this research study because you have tested positive for tuberculosis (TB). TB is a disease caused by a bacterium called *Mycobacterium tuberculosis*. The TB bacteria usually attack the lungs, but can also attack other parts of the body such as the kidney, spine, and brain. If not treated properly, TB disease can be fatal. TB is spread through the air from one person to another. For most people who become infected with TB, the body is able to fight the bacteria to stop them from growing. If the body’s immune system cannot stop them from growing and the TB bacteria are active (multiplying in your body), this is called TB disease.
Use plain language.

• Our rapacious pursuit of individual excellence from our perspective on career management has convinced us of your particular significance in the ongoing expansion and conclusion of our collegial ambitions. Therefore, your revenue will henceforth be augmented by additional semiannual compensation.

• You are a good worker. We are going to give you a bonus twice a year.
Use short sentences. Delete conjunctions like “and” and “but.”

• You will have an x-ray done of your wrist and this will show us your bone density but you will not have this x-ray unless you haven’t already had one done in the last three months. (Grade Level = 12.2)

• You will have an x-ray of your wrist. This will show us your bone density. You won’t have this x-ray if you’ve already had one in the last three months. (Grade Level = 1.8)
Use active rather than passive voice.

• An x-ray will be done of your wrist. This will show us your bone density. This x-ray will not be done if you’ve already had one done in the last three months.

• We will x-ray your wrist to measure your bone density. You will not have this x-ray if you’ve already had one in the last three months.
1st Person, 2nd Person, 3rd Person

- Strike most uses of first person as unduly persuasive.
  - “I understand . . . .”

- Strike most uses of third person as confusing and ungrammatical.
  - “Subjects will have an x-ray.”

- Use second person throughout the form.
  - “You can withdraw from the study at any time.”
Avoid language that fosters the therapeutic misconception.

- Patient - subject
- Your doctor - the study doctor, the investigator
- Study medication - study drug
- Undergoing the study treatment - taking the study drug
- During your study therapy - while you are in the study
Avoid legal and medical/scientific terminology.

- Capitalization of Sponsor, Study Doctor, Investigator, Institution
- On study, off study, informed consent
- Name of study drug (“QRIST-9003”), registered trademarks™ ®
- Data analysis, cross over, assay
- Anatomical terms (intradermal)
- Other medical terms (latent, scleritis)
Write from the subject’s perspective – common correction

• A medical history will be taken, including past medical concerns and surgeries, drugs you’ve taken (both over-the-counter and prescribed), and current medications and health status.  
  (Grade Level = 17.2)

• We will ask you questions about your health.  
  (Grade Level = 2.2)
Write from the subject’s perspective, cont.

Describe procedures from the subject’s perspective.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Day 1</th>
<th>Day 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood for CBC</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Blood for genetic testing</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Blood for HLA testing</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Blood Draw</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Write from the subject’s perspective, cont.

Describe risks from the subject’s perspective.

• Changes to CBC
• Leukopenia due to myelosuppression
• Decrease in red blood cells, which may cause you to feel tired and weak
• Decrease in white blood cells, which may affect your body’s ability to fight infections
• Decrease in platelets, which may increase the risk of bruising and bleeding
Reminder! Before you begin . . .

- Read the protocol.
Organization - Avoid redundancy.

- Visits 3 - 10 will be the same as Visit 2. You will also turn in your drug diary at these visits.
Organization – common problems

Procedures

• At the first and last visits, we’ll ask you questions about your health.

• At Visit 4, you’ll answer health questions.

• Visit 2 and Visit 5
  ▪ We’ll Interview you regarding your health.

SOLUTION: List procedures consistently and in chronological order.
Organization – common problems

Risks

One subject who took the study drug experienced depression. 25% of subjects vomited. There have been three reports of heart attacks.

SOLUTION: List risks in order of likelihood.
Organization – common problems

Risks

• Mild headache
• Sudden loss of consciousness
• Severe headache

Solution: List risks in order of gravity.
Organization – common problems

Risks

Nausea and vomiting are common side effects. Also common are:

• Fainting
• Muscle aches

Many subjects experience fatigue. In one study, nearly everyone who took the drug fell asleep almost instantly.

SOLUTION: List risks in a consistent format (bullet points are preferred).
Before you begin . . .

Please read the protocol.
New Consent/HIPAA Templates

- Clinical Template and Non-Clinical Template
  - Replacing 6 current templates and the HIPAA Authorization templates
- Use the clinical template if your study includes any clinical procedures, like blood draws, imaging procedures, clinical lab tests, non-invasive exams, or dental work.
- When in doubt, use the clinical template.
List of Consent Templates Replaced by “Clinical Consent Template” and “Non-Clinical Consent Template”

<table>
<thead>
<tr>
<th>Category</th>
<th>Template Name</th>
</tr>
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<tbody>
<tr>
<td>Clinical Research Billing Schedule</td>
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<tr>
<td>Clinical Trials</td>
<td></td>
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<tr>
<td>Consent Form</td>
<td></td>
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<tr>
<td>Consent Form - Children's Oncology Group (COG) studies</td>
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<tr>
<td>Consent Form - Consent and HIPAA Authorization</td>
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<tr>
<td>Consent Form - Gene Transfer</td>
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<td>Consent Form - Genetic</td>
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<td>Consent Form - Knight Cancer Institute</td>
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<td>Consent Form - Low Risk</td>
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<td>Consent Form - Media</td>
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<td>Consent Form - Repository Consent/Authorization</td>
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<td>Consent Form - Shriner's</td>
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<tr>
<td>Consent Form - Treatment Use of Drug or Device</td>
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<tr>
<td>Consent Form INSTRUCTIONS (NEW! 3.7.2012)</td>
<td></td>
</tr>
<tr>
<td>Consent Form Signature Templates - Children Ages 15-17</td>
<td></td>
</tr>
<tr>
<td>Consent Form, short - Arabic</td>
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</tbody>
</table>
New Consent/HIPAA Templates

• HIPAA authorization forms are attached at the end of the new templates.
• Andrea Johnson has made them much easier to understand!
• Stand-alone HIPAA authorization forms will no longer be used.
New Consent/HIPAA Templates

• New Consent Summary Sheet
  ▪ Goal is to summarize study in just a few sentences
  ▪ Subjects may show this to friends and relatives or put on the fridge
  ▪ Helpful for reviewers or outside healthcare workers to have a quick understanding of the study
  ▪ Helpful as “refresher” for subjects throughout the study
New Summary Sheet

Clinical Research Consent Summary

You are being asked to join a research study. You do not have to join the study. Even if you decide to join now, you can change your mind later.

If you decide to join, you will be asked to sign a consent form, which shows you give permission to be in the study, and an authorization form, which shows you give permission for us to use your health information for the study.

The purpose of this study is to learn more about diabetes.
In this study, we will learn about a drug called gluconomore. **Gluconomore will be called “the study drug” throughout this form.** We want to learn
- If the study drug is safe and
- What side effects are caused by the study drug.

The study drug is being developed by MaximumPharm, Inc. MaximumPharm, Inc. is paying for the research study. We do not know if the study drug works.
The study drug has not been approved by the Food and Drug Administration (FDA).
The study drug is a tablet taken three times a day with meals.
If you join the study, you will receive the study drug for 8 weeks. You will have 14 visits to OHSU. We will call you once a year for 5 years to check on your health.

There are risks involved in participating in the study, some of which may be very serious.
New Consent/HIPAA Templates

• August 1, 2012 deadline
  ▪ All studies submitted on or after this date must use the appropriate new template.

• Schedule for future updates is every six months.

• Your feedback is welcome.
Brown Bag Sessions will return in September.

Visit our website for more information:
www.ohsu.edu/researchintegrity