



INFORMED CONSENT 201

Writing Informative Informed Consents

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Special Thanks to Original Author and Presenter: Ana Austin,
Michigan Institute for Clinical and Health Research

Objectives:

- Provide information on the available resources at the University of Michigan for developing the consent form.
- Learn how to use a protocol, grant and sponsor's suggestions in a consent form.
- Provide tips and suggestions for difficult sections.

Why is informed consent so important?

- Pragmatic reason—regulations require informed consent except when the IRB can grant a waiver
 - “Except as provided elsewhere in this policy, **no** investigator may involve a human being as a subject in **research** covered by this policy **unless** the investigator has obtained the legally effective informed **consent** of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative **sufficient opportunity to consider** whether or not to participate and that **minimize** the possibility of **coercion** or undue influence. The information that is given to the subject or the representative shall be **in language understandable to the subject** or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.”
45 CFR 46.116

Why is informed consent so important?

- The real reasons—the ethical reasons
 - ‘Respect for Persons’ –an ethical principle expressed by giving prospective subjects the information, time, and conditions they need to make a decision about participating in a study

Types of Informed Consent:

- **This talk will cover written informed consent using the standard IRB Template.**
- Other important types of consent include:
 - IRBMED 'Brief' comprehensive templates
 - For use on minimal/minor over minimal risk studies without billing connected to the study
 - *Currently available from IRBMED staff upon request (to be posted on website in 2008)*
 - Telephonic and web-based consent (ask staff for assistance)
 - Assent of Children (*partially covered in Regs 201*)
 - Waivers of consent (*IC 101*)
 - Waiver of Documentation of consent—an informed consent process takes place but a signature is not collected (*IC 101*)

Informed consent is a PROCESS

- A subject's signature is just one step near the beginning.
- How do you truly make consent an ongoing process?
 - Be empathetic
 - Encourage questions
 - Document the process throughout the visits
 - Validate subjects' comprehension

Why is written informed consent so important?

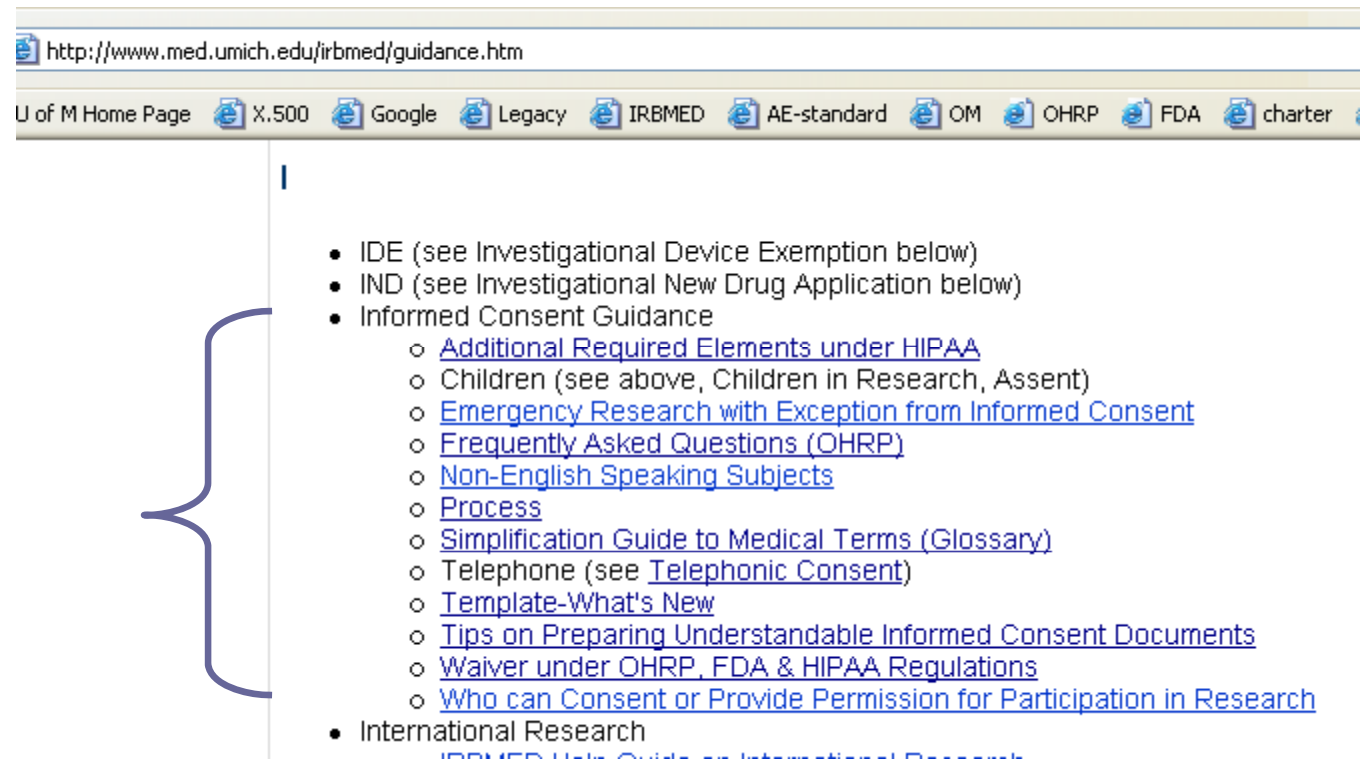
- Both before and after signing a form the form is part of the on-going consent process
 - It reminds subjects:
 - About the purpose of what they are doing
 - About risks to be aware of
 - Who to contact about concerns
 - That they can quit any time without penalty
 - It helps counter the vulnerability of subjects who are under pressure of their circumstances
 - Allows review with others
 - Allows time for reflection

Consent template from UMMS IRB

- STEP-BY-STEP INSTRUCTIONS
- REQUIRED READING: Important instructions appear as “pop-up” bubbles in the template itself. Carefully read all instructions.
- Informed Consent Templates:
- <http://www.med.umich.edu/irbmed/ict.htm>

Resources:

- Your IRB Application Team is there to help!
- The general IRB web page should always be checked to ensure you get the latest forms:
 - <http://www.med.umich.edu/irbmed/>
 - There is also posted guidance about informed consent on the IRBMED Guidance page:



U of M Home Page X.500 Google Legacy IRBMED AE-standard OM OHRP FDA charter

- IDE (see Investigational Device Exemption below)
- IND (see Investigational New Drug Application below)
- Informed Consent Guidance
 - [Additional Required Elements under HIPAA](#)
 - Children (see above, Children in Research, Assent)
 - [Emergency Research with Exception from Informed Consent](#)
 - [Frequently Asked Questions \(OHRP\)](#)
 - [Non-English Speaking Subjects](#)
 - [Process](#)
 - [Simplification Guide to Medical Terms \(Glossary\)](#)
 - Telephone (see [Telephonic Consent](#))
 - [Template-What's New](#)
 - [Tips on Preparing Understandable Informed Consent Documents](#)
 - [Waiver under OHRP, FDA & HIPAA Regulations](#)
 - [Who can Consent or Provide Permission for Participation in Research](#)
- International Research
 - [IRBMED Help Guide on International Research](#)

Sample Consent Form Text

- We'll review some FAQs
- We'll focus on writing of "Problem" Sections:
 - 2.1: Purpose
 - 3.1: Who may participate
 - 4.1: Procedures
 - 5.1: Risks

If consent doesn't make sense to you, it probably won't make sense to your participant.

What information is required by regulations?

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

Regulations also require additional elements ‘as appropriate’

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study
- If the study falls under the FDA's oversight the consent must be dated when signed.

To view the comments:

The screenshot displays the Adobe Acrobat interface. The 'Show' menu is open, with 'Comments' selected. A red arrow points to the 'Comments' option. The document content includes a header with 'UNIVERSITY OF MICHIGAN' and 'PART OF A RESEARCH STUDY', followed by a section titled 'INFORMATION ABOUT THIS FORM'. Below this, there is a paragraph of text and a section titled '1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS'. Three comment boxes are visible on the right side of the document, each with a dashed line connecting it to a specific part of the text. The first comment, [IRBMED1], is yellow and discusses not altering the header. The second, [IRBMED2], is yellow and discusses using the same informed consent document. The third, [IRBMED3], is white and discusses matching titles on all documents.

Final Showing Markup

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Study No.: «ID»
IRB: «IRB»

Project Approval Expires On: «ExpirationDate»

UNIVERSITY OF MICHIGAN
PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. *Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.*

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

Comment [IRBMED1]: e) Users: Do not alter the header of the page. The information is completed when the IRBMED the document in eResearch. Legacy (paper applicants) Use the IRBMED study number, and expiration dates (if known submitting).

Comment [IRBMED2]: F that use the same informed consent document for both adult and subjects, the following text must be substituted for the first paragraph: You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Comment [IRBMED3]: The title must match on all documents (application, protocol, consent etc.). If applicable, add a local note to the title bar.

Page 1 Sec 1 1/8 At 1" Ln 1 Col 1 REC TRK EXT OVR English (U.S)

FAQ: How do I delete the comments?

1. Turn on track changes (in Tools).
2. Click the arrow next to the red X.
3. Click "Delete all Comments in Document"

Standard_ICT.doc - Microsoft Word

File Edit View Insert Format Tools Table Window Help Adobe PDF Acrobat Comments

Title + 18 pt, 5 Arial 18 B I U

Final Showing Markup Show

Reject Change/Delete Comment

Reject All Changes Shown

Reject All Changes in Document

Delete All Comments Shown

Delete All Comments in Document

Delete All Ink Annotations in Document

Study No.: «> IRB: «IRB» Consent Approved On: «ApprovalDate» Project Approval Expires On: «ExpirationDate»

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. *Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.*

Comment [IRBMED]
INFORMATION ON A
INFORMED CONSEN
LANGUAGE

The template wording
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Section 1: General Information

- **Title:** Informed Consent: an Interventional Study
- **Sponsor:** University of Michigan IRBMED
- **Researchers:**
 - Principal Investigator: Ana Austin, Healthcare Administrator, Michigan Institute for Clinical and Health Research, University of Michigan
 - Co-Investigator: June Insko, IRBMED Education Coordinator, University of Michigan

Section 2: Purpose

- **Required?:**
 - Yes. 45 CFR 46.116 requires “an explanation of the purposes of the research”

- **Good sources:**
 - Protocol ‘background and significance’ sections, as well as ‘specific aims’

Section 2: Purpose—Examples

Typical Problems

This study is being conducted to assess the impact of DFG-995 and/or therapeutic intervention on the “Informed Consent Anxiety” scale, to assess efficacy.

During screening, Participants will complete an EKG and an OGTT...

We believe that therapy will be most effective for highly anxious participants pre-disposed to confusion and depression.

One Possible Fix

Many study coordinators find writing an informed consent the most challenging part of their job.

Several approaches may reduce the frustration of consent writing.

The study will compare using a drug, using counseling, and using both a drug and counseling together, to see which is most effective.

Section 2: Purpose

The Bottom Line:

Do Not

- ...simply 'cut and paste' protocol sections, as these are rarely in lay language
- ...give elaborate details of the procedures of the protocol
- ...include highly scientific objectives or hypotheses that are of little relevance to the participants. These may bias your results or confuse participants.

Do

- ...Consider what the participant would want to know.
- ...Remember that technical scientific hypotheses may not be relevant to the participant's experience.

Section 3: Who may Participate?

Required?

This section is required by UM IRBMED, but not *explicitly* by the code of federal regulations.

- The purpose of the requirement is to provide additional protections to the subject by presenting the inclusion/exclusion criteria

This means that the level of detail you include is up to you, the investigator, and the IRB.

Good sources: Use your protocol inclusion and exclusion criteria with caution!

Section 3: Who may Participate? Examples

Typical Problems

To participate, you must have:

Medically documented frustration during informed consent writing not requiring hospitalization.

No clinically significant medical condition judged by the investigator to compromise safety.

No atypical anxiety syndromes due to anticholinergic drugs, or metabolic neurogenetic disorders, or other degenerative diseases.

One Possible Fix

To participate, you must have frustration when writing an informed consent. You should not participate if you have ever been hospitalized because of frustration. If your frustration is caused by a medical problem, you may not be able to participate.

There are many reasons why you may not be able to participate. It is important to discuss your full medical history with the study doctor. We must also review your medical record.

Section 3: Who may Participate?

The Bottom Line

Do Not

- ...simply 'cut and paste' all inclusion exclusion criteria.
 - Not only do they include scientific language, they are often meaningless to participants.
 - Thoroughness should be balanced with keeping your consent short enough to fit reading level guidelines.

Do

- ...Consider what the participant would want to know, especially criteria that participants can judge for themselves.
- ...If you do not list all criteria, be sure to stress the importance of giving a FULL and COMPLETE medical history.

Section 3: How Many will Participate?

Required?

Included in the standard IRBMED template; 45 CFR 46.116 states this information shall be provided “when appropriate.”

Tip:

Be realistic, but give yourself justifiable ‘wiggle room.’ It is better to say ‘No more than 10’ than to say ‘6’ and have to amend the consent half way through!

Also acceptable to introduce here the concept of screen failures:
“We expect to about 100 people to have the screening tests done. Out of those 100, we expect about 35 will be suited to complete the research part of the study.”

Section 4.1: Procedures

Required?:

YES. 45 CFR 46.116 requires 'a description of the procedures to be followed, and identification of any procedures which are experimental.'

Good sources: A sponsor provided study calendar, the 'procedures' section of your protocol.

Section 4.1: Procedures

Examples: Typical Problems

Examples of poor sections are difficult to include, as they are usually prohibitively long! Here is a much-shortened example...:

Section 4.1: Procedures

Examples: Typical Problems

At visit 1 you will have your blood pressure taken lying down and standing up. You will answer questionnaires "Anxiety while writing", "overall anxiety scale" and "SAGM". Your blood will be drawn for tests of iron, creatinine, hematocrit, liver function and other tests. You will be Randomized to group A, B, or C

At visit 2 if you are in group A, your visit will occur in 4 weeks and you will have your blood pressure measured lying down and standing up. If you are in group B, your visit will occur in 6-12 weeks, after you have been assigned a counselor, and you will have your blood pressure measured while lying down and standing up...At visit 3 you will have your blood pressure measured...etc.

Section 4.1: Procedures

Examples: One Possible Fix

During the study, you will be randomized into one of three groups. Random means by chance, like flipping a coin. You have an equal chance of being in any of the three groups.

Below is an explanation of what will happen at each visit, no matter what group you are in. Then there is a section explaining what extra things will happen depending on what group you are in. The diagram at the end of the section also shows what will happen in the study.

Formats for Procedures Section

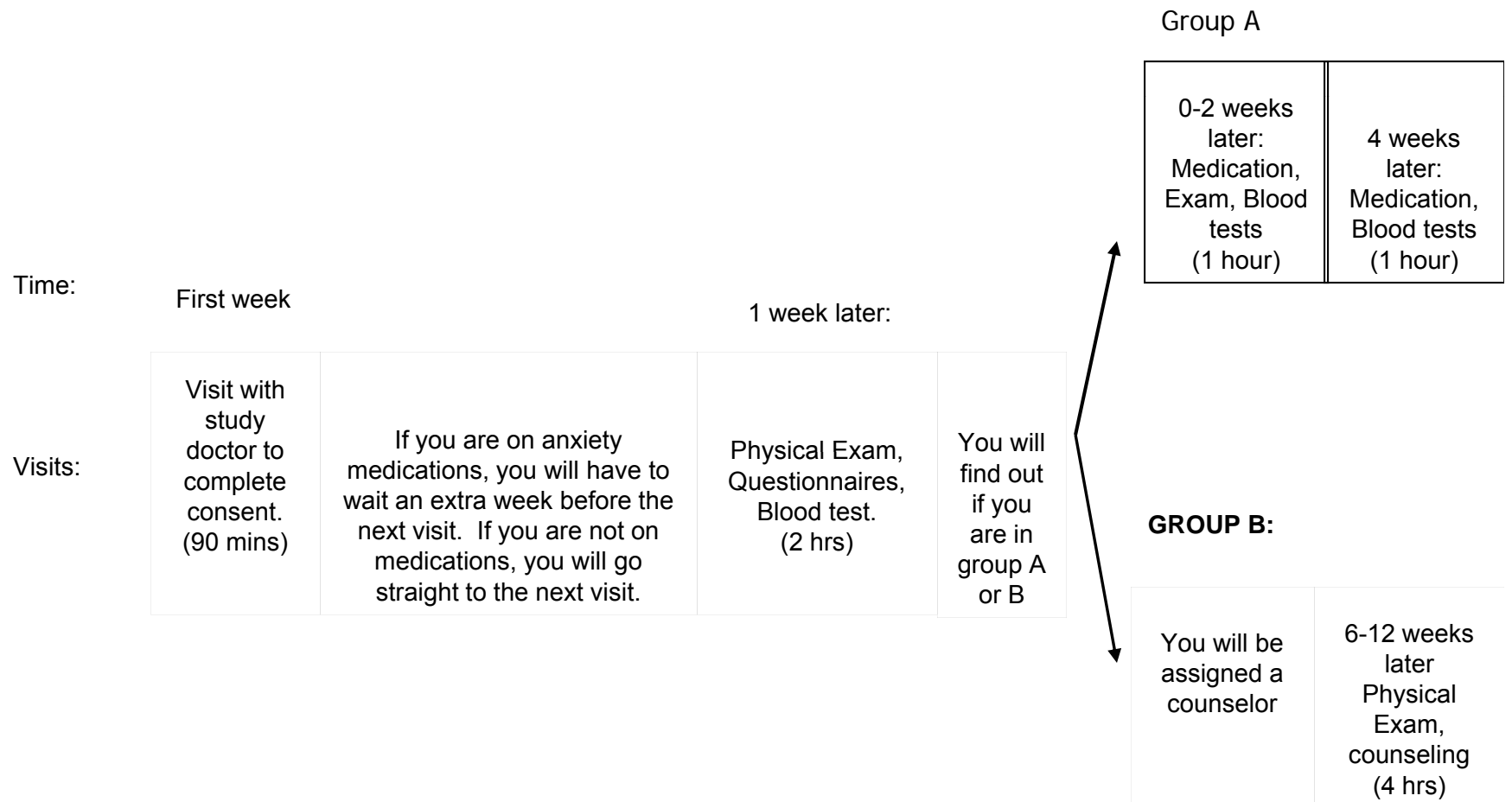
- Describe Visits in Chronological Order
- Describe Procedures one by one, indicating how often each one will occur
- Break visits into 'types' (ie. Short, Medium, Long) and describe each type
- Break Procedures into those that will happen at every visit, then those that happen less frequently
- Explain what will happen regardless of whether the participant enrolls or not (clinical care), then what 'extra' things will happen due to the study (experimental procedures)

Section 4.1: Procedures

**An additional tool:
Diagrams**

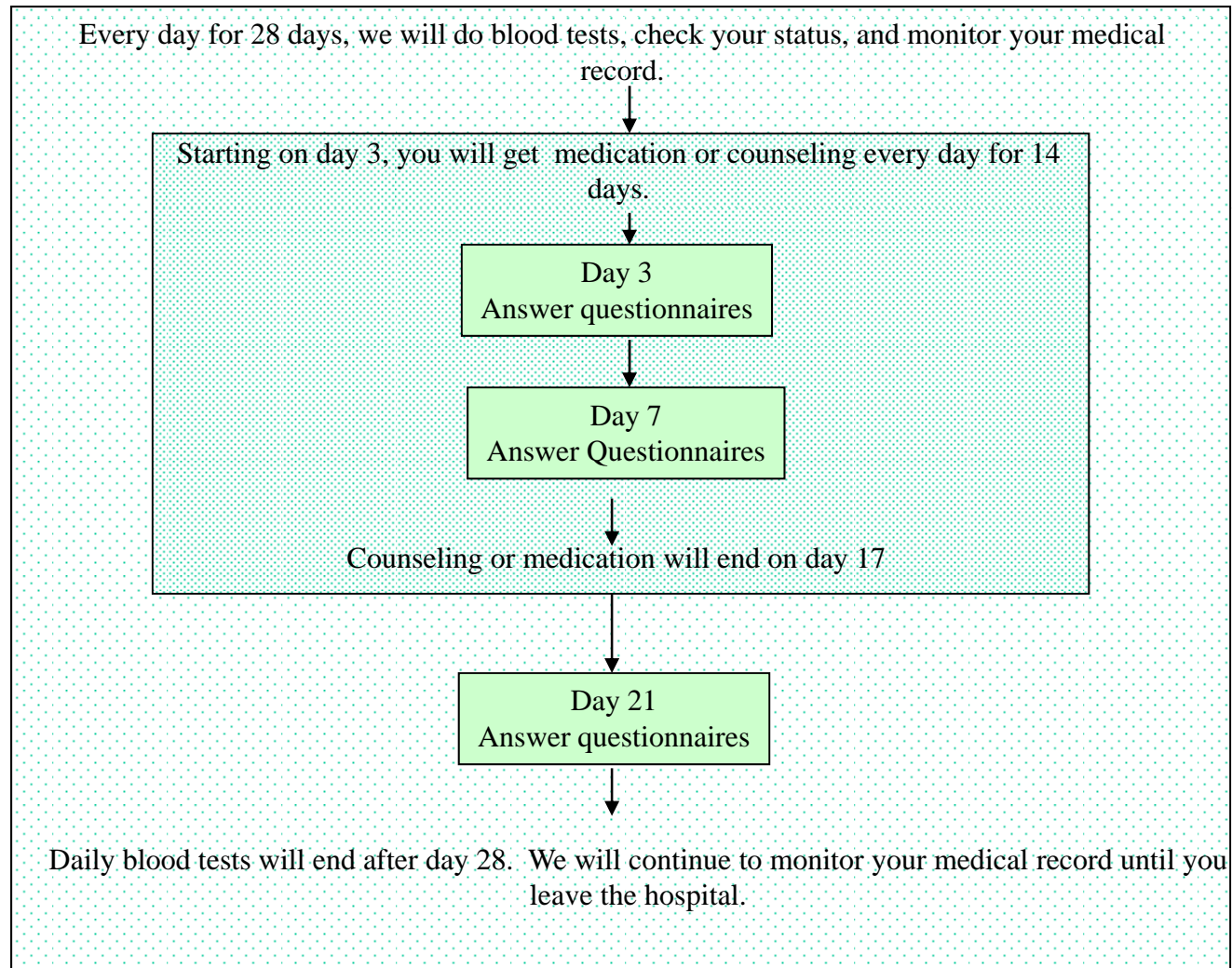
Section 4.1: Procedures

One Possible Fix: Group Flow Diagrams



Section 4.1: Procedures

One Possible Fix: Flow Chart



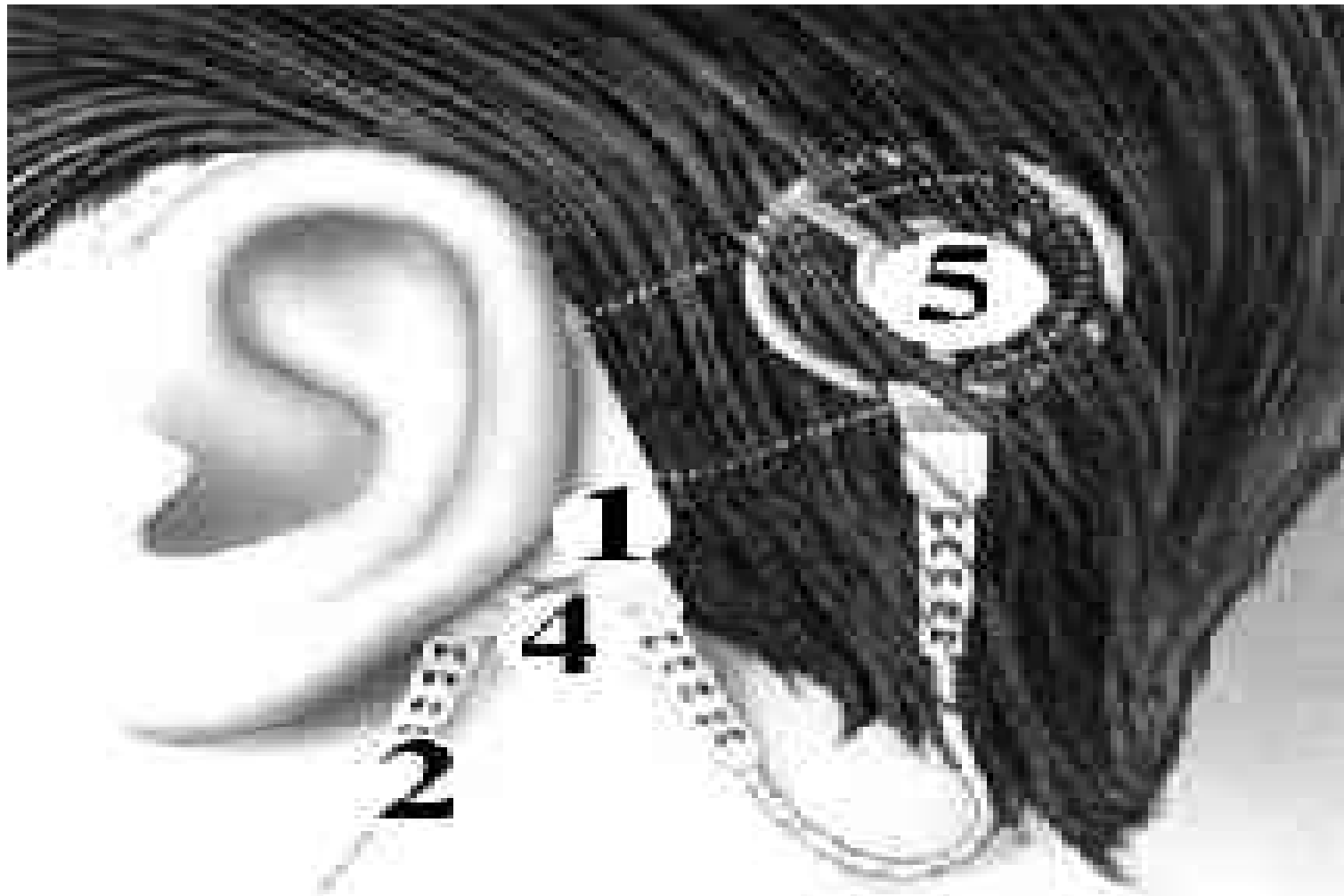
Section 4.1: Procedures

One Possible Fix: "Study Calendar" Diagrams

Procedure	Visit 1	Visit 2	Visit 3
Physical Exam	X		
Survey	X	X	X
Blood Draw	X		X
Urine sample	X		X
Counseling	X	X	X

Section 4.1: Procedures

One Possible Fix: Pictures or Diagrams



Section 4.1: Procedures

The Bottom Line

Do Not

...Be repetitive. If some procedures happen at every visit, consider identifying them separately.

...Get locked in to one format. Procedures are usually presented chronologically, but other formats may be more useful for longer studies.

... Limit yourself to words, especially for complex studies (multiple groups, visits that change depending on labs).

...**eliminate words when you use diagrams.** Diagrams should be in ADDITION TO, not INSTEAD OF words.

Section 4.1: Procedures

The Bottom Line

Do

...Consider what the participant would want to know.

...**Avoid unnecessary details. For instance, if participants must fill out questionnaires, they usually want to know the topic area, not the names of the different forms.**

BUT Do ...Remember the necessary details. Things that are routine for researchers may be important to participants (weighing, needlesticks)

...This is the place to explain randomization and blinding, if they will be used.

Section 4.1: Procedures

The Bottom Line

Again:

- **Avoid unnecessary details and repetition.**
- **Use a separate study calendar for details**
- **Remember the regulation for this section is to provide “*a description of the procedures to be followed, and identification of any procedures which are experimental*”**
 - ‘A description of’ ≠ every single procedure in the exact order the protocol delineates

4.2 How much of my time will be needed to take part in this study?

4.3 When will my participation in the study be over?

Required?

YES. 45 CFR 46.116 requires an explanation of the “expected duration of the subject’s participation”

Remember to include any follow-up periods. Researchers sometimes don’t consider follow-up visits ‘part of the study’ but participants and regulators do.

When estimating visit times, be generous – you’ll still probably underestimate!

Section 5.1: Risks

Required?

YES. 45 CFR 46.116 (6) requires a description of reasonably foreseeable risks and discomforts.

Good Sources:

Investigator's Brochure, Drug Inserts, IRB Informed Consent Document Guidelines, occasionally protocol.

Section 5.1: Risks

Examples: Typical Problems

...No studies exist regarding the possible teratogenicity of study drug during pregnancy.

...During the study, you may be prescribed aspirin for headaches. Aspirin can cause stroke, stomach upset, death, ulcer, or severe allergic reaction.

...You will only be filling out surveys, so there are no risks to this study.

Section 5.1: Risks

Examples: One Possible Fix

...It is not known whether study drug could cause birth defects....

...During the study, you may be prescribed aspirin. Aspirin often causes mild stomach upset. In very rare cases, it can cause stroke, death, ulcer, or severe allergic reaction. To reduce this risk, we will monitor you for side effects whenever aspirin is given...

Section 5.1: Risks

The Bottom Line

Do Not:

... Assume your procedure is risk – free, even if it’s “just” filling out self-report forms. Do not overlook “soft” risks such as confidentiality and embarrassment.

... Leave out an explanation of the way the investigator is trying to reduce that risk.

Section 5.1: Risks

The Bottom Line

Do:

...Add the likelihood, but explain numbers in lay terms. "About one person in one hundred people get an infection." Use numbers with caution!

...Use the IRB's prepared language for certain tests, e.g., MRI, X-rays and other tests involving radiation.

- Risks modules coming to the IRB website this year

Section 5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

Use the IRBMED's standard template language:

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. **You should also tell your regular doctors.**—*Delete this last sentence if it doesn't fit your study.*

Don't repeat information provided in section 5.1 but add general directions or steps if appropriate, for example:

- "first aid will be provided" or
- "the drug dose will be lowered or stopped altogether"

DO NOT include any information about **payment** for research related side effects or injuries in this section!!!!

Section 5.4: Benefits

REQUIRED?:

YES. CFR 46.116 (3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

Section 5.4: Benefits

The Bottom Line

DO NOT:

...List monetary compensation i.e. "You will receive \$100.00 for participating." This information should go in section 8.2.

...promise benefits that may not occur.

Section 5.4: Benefits

The Bottom Line

DO

...Leave the first sentence: "You may not receive any personal benefits from being in this study."

...Include future benefits to others. "Information from this study may help other consent writers in the future."

... Remind placebo study participants that *only some of them may experience benefit*. "If you are in the group of subjects who actually receive the study drug, and if the drug works, you may see improvement in your frustration levels."

Section 6.1: Alternatives

Required?

YES. 45 CFR 46.116 requires explanation of the alternatives to participation.

Good Sources: For disease studies, your Principal Investigator may be a good source.

Section 6.1: Alternatives

Examples: Typical Problems

...There are many treatments for anxiety. Methotrexate is a medication commonly used to treat anxiety. Side effects include decrease in white blood cells that fight infection, decrease in platelets (may cause bleeding and/or bruising), fever, symptoms of infection, shortness of breath, nausea, vomiting, lymph node swelling, liver disease, including cirrhosis of the liver and lung inflammation or fibrosis.

...There are no known alternative treatments for your condition.

Section 6.1: Alternatives

One Possible Fix:

...You do not have to participate in this study to receive treatment for your anxiety. There are many treatments for anxiety. The most common treatment is methotrexate. Like all medications, this treatment has benefits and risks, including serious risks. If you are interested in other treatments, you should ask your doctor or the researchers.

...Participation in this study is voluntary. If you choose not to participate, you will not lose any health care benefits that you have now.

Section 6.1: Alternatives

The Bottom Line

The level of detail is up to you, the investigator, and the IRB.

It may be acceptable to say “there are many effective treatments, including medications. You should ask your doctor if you have questions about alternative treatments.”

Non-participation is always an option!

If the study medication is available by regular prescription, be sure to mention this fact.

Section 8.1

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study? _____

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1. _____

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like: _____

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Treatment of complications _____
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's **medical reviewer**. _____

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study. _____

NEVER DELETE this last part!!!!

Comment [UpdateCRB24]: If there is a separate paragraph for this section, delete THE LAST PARAGRAPH and state "The study will pay for research-related items or services that are provided only because you are in the study."

Comment [UpdateCRB25]: "The study will pay for research-related items or services that are provided only because you are in the study."

Comment [UpdateCRB26]: The study will pay for research-related items or services that are provided only because you are in the study. The final approved billing plan is attached to the study.

Note: Change the text in this paragraph if you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

Comment [UpdateCRB27]: If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. For example, "the sponsor will pay for research-related items or services that are provided only because you are in the study."

Comment [UpdateCRB28]: If there are any items or services in this list edit this section accordingly.

Comment [UpdateCRB29]: If there are any complications that occur as a result of participating in the study, add to the end of this list.

Comment [UpdateCRB30]: •If appropriate for this study, and modify the boilerplate at the end of this section to include the following important information. For example, research-related items or services that are provided only because you are in the study, the cost of the item or service, and you are provided with contact information for a person who can help you determine if you are eligible for insurance coverage for the "standard" or "routine" care. •There is no need to identify in the consent for the study, the cost of the item or service, and you are provided with contact information for a person who can help you determine if you are eligible for insurance coverage for the "standard" or "routine" care. (likely the study coordinator or other person who can help you determine if you are eligible for insurance coverage for the "standard" or "routine" care.)

Assessment of readability

- 8th grade reading level or lower is ideal, and there are two widely-used measures:
- Flesh-Kincaid
 - In MS Word, open your document and go to the Tools Menu. Choose “Spelling and Grammar”. When the box pops up, make sure the box labeled “check grammar” is checked. Check the full document. When the check is finished, your readability statistics will automatically pop up.

Microsoft Word interface showing the Tools menu. The menu items are: Spelling and Grammar... (F7), Research..., Language, Word Count..., AutoSummarize..., Speech, Shared Workspace..., Track Changes (Ctrl+Shift+E), Compare and Merge Documents..., Protect Document..., Online Collaboration, Letters and Mailings, Macro, Templates and Add-Ins..., AutoCorrect Options..., Customize..., and Options... A red arrow points from the 'Spelling and Grammar' option to the 'Tools' menu header.

1. GENERAL INFO

Study title: A double-blind, randomized, multicenter study to assess the efficacy, safety and tolerability of bosentan in patients with idiopathic pulmonary fibrosis.

Company or agency sponsor: Genentech Pharmaceuticals, Ltd.

James, degrees, and affiliation: Department of Internal Medicine, University of Michigan Health System

Fernando J. Martinez, M.D., Kevin Flaherty, M.D., Victor J. Thannickal, M.D., Robert C. Hyzy, M.D., Steven E. Gay, M.D.

2. PURPOSE OF THIS STUDY

Study purpose: Patients with idiopathic pulmonary fibrosis usually experience a reduced ability to exercise and feel breathless. The main purpose of the study is to evaluate the effect of long-term (12 months) bosentan therapy on exercise capacity. The second purpose of the study is to assess the effect of bosentan treatment on lung function and your quality of life, and to determine if bosentan improves your disease symptoms.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no

Microsoft Word status bar showing page 1 of 13, section 1, at 4.2 inches, line 18, column 75, with REC, TRK, EXT, and OVR options.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

Study title: A double-blind, randomized, placebo-controlled study to assess the efficacy, safety and tolerability of bosentan in patients with idiopathic pulmonary fibrosis.

Company or agency sponsor: [Redacted]

James, degrees, and affiliation: [Redacted]

Department of Internal Medicine, Pulmonary and Critical Care Medicine

Fernando J. Martinez, M.D.

Kevin Flaherty, M.D., Assistant Professor

Victor J. Thannickal, M.D., Assistant Professor

Robert C. Hyzy, M.D., Clinical Professor

Steven E. Gay, M.D., Clinical Professor

Spelling and Grammar: English (U.S.)

Not in Dictionary:

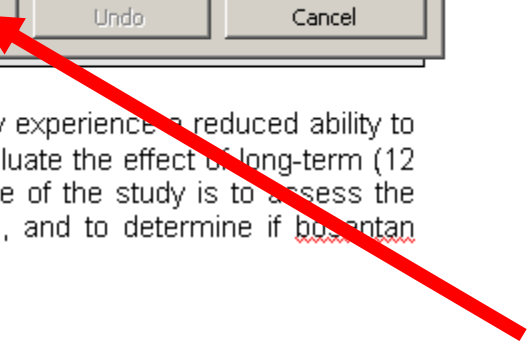
Study title: A double-blind, randomized, placebo-controlled, **multicenter** study to assess the efficacy, safety and tolerability of bosentan in patients with idiopathic pulmonary fibrosis.

Suggestions:

- multimember
- multicoated

Check grammar

Options... Undo Cancel



Study purpose: Patients with idiopathic pulmonary fibrosis usually experience a reduced ability to exercise and feel breathless. The main purpose of the study is to evaluate the effect of long-term (12 months) bosentan therapy on exercise capacity. The second purpose of the study is to assess the effect of bosentan treatment on lung function and your quality of life, and to determine if bosentan improves your disease symptoms.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no

1. GENERAL INFORMATION A

Study title: A double-blind, randomized safety and tolerability of bosentan in patient

Company or agency sponsoring the

James, degrees, and affiliations of th

Department of Internal Medicine, Pulmonar

Fernando J. Martinez, M.D., MS, I

Kevin Flaherty, M.D., Assistant Pro

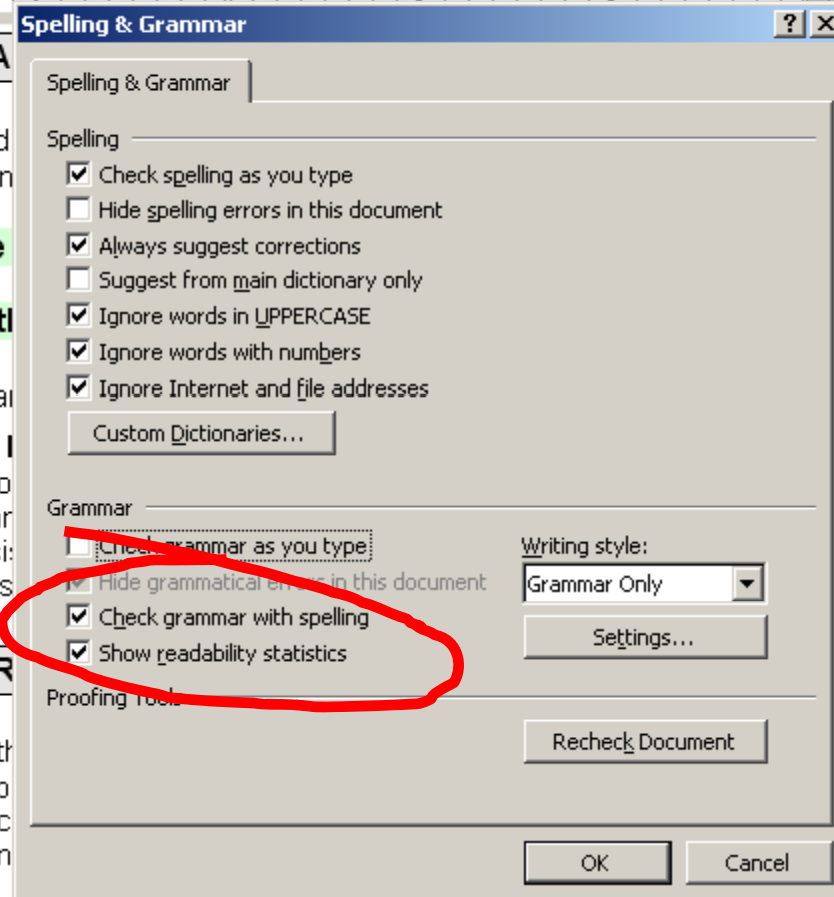
Victor J. Thannickal, M.D., Assista

Robert C. Hyzy, M.D., Clinical Assi

Steven E. Gay, M.D., Clinical Assis

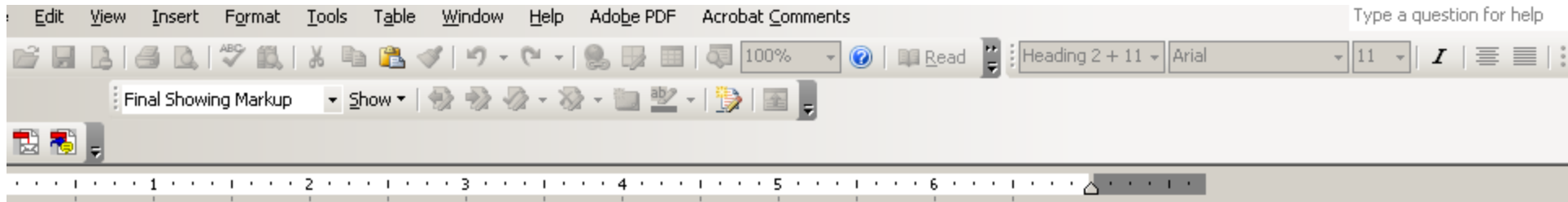
2. PUR

Study purpose: Patients with idiopath exercise and feel breathless. The main p (months) bosentan therapy on exercise c effect of bosentan treatment on lung fun improves your disease symptoms.



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Study title: A double-blind, randomized, placebo-controlled, multicenter study to assess the efficacy, safety and tolerability of bosentan in patients with idiopathic pulmonary fibrosis.

Company or agency sponsor: [Redacted]

James, degrees, and affiliation: [Redacted]

Department of Internal Medicine, Pulmonary and Critical Care Medicine, Brigham Young University School of Medicine, Salt Lake City, Utah

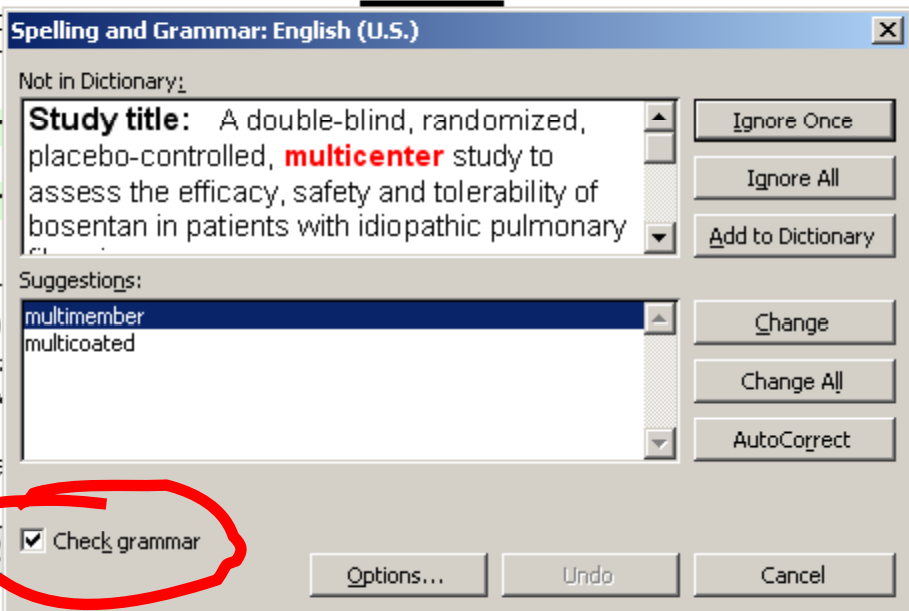
Fernando J. Martinez, M.D.

Kevin Flaherty, M.D., Assistant Professor

Victor J. Thannickal, M.D., Assistant Professor

Robert C. Hyzy, M.D., Clinical Professor

Steven E. Gay, M.D., Clinical Professor

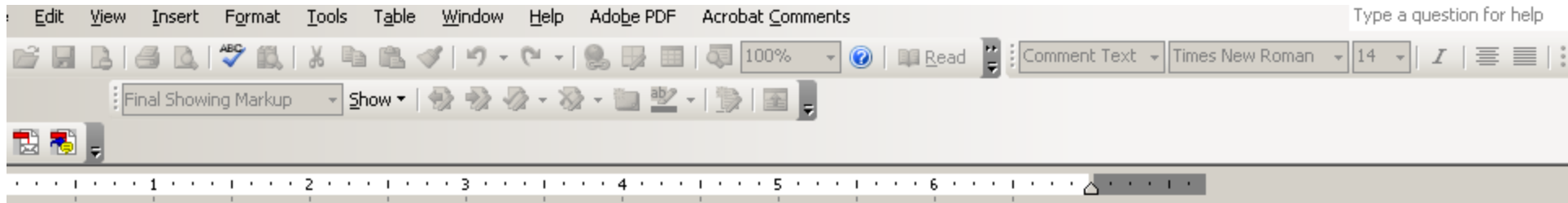


Study purpose: Patients with idiopathic pulmonary fibrosis usually experience a reduced ability to exercise and feel breathless. The main purpose of the study is to evaluate the effect of long-term (12 months) bosentan therapy on exercise capacity. The second purpose of the study is to assess the effect of bosentan treatment on lung function and your quality of life, and to determine if bosentan improves your disease symptoms.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

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517 W. William, Argus 1
Ann Arbor, MI 48103-4943

Telephone: 734-763-4768
Fax: 734-615-1622
e-mail: irbmed@umich.edu

Readability Statistics

Counts	
Words	8624
Characters	44540
Paragraphs	276
Sentences	257

Averages	
Sentences per Paragraph	2.2
Words per Sentence	18.1
Characters per Word	4.7

Readability	
Passive Sentences	32%
Flesch Reading Ease	46.7
Flesch-Kincaid Grade Level	11.2

OK

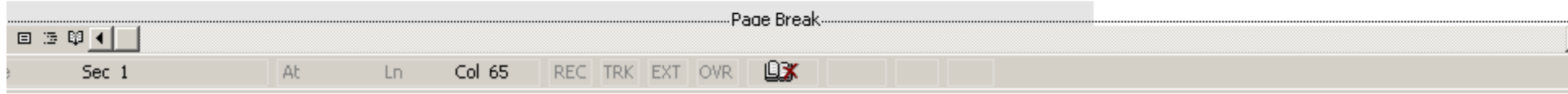
If you are concerned about a possible violation of your privacy, contact the University Health System Privacy Officer at 1-888-296-2481.

When you call or write about a concern, please provide the name of the researcher, the IRBMED number (at the time of the concern). This will help University officials to look into your concern. You do not have to give your name unless you want to.

11. RECORD OF INFORMATION

What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:



Assessment of Readability

- SMOG (Simplified Measure of Gobbledygook) test
 - Select 3 samples of 10 consecutive sentences (at least 100 words)
 - Count the number of words with > 3 syllables
 - Use your calculator and find the square root of the number then add 3

e.g., total words = 64
sq root = 8
8 + 3 = 11th grade reading level
- SMOG details
 - <http://www.sph.emory.edu/WELLNESS/reading.html>

What about Comprehension?

Focus groups with research subjects have yielded the following suggestions:

- 1) Emphasize and Summarize Important Information.
- 2) Use graphics and videos.
- 3) Use larger fonts.
- 4) Add space to write questions.
- 5) Make general information about clinical trials available.

Source: Horchhauser, Mark. "Informed Consent: Reading and Understanding are not the Same." Applied Clinical Trials. April 1, 2004.

What about Comprehension?

A review of the studies that have tested comprehension of informed consent forms have found comprehension levels ranging from 40% to 65%.

Lowering the reading level can improve comprehension somewhat, but most studies showed only modest improvements.


Dialogue, questions and answers, and ongoing discussion are necessary to complete the consent process.

Source: Horchhauser, Mark. "Informed Consent: Reading and Understanding are not the Same." Applied Clinical Trials. April 1, 2004.

Loose Ends


- Don't be Afraid to Modify:
 - 7.2: "Harm from being in multiple studies"
 - 7.3: "Could the researchers withdraw me?"
 - 8.3: "Who will benefit financially?"
 - 9: Bulleted items regarding confidentiality
 - 12: Unused Signature Lines

If it doesn't make sense to you, it probably won't make sense to your participants.



Thank you for your dedication to
our research participants

Questions?



Additional information can be found in the handout for sections that may not have been covered here.

Thank you for attending!