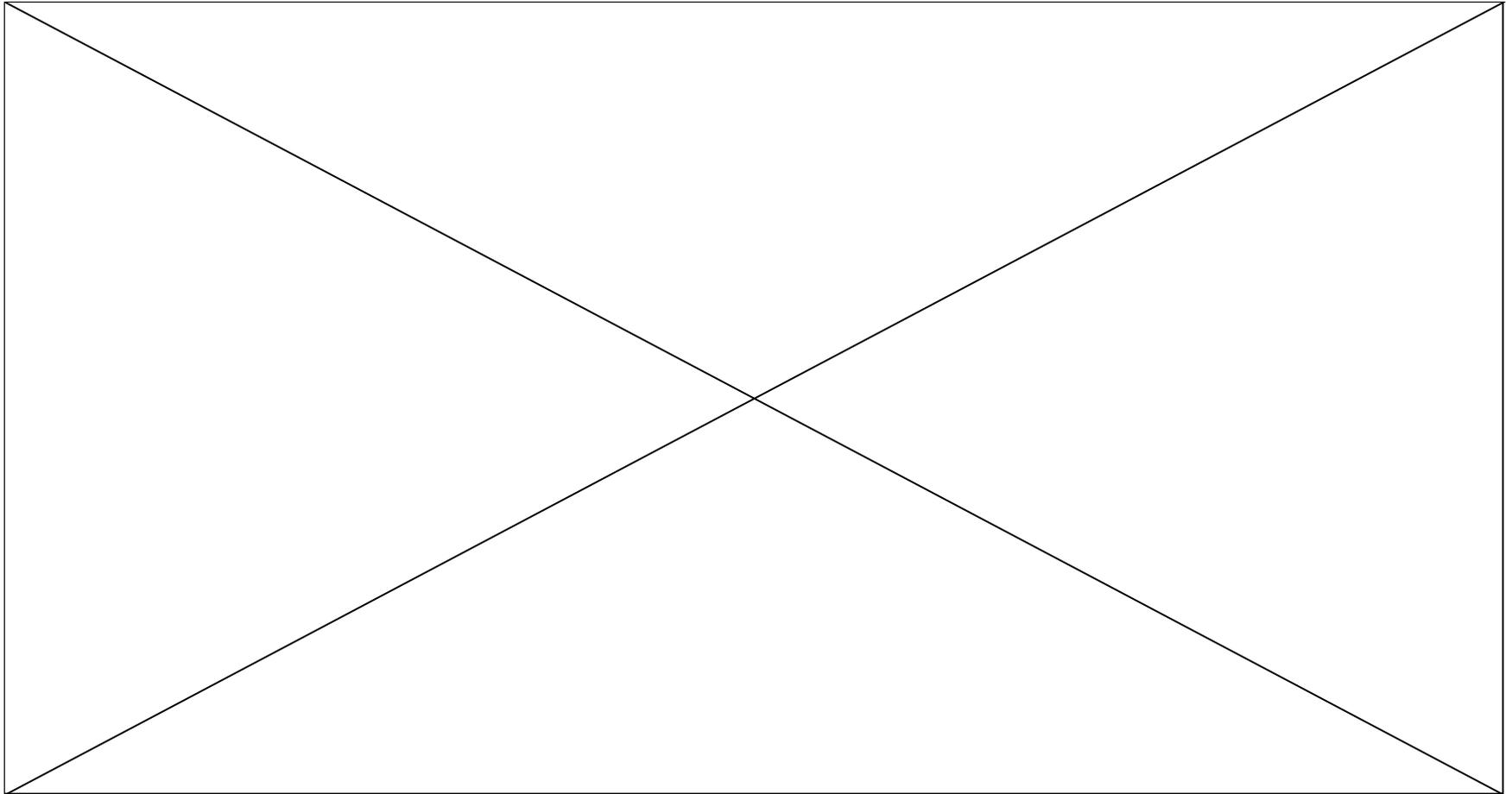


Informed Consent

Yvonne Lau, MBBS, MBHL, PhD
Director, Division of Education &
Development, OHRP

Video Segment – “Dr. Peter Part 1”

Acknowledgement – Seattle Children’s Hospital Research Foundation

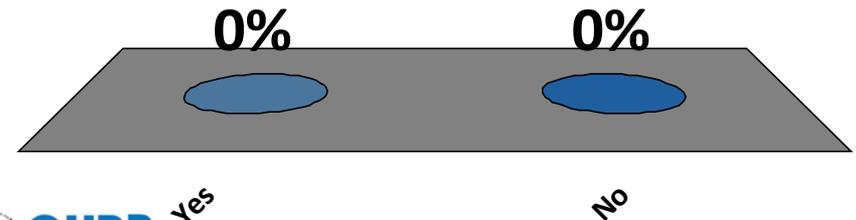


Poll

Have you had the experience of asking folks for informed consent for participation in research?

A. Yes

B. No



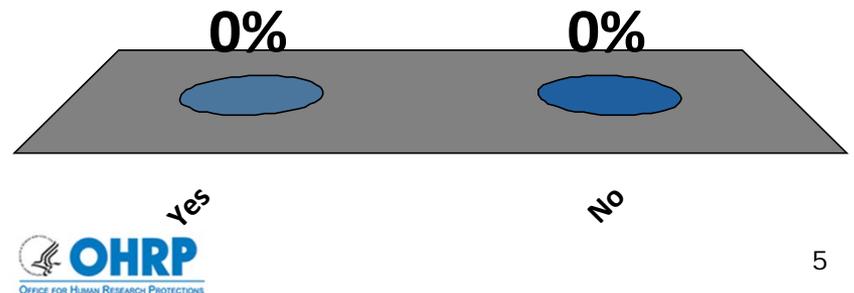
Comments? Thoughts?

- ❑ Who normally gets to ask for informed consent at your institution?
- ❑ How do the young physician-researchers in the video see their role in the process?
- ❑ How do you see the role of the person asking for consent?
- ❑ What are your thoughts about the informed consent process? What functions does it serve?
- ❑ What are some of the issues, obstacles in getting informed consent?

Poll

Have you ever been asked for your consent to participate in a research study?

- A. Yes
- B. No



Comments? Thoughts?

- ❑ Can you describe your experience (or the experience of those whom you know well?)
- ❑ What did you look for? What made you agree or not agree to participate?
- ❑ Were there things that could have been done differently to convince you about participating or not?

THE HHS REGULATIONS ON INFORMED CONSENT IN RESEARCH

Significance of Informed Consent

□ Respect for Person

- Subjects make informed decisions about participation

□ Subjects' Protection

- Subjects make decisions about the risks that are acceptable to them
- Heightens subjects' awareness when risks become reality

Requirement for Informed Consent

No investigator may involve a human being as a subject in research...unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.



46.116

Legally Effective Informed Consent

- Obtain & document (unless waived)

- Who is the “human subject”?

Living individual about whom an investigator obtains

1. Data through intervention or interaction with the individual, or
2. Identifiable private information

- Who must provide the consent?

The “subject”/legally authorized representative (LAR)

- Local Laws
- Parental permission/child assent

Legally Effective Informed Consent

- Understandable information
- Opportunity to consider
- Minimize coercion or undue influence
- No exculpatory language



Generally considered as language that has the effect of freeing an individual/entity from malpractice, negligence, blame, fault or guilt

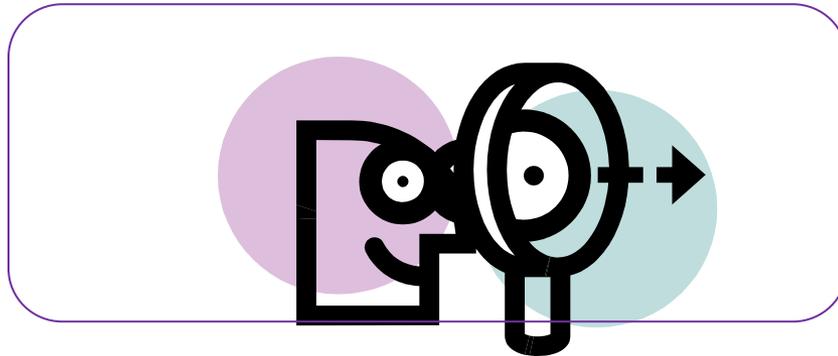
<http://www.hhs.gov/ohrp/newsroom/rfc/exculpatorydraft2011.html>

Coercion and Undue Influence

The Belmont Report (1979)

- **Coercion** occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.
- **Undue influence**...occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance.

Required Elements of Informed Consent



1) Research

- purpose
- duration
- procedures

2) Risks, discomforts

3) Benefits

4) Alternatives

5) Confidentiality

6) Compensation for injury

7) Whom to contact

8) Right to refuse, withdraw without penalty

§46.116(a)

Describing the Research



“The study involves research”

Explain the purpose clearly!

Help subjects understand -

- What the study is about and whether they share an interest
- What the study entails and whether the risks/benefits of participation are acceptable to them

Hypothetical Research - 1

- To study the relationship between certain physical performance characteristics of track athletes and their risks of injuries.
- The athletes are asked to undergo a series of strenuous performance tests not normally included in their routine assessment.

**What would you want to know
if you were asked to participate?**

Hypothetical Research - 2

- ❑ To study the coping mechanisms of individuals who were victims of sexual abuse as children
- ❑ Eligible adult subjects will be referred by their therapists to participate in focus groups and in-depth surveys by researchers.

What kind of information might be pertinent to you making a decision on participation?

It's the Subject's Choice!

A statement stating that

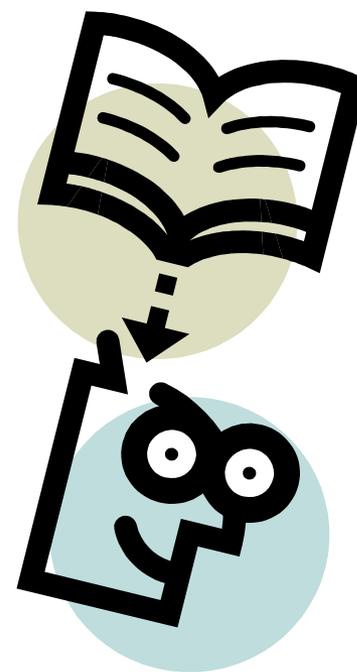
- ❑ Participation is voluntary
- ❑ Refusal to participate will not incur penalty/loss of benefits
- ❑ Can discontinue participation any time without penalty/loss of benefits



Informed Decision Making

Key factors:

- Information
- Voluntariness
- **Comprehension**



Communicating Complex Info

Membership Fee:

The accompanying letter indicates whether your account is subject to a membership fee. If it is, the fee is added to the standard purchase balance and is non-refundable unless you notify us to cancel your account within 30 days from the mailing or delivery date of the billing statement on which the fee is billed.

Billing:

Your billing statement shows the total balance, any finance charges, fees, the minimum amount due, and the payment due date. It also shows your current revolving credit line and cash advance limit; an itemized list of current charges, convenience checks, payments and credits; a summary of the purchase and cash advance activity, including the finance charges; a rate summary; and other important information. If we deem your account uncollectible or if we institute delinquency collection proceedings by sending it to an outside collection agency or attorney for collection, we may, in our sole discretion, stop sending you billing statements. However, finance charges and fees will continue to accrue whether or not we send you billing statements.

You must notify us of a change in your address by contacting Customer Service by telephone or mail. We will mail or deliver the billing statement to only one address.

How We Determine the Balance:

The total outstanding balance (the amount you owe us) appears as the "New Balance" on the billing statement. To determine the New Balance, we begin with the outstanding balance on your account at the beginning of each billing period, called the "Previous Balance" on the billing statement. We add any purchases or cash advances and subtract any credits or payments credited as of that billing period. We then add the appropriate finance charges and fees and make other applicable adjustments.

Annual Percentage Rates for Purchases and Cash Advances:

Your annual percentage rates and the corresponding daily periodic rates appear on the accompanying letter. A daily periodic rate is the applicable annual percentage rate divided by 365. Whether or not an annual percentage rate is based on the U.S. Prime Rate plus a margin is indicated on the accompanying letter. Please see the section entitled "Variable Annual Percentage Rates for Purchases and Cash Advances" for details relating to how these rates may change, including if you default under any Card Agreement that you have with us.

Variable Annual Percentage Rates for Purchases and Cash Advances:

If any annual percentage rate is based on the U.S. Prime Rate plus a margin, we will calculate the rate by adding the applicable margin that appears in the accompanying letter to the U.S. Prime Rate published in *The Wall Street Journal*. If more than one U.S. Prime Rate is published, we may choose the highest rate. If *The Wall Street Journal* ceases publication or to publish the U.S. Prime Rate, we may use the U.S. Prime Rate published in any other newspaper of general circulation, or we may substitute a similar reference rate at our sole discretion.

Whether the U.S. Prime Rate is reviewed on a billing period, month end or quarterly basis is indicated on the accompanying letter.

- If the U.S. Prime Rate is reviewed on a billing period basis, for each billing period we will use the U.S. Prime Rate published two business days prior to your Statement/Closing Date for that billing period. Any increase or decrease in a variable annual percentage rate due to a change in the U.S. Prime Rate takes effect as of the first day of the billing period in which we calculate the variable annual percentage rate.
- If the U.S. Prime Rate is reviewed on a month end basis, we will use the U.S. Prime Rate published on the last business day of the month. Any increase or decrease in a variable annual percentage rate due to a change in the U.S. Prime Rate takes effect as of the first day of the billing period that begins in the month directly following the month in which the U.S. Prime Rate used to calculate your variable annual percentage rate is published.
- If the U.S. Prime Rate is reviewed on a quarterly basis, we will use the U.S. Prime Rate published on the third Tuesday of March, June, September, and December of each year. If the third Tuesday is a holiday, we will use the U.S. Prime Rate published the next day. Any increase or decrease in a variable annual percentage rate due to a change in the U.S. Prime Rate takes effect on the first day of the billing period directly following the billing period in which the U.S. Prime Rate used to calculate your variable annual percentage rate is published.
- When a change in an applicable variable annual percentage rate takes effect we will apply it to any existing balances, subject to any promotional rate that may apply.

Your annual percentage rates may also vary if you default under any Card Agreement that you have with us because you fail to make a payment to us when due, or you make a payment to us that is not honored. In such circumstances, we may increase your annual percentage rates (including any promotional rates) on all balances to a variable default rate of up to the rate indicated on the accompanying letter. The maximum variable default rate currently in effect and the corresponding daily and/or monthly periodic rates appear on the accompanying letter. Factors considered in determining your variable default rate may include how long your account has been open, the timing or seriousness of a default under any Card Agreement that you have with us, or other indications of account performance. The variable default rate takes effect as of the first day of the billing period in which you default. Your account may again become eligible for a lower annual percentage rate on new purchases, new cash advances, or both after you have met the terms of all Card Agreements that you have with us for six consecutive billing periods. Your existing balances will remain subject to the variable default rate until they are paid in full, unless we tell you otherwise.

An increase in the variable annual percentage rate means you will incur a higher finance charge and perhaps a higher minimum payment.

Promotional Rate Offers:

At our discretion, we may offer you a promotional annual percentage rate for all or a part of any balances. The period of time for which the promotional rate applies may be limited. Any applicable promotional rate, the corresponding periodic rates, and the period of time during which it is in effect will appear on the accompanying letter.

Any promotional rate offer will be subject to the terms of the offer and this Agreement.

Finance Charges:

Finance charges for purchases, balance transfers, and cash advances will begin to accrue from the date the transaction is added to the daily balance, as described below, and continue to accrue until payment in full is credited to your account. However, if you paid the total New Balance, if any, listed on the last billing statement by the payment due date on that statement you will have until the payment due date on your current statement to pay your total New Balance to avoid imposition of additional finance charges on purchases (excluding balance transfers). If you have accepted certain balance transfer offers for which you may be eligible, you may not be able to avoid additional finance charges on purchases, as described in your balance transfer offer.

We will calculate finance charges as follows:

- We figure a portion of the finance charge on your account by multiplying the daily balance on each feature (e.g., standard purchases or standard advances) by the applicable daily periodic rate and separately adding together any such finance charges for each feature for each day in the billing period.
- For finance charge calculation purposes, the billing period begins on the day after the Statement/Closing Date of the previous billing period and includes the Statement/Closing Date of the current billing period. The number of days in the billing period may vary.
- To get the daily balance, we take the beginning balance for each feature every day (which may include unpaid finance charges from previous billing periods), add any new transactions, any new fees, and any finance charge on the previous day's balance, subtract any credits or payments credited as of that day, and make other adjustments. A credit balance is treated as a balance of zero.
- We add a new purchase to the appropriate purchase balance as of the Sale Date shown on your billing statement.
- We add a new balance transfer or cash advance to the appropriate purchase or advance balance as of the Post Date shown on your billing statement. The Post Date is the date we receive your request for the balance transfer or cash advance, including a request that we complete a balance transfer check or convenience check for a specific amount. If you send a balance transfer check or convenience check directly to someone, the Post Date is the date we receive the check for payment.
- The Balances Subject to Finance Charge on the billing statement are the averages of the respective daily balances during the billing period. If you multiply this figure for each feature by the number of days in the billing period and by the applicable daily periodic rate, the result will be the periodic rate finance charges assessed for that feature, except for minor variations caused by rounding. This method of calculating the balance subject to finance charge and the periodic rate finance charges results in daily compounding of finance charges.

Transaction Fee for Balance Transfers:

You have obtained a balance transfer for which we assess a balance transfer transaction fee if you transfer a balance by means other than a convenience check, or you obtain funds through a balance

2

3

4

Facilitating Communication – Providing Context (1)

USING YOUR CARD

You can use your account in the following ways. Your account is to be used only for personal, family or household purposes. You cannot use your account for illegal purposes, such as Internet gambling and writing checks against uncollected funds.

TRANSACTIONS	WHAT IT MEANS TO YOU	OUR RESPONSIBILITY
Purchases	You may use your account to buy goods and services.	We authorize charges to your account in accordance with the terms of this agreement.
Balance Transfers	You can transfer balances to your account by using balance transfer checks, visiting our website or calling us.	We permit balance transfers from most non-Chase accounts. We do not permit balance transfers from other accounts or loans with us or any of our related banks.
Cash Advances	You may obtain cash from automatic teller machines, at banks or by using cash advance checks. Balance transfer checks or promotional checks made payable to cash or yourself will be treated as cash advances.	We treat certain other transactions as cash advances. See the Cash-like Transactions section under Important Definitions above.
Checks	For your protection, balance transfer and cash advance checks must be signed by the person whose name is printed on the checks.	We may provide balance transfer checks and cash advance checks for your use; we have the right not to pay a check for any reason.
Overdraft Advances	You may set up this account to cover overdrafts on your checking account.	We allow Chase credit card accounts to be linked to a checking account with one of our related banks. The terms of this agreement and your checking account agreement will apply.
Automatic Charges	You may set up scheduled and repeat transactions to your account. If your account is closed or suspended, or your account number changes, you will need to contact any persons that you are paying by automatic transactions.	We are not responsible for scheduled and repeat transactions if your account is closed, suspended or the account number changes.
Promotions	You may receive special offers related to your account.	Any special offer is subject to this agreement, unless explained otherwise.

Foreign Transaction Fee and Exchange Rate	There is a fee, unless "None" is stated in the Rates and Fees Table, for transactions that take place outside of the United States, even if the currency used is U.S. Dollars. Our fee is calculated on the U.S. Dollar amount of the transaction. Please see the Rates and Fees Table for the amount of this fee, if any.	If a transaction is in a foreign currency, Visa International or MasterCard International will convert the transaction into U.S. dollars using their own currency conversion procedures, and then will send us the transaction amount. The exchange rate will be determined using either the range of rates available in the wholesale currency markets for the processing date (which may be different from the rate the card association receives) or a government-mandated rate in effect on that date. The exchange rate used by Visa or MasterCard may differ from the rate on the date of your transaction.
Authorization of Transactions / Closing Your Account	We are not obligated to honor every transaction, and we may close or suspend your account. Sometimes we close accounts based not on your actions or inactions, but on our business needs.	We may decline transactions for any reason, including: operational matters, the account is in default, or suspected fraudulent or unlawful activity. We are not responsible for any losses associated with a declined transaction.

Facilitating Communication – Providing Context (2)

“HOW TO AVOID...”

7

Certain transactions and situations may cause your account to receive a fee or have another impact on your account. The information below explains how you can avoid these outcomes. Amounts of these fees are listed in the Rates and Fees Table. The Rates and Fees Table indicates amounts “up to” certain limits for penalty fees because applicable law may restrict our ability to impose the full amount of the penalty fee in some circumstances. See the “Penalty Fees” provision below the Rates and Fees Table for additional detail reflecting limitations imposed under applicable law. Special services you request may incur additional service fees; be sure to carefully review the details of any additional services to understand the terms.

“HOW TO AVOID...”	WHAT TO DO	WHAT IT MEANS
Late Fee	Ensure Chase receives at least the minimum payment shown on your billing statement when due.	If any payment is late, we may charge you a late fee. If the fee is based on a balance, we calculate the fee using the total balance at the end of the day the fee is charged.
Return Check Fee	Do not stop payment on cash advance and balance transfer checks, and do not default.	We may charge a return check fee if we stop payment on a cash advance check or balance transfer check at your request, or we refuse to pay a cash advance check or balance transfer check for any reason, including because your account is in default.
Return Payment Fee	Do not submit a payment that could be returned unpaid.	We may charge this fee if the payment you offer to us is not honored, is returned unpaid, or cannot be processed.
Penalty APR	Do not: <ul style="list-style-type: none"> • Fail to make any minimum payment by the date and time due (late payment); or • Make a payment to us that is returned unpaid. 	We can impose a penalty APR, which is higher than the rate you would otherwise pay, for any of these reasons. If we impose a penalty APR, it may apply indefinitely to future transactions. If we do not receive any minimum payment within 60 days of the date and time due, the penalty APR will apply to all outstanding balances, as well as to future transactions. However, in connection with a payment default of 60 or more days, the penalty APR will stop being applied to transactions that occurred prior to or within 14 days after we provided notice about the increase to the penalty APR if we receive six consecutive minimum payments when due beginning immediately after the increase to the penalty APR.
Collections	Do not default.	If you are in default, we may take the actions described above in the Default section under Important Definitions above.

Facilitating Communication – Providing Context (3)

Consent 1 – Risks/Side effects

Neurological

- Chronic nerve damage
- Peripheral nerve damage
- Psychological intolerance (fear of loss of LAP monitoring function)
- Stroke/transient ischemic attack
- Subdural, epidural hematoma

Cardiac

- Acute coronary syndrome (sudden worsening of chest pain, heaviness or pressure)
- Arrhythmias (irregular heart rhythm)
- Acceleration of arrhythmia (make irregular heart rhythm go faster)
- Atrial septal defect (hole in the tissue between upper chambers of the heart)
- Cardiac arrest
- Cardiac perforation
- Cardiac tamponade
- Damage to heart valves
- Emergency heart surgery
- Emergency vascular surgery
- Low cardiac output state
- Heart block
- Hypotension

Consent 2 – Risks/Side effects

Those more **likely to occur** include:

- Nausea and or vomiting following drug injection. You will be monitored for 12 hrs following the injection, should any of these effects occur, we will examine you and give you appropriate medical care.

Those **less likely to occur but are serious** include:

- Hypoglycemia (low blood sugar) during testing days. You will be monitored during your testing. If symptoms such as occur, we will measure your blood sugar and if it is low, we will stop the test and give you juice or candy and retest your blood sugar.
- Serious allergic reaction to the drug. If this happens, the study regimen will be stopped and you will receive the appropriate treatment and management.

Informed Consent

Process of continuous engagement

Respect for the rights & welfare of research subjects



Framework of Shared Responsibilities

- Balancing public good of research with protecting research subjects – **IRBs have crucial role**
- Informed consent is about respecting people's autonomy & for their protections – **Investigators have primary responsibility**
- **Regulations** provide a framework that guides actions & manages conflicts



Nurturing TRUST is vital!

Contact OHRP

- Visit OHRP Website
(<http://www.hhs.gov/ohrp/index.html>)
- Email OHRP with Questions
ohrp@hhs.gov
- Phone Inquiries
240-453-6900; (866)447-4777
- Join OHRP ListServ for Event Updates
<http://www.hhs.gov/ohrp/newsroom/index.html>

THANK YOU FOR YOUR ATTENTION