Graphic Medicine at Work: Drawing Adolescents in With Graphic Assent

Leah Eisenberg, JD, MA
Thank You

Rose Anderson
Service Designer at the Mayo Clinic Center for Innovation
Disclosures

None.
The Concept of Assent

*Assent* is defined as “a child’s affirmative agreement to participate in research.”

The US Code of Federal Regulations states that “the IRB shall determine that adequate provisions are made for soliciting the assent of the children.”

1. 45 CFR §46.408(a) (2010).
2. 45 CFR §46.402(b) (2010).
What Makes Assent Meaningful?

According to The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, an assent document should at least:

- briefly describe the research protocol,
- and explain that the minor’s participation is voluntary.³

Why Look at Assent?

A comparison of a standard written assent form versus a “storybook” version of the assent found that less than 35% of participants ages 7-17 earned a perfect score on a post-assent questionnaire. The average quiz scores were less than 80% for all tests. 4

Use of a multimedia presentation improved the comprehension of children of assent versus a standard paper format, but over 75% of the children involved still were not able to appreciate the risks involved in study participation. 5

Why Comics?

Comprehension scores are better when patients are given medical information that contains both illustrations and text.  

Form T

Assent Form to Take Part in a Research Study

TITLE: Individualized Medicine Biobank for Mitochondrial Diseases

IRB#: 09-00265

PRINCIPAL INVESTIGATOR: Dr. Devin Oglesbee, Ph.D. and Colleagues

Protocol Last Approved by Institutional Review Board:
THIS FORM APPROVED:

What is the Mitochondrial Disease Biobank, and why is it important?

This Biobank is run by a group of scientists who are studying mitochondrial disease. Their research might help them learn more about how medicines work, how your body works, and to find better ways to take care of and treat people who are sick with mitochondrial diseases. You are being invited to be a part of the Biobank.

A Biobank is like a library, but for blood samples and other specimens. This Biobank has samples that come from people who either have mitochondrial disease, or are related to someone who has one. Scientists can ask to use the samples in the Biobank when they are studying mitochondrial disease.

What do you have to do to join the Biobank?

You will need to give a blood sample. This might hurt for a few seconds, and some people might get a bruise. If you have ever had a biopsy, the scientists will ask if they can have samples from the biopsy that your doctors are done using. This sample can not be put back in your body, and you will be fine without it. If you have not had a biopsy, you can still join the Biobank.

Researchers will also ask permission to look at the records that your doctor keeps about you. You will be asked a few questions about your health and your family’s health.

You can ask whatever questions you want. You do not have to be in this research project. You do not have to sign the form if you don’t want to. It’s totally up to you. No one will be mad at you if you say no.

To the professional:

If the child does not sign the form, but you believe the child has actively assented, please document on this form. State the specific behaviors (head shake yes, child said okay after you described the procedure, etc.).

(Printed Name of Individual Obtaining Assent)* (Date)

(Signature of Individual Obtaining Assent)

* Individual Obtaining Assent can be member of Mitochondrial Disease Biobank staff or child’s health care provider

For Mayo Clinic staff use only:

(Date / Time) (Printed Name of Individual in Receipt of Consent)

(Signature of Individual in Receipt of Consent)
What exactly is a biobank anyway?

I remember that it's kinda like a library, but for blood samples and other things like that.

Yep, that's right! And this biobank has samples that come from people who either have mitochondrial disease, or are related to someone who has one.

Oh! So it's like, scientists can ask to use the samples in the biobank when they're studying mitochondrial disease?

Yep, that's right!

Uh, okay, that sounds like something I want to be a part of!

But... what do we have to do, exactly?

Well, there's a few things you'll do if you agree to be in the project.

For one, you will give a blood sample.

Will that hurt?

It might hurt for a few seconds, and some people get a bruise.

That's not so bad. What else?

Have you ever had a biopsy?

Uh... I'm not sure. What is a biopsy?

It's when a doctor takes tissue samples from your body to study.

Wait a second! Oh no! I've never had one of those. Does that mean I can't join their research?

Don't worry! That's not a problem. You don't need a biopsy to participate. But if you have had one...
The scientists will ask if they can have samples from the biopsy that the doctors are done using.

Here you go!

Thanks!

They will also ask permission to look at the records that your doctor keeps on you.

And that’s it!

Wait! What if I have more questions?

You can ask whatever questions you want.

You don’t have to be in this research project.

No one will be mad at you if you say no.

Thanks, guys. I feel like I understand this a lot better.

I mean, better than I already did, of course!

No problem! Glad we could help!

I feel ready to make my own decision now.

They will also be asked a few questions about your health and your family’s health.
To the professional:

If the child does not sign the form, but you believe the child has actively assented, please document on this form. State the specific behaviors (head shake yes, child said "okay" after you described the procedure, etc.).

________________________________________
________________________________________

(Printed Name of Individual Obtaining Assent)* (Date)

________________________________________

(Signature of Individual Obtaining Assent)

* Individual Obtaining Assent can be member of Mitochondrial Disease Biobank staff or child's health care provider

For Mayo Clinic staff use only:

(Date/Time) (Printed Name of Individual in Receipt of Consent)

________________________________________

(Signature of Individual in Receipt of Consent)
Evaluating Comic Assent
Study Procedures

• 267 participants age 12-17
• Grades 6-12
• Median age= 16
• Each grade was randomly split into two groups: those that saw the comic assent first, and those that saw the text first.
Study Procedures

Mitochondrial Disease Biobank - Assent Comprehension Assessment

- Anyone can join the Mitochondrial Disease Biobank. True False
- You have to give a blood sample in order to join the Biobank. True False
- You have to have a biopsy in order to join the Biobank. True False
- You must join the Biobank. True False
- Biobank staff will look at your medical records. True False
- The Biobank is used to study many kinds of diseases. True False
- The Biobank is only be used for research studies. True False
- Participating in the Biobank will make your health better. True False

What words best describe this form? Choose 3.
- Clear
- Confusing
- Informative
- Short
- Clear
- Just right

Demographic Information
- Sex: Male Female
- Age: 12 13 14 15 16 17
- In the past year, how many times have you visited any doctor’s office?
  - 0 times 1-3 times 3-5 times 5 or more times
- Are you taking ESL classes? Yes No

After reviewing the first assent, students filled out a one-page comprehension assessment.
Study Procedures

Students were then shown the second form, and all filled out a one-page preference assessment.

Mitochondrial Disease Biobank - Assent Preference Assessment

Which document did you read first?
Form M    Form T

Which document was more interesting to read?
Form M    Form T

Learning from Form M was:

1  2  3  4  5
Very easy Easy Neither easy nor hard Hard Very hard

Learning from form T was:

1  2  3  4  5
Very easy Easy Neither easy nor hard Hard Very hard

If you were only going to be given one document which would you prefer?

1  2  3
I prefer Form M They are about the same I prefer Form T

Is there anything else you would like us to know about these forms?

Demographic Information

Sex:  Male  Female

Age:  12  13  14  15  16  17

In the past year, how many times have you visited any doctor’s office?

0 times  1-3 times  3-5 times  5 or more times

Are you taking ESL classes?  Yes  No
Study Procedures

- 267 participants age 12-17
- Grades 6-12
- Median age = 16
- Each grade was randomly split into two groups: those that saw the comic assent first, and those that saw the text first.
Comprehension Assessment

There was no significant difference on comprehension scores based on the student’s age, sex, or number of doctor’s visits in the last year.
**Preference Question**

Rate how it was to learn from the assent documents.*

<table>
<thead>
<tr>
<th></th>
<th>Easy</th>
<th>Same</th>
<th>Hard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comic Assent Difficulty</td>
<td>113 (84.3%)</td>
<td>16 (11.9%)</td>
<td>5 (3.8%)</td>
</tr>
<tr>
<td>Text Assent Difficulty</td>
<td>55 (41.1%)</td>
<td>53 (39.6%)</td>
<td>26 (19.4%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Easy</th>
<th>Same</th>
<th>Hard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comic Assent Difficulty</td>
<td>86 (64.7%)</td>
<td>39 (29.3%)</td>
<td>8 (6.0%)</td>
</tr>
<tr>
<td>Text Assent Difficulty</td>
<td>76 (56.7%)</td>
<td>36 (26.9%)</td>
<td>22 (16.4%)</td>
</tr>
</tbody>
</table>

* Kruskal-Wallis Test
**Preference Question**

Which assent was more interesting to read?*

<table>
<thead>
<tr>
<th>If student saw the comic assent first</th>
<th>If student saw the text assent first</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comic</td>
<td>Text</td>
</tr>
<tr>
<td>97 (72.4%)</td>
<td>107 (80.4%)</td>
</tr>
<tr>
<td>37 (27.6%)</td>
<td>26 (19.6%)</td>
</tr>
</tbody>
</table>

* $\chi^2$ test
Describing Assent

Students were asked to choose words describing each assent form:

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**Mitochondrial Disease Biobank - Assent Comprehension Assessment**

<table>
<thead>
<tr>
<th>Statement</th>
<th>True</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anyone can join the Mitochondrial Disease Biobank.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>You have to give a blood sample in order to join the Biobank.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>You have to have a biopsy in order to join the Biobank.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>You must join the Biobank.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biobank staff will look at your medical records.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Biobank is used to study many kinds of diseases.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Biobank is only be used for research studies.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participating in the Biobank will make your health better.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What words best describe this form? Choose 3.

- □ Clear
- □ Confusing
- □ Interesting
- □ Informative
- □ Boring
- □ Fun
- □ Short
- □ Childish
- □ Long
- □ Just right
- □ Complicated
- □ Simple
- □ Other ____________________________

**Demographic Information**

<table>
<thead>
<tr>
<th>Sex:</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age:</td>
<td>12</td>
<td>13</td>
</tr>
</tbody>
</table>

In the past year, how many times have you visited any doctor’s office?

- □ 0 times
- □ 1-3 times
- □ 3-5 times
- □ 5 or more times

Are you taking ESL classes?  □ Yes  □ No
What words best describe this form?

- 83 male, 50 female
- 19 English as a second language students
Students Who Saw The Comic Assent First

What words best describe this form?

- 78 male, 52 female
- 23 English as a second language students
### How Do Students Describe The Assent Forms?

<table>
<thead>
<tr>
<th>Form Seen First</th>
<th>Comic Assent</th>
<th>Text Assent</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear, n (%) yes</td>
<td>71 (51.1%)</td>
<td>54 (42.9%)</td>
<td>0.18</td>
</tr>
<tr>
<td>Confusing, n(% yes</td>
<td>9 (6.5%)</td>
<td>30 (23.8%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Interesting, n(%) yes</td>
<td>36 (25.9%)</td>
<td>12 (9.5%)</td>
<td>0.0005</td>
</tr>
<tr>
<td>Informative, n(%) yes</td>
<td>72 (51.8%)</td>
<td>63 (50.0%)</td>
<td>0.77</td>
</tr>
<tr>
<td>Boring, n(%) yes</td>
<td>21 (15.1%)</td>
<td>53 (42.1%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Fun, n(%) yes</td>
<td>28 (20.1%)</td>
<td>3 (2.4%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Short, n(%) yes</td>
<td>24 (17.3%)</td>
<td>38 (30.2%)</td>
<td>0.013</td>
</tr>
<tr>
<td>Childish, n(%) yes</td>
<td>47 (33.8%)</td>
<td>6 (4.8%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Long, n(%) yes</td>
<td>18 (13.0%)</td>
<td>15 (11.9%)</td>
<td>0.80</td>
</tr>
<tr>
<td>Just Right, n(%) yes</td>
<td>30 (21.6%)</td>
<td>28 (22.2%)</td>
<td>0.90</td>
</tr>
<tr>
<td>Complicated, n(%) yes</td>
<td>5 (3.6%)</td>
<td>17 (13.5%)</td>
<td>0.004</td>
</tr>
<tr>
<td>Simple, n(%) yes</td>
<td>65 (46.8%)</td>
<td>30 (23.8%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

* $\chi^2$ test
Limitations

- Study participants were not a random group.
- Comprehension questions have not been validated.
- Not all assessment forms were completed.
- Comprehension of facts surrounding who can join the Biobank and what it is used for remained below 80% regardless of assent type.
Qualitative analysis – focus group themes:

- Students’ description of an ideal consent form
- Length and format preferences
- Preferences for engagement with information
- Age appropriateness
- Writing Style and Characters
- Conflicting responses
- A hybrid approach
What's Next? Biobank Consent

1. General Information About The Mitochondrial Disease Biobank

Study Title: “Individualized Medicine Biobank for Mitochondrial Diseases”

Name of Principal Investigator on this Study: Dr. D. Oglesbee and Colleagues

A. Eligibility and Purpose

Researchers at Mayo Clinic are developing a new tool for studying mitochondrial diseases called a biobank. The Mitochondrial Disease Biobank is a place to store blood and tissue samples from people with symptoms of mitochondrial disease. Health information about each donor will be attached to the samples.

The Biobank is like a library for scientists. In the past, in order to study mitochondrial disease, a researcher had to find people to take part in the study. Now he or she can just use samples from the Biobank. It is easier to do research studies when samples and information from hundreds of people are kept in one place. The Biobank is also a place for scientists to share information they collect.

You are being asked to give samples and information to the Mitochondrial Disease Biobank because either you or a family member have symptoms of a mitochondrial disease.

In order to participate in the Biobank, you must:
- fill out a form about your health,
- allow researchers to look at your medical records at Mayo Clinic now and in the future, and
- give a blood sample or allow researchers to use your tissue that is already stored at Mayo Clinic.

Researchers may contact you in the future to ask you to fill out another health form or give a new blood sample.

Illustrations by Magnolia Porter
What’s Next? HIPAA

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.

This notice applies to the following Mayo entities and health care practices (collectively referred to as “Mayo Clinic”):

Minnesota: Mayo Clinic Rochester, Saint Mary’s Hospital, Rochester Methodist Hospital, Mayo Proctor, and the John H. Strode, Mayo Clinic’s federal catchment area.

Florida: Mayo Clinic Jacksonville and its affiliated hospitals and the primary care practices in Jacksonville, St. Augustine, and Ponte Vedra.


Ohio: Mayo Clinic Cleveland and its affiliated hospitals and the primary care practices in Cleveland and Columbus.

Additional applicable state law requirements:

The notice covers Mayo Clinic personnel, volunteers, students, and trainees. It also covers other health care providers that come to Mayo Clinic’s facilities to care for patients (such as physicians, physician assistants, therapists, and other health care providers not employed by Mayo Clinic), unless those other health care providers give you their own notice of privacy practices that describes how they will protect your medical information.

Federal and state law require Mayo Clinic to protect your medical information and federal law requires Mayo Clinic to describe to you how we handle that information. When federal and state privacy laws differ, the stricter law will apply. For example, if we have specifically identified additional applicable state law requirements in this notice, the referenced Mayo entities will follow the more stringent state law requirements.

Part I - Most Common Uses and Disclosures

This section describes the most common circumstances in which Mayo Clinic may use or disclose protected health information.

Treatment

Mayo Clinic may use and disclose protected health information to provide, coordinate, or manage your care. This includes communication and consultation between health care providers, nurses, technicians, and other members of your medical team. This applies to disclosures for treatment purposes to health care providers both inside and outside of Mayo Clinic. For example, following orthopedic surgery, your doctor may refer you for rehabilitation. Information will be shared between caregivers to ensure continuity of care.

Additional Applicable State Law Requirements

States generally require consent for disclosures of protected health information by Mayo Clinic entities for treatment purposes, unless the disclosure is to a Mayo-related entity or consent is not possible due to a medical emergency.

Payment

Mayo Clinic may use and disclose protected health information to create bills and collect payment from insurance companies, Medicare, and other payers. This may include providing information such as dates of service, symptoms and diagnosis to your insurance company to show that Mayo Clinic provided medical services to you. Mayo Clinic may also disclose protected health information to other health care providers if such information is needed by the other health care provider to obtain payment for medical services provided to you.

Additional Applicable State Law Requirements

States generally require consent for disclosures of protected health information by Mayo Clinic entities for payment purposes, unless the disclosure is to a Mayo-related entity.

Appointment Reminders

We may use your health information to contact you about your appointment.

Research studies have to be approved by a Mayo Clinic review board. The Institutional Review Board... which may require the researchers to get your signed permission.

Less common ways your health information can be used and shared

With donor organizations for organ and tissue donation.

With coroners, medical examiners, or funeral directors for identification, cause of death, or to carry out wishes.

Illustrations by Magnolia Porter
Thank You!

Leah Eisenberg, JD, MA  
LREisenberg@uams.edu

Rose Anderson  
anderson.jiliarose@mayo.edu

Mayo Clinic Center for Individualized Medicine  
Mayo Clinic Center for Innovation  
Mitochondrial Disease Biobank at Mayo Clinic

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