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# Site Specific Informed Consent - AACTG 8-2004

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## The 10 Top Reasons for Disapproval



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# Review of Site Informed Consent

- Review Process
- Reasons for Disapproval
- How to Avoid Disapproval
- How to Get Assistance

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# Site IC Review Process

- Regulatory Compliance Center Receives Registration Packet, including IC
- Data Entry
- Review of Documents
- To RCC IC Reviewer
- Documentation of Review
- Message from Protocol Registration

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## Second Quarter 2004-All Networks

- 374 Approvals (71%)
- 107 Disapprovals (20%)
- 26 Incomplete Materials (5%)
- 23 Under Review (4%)

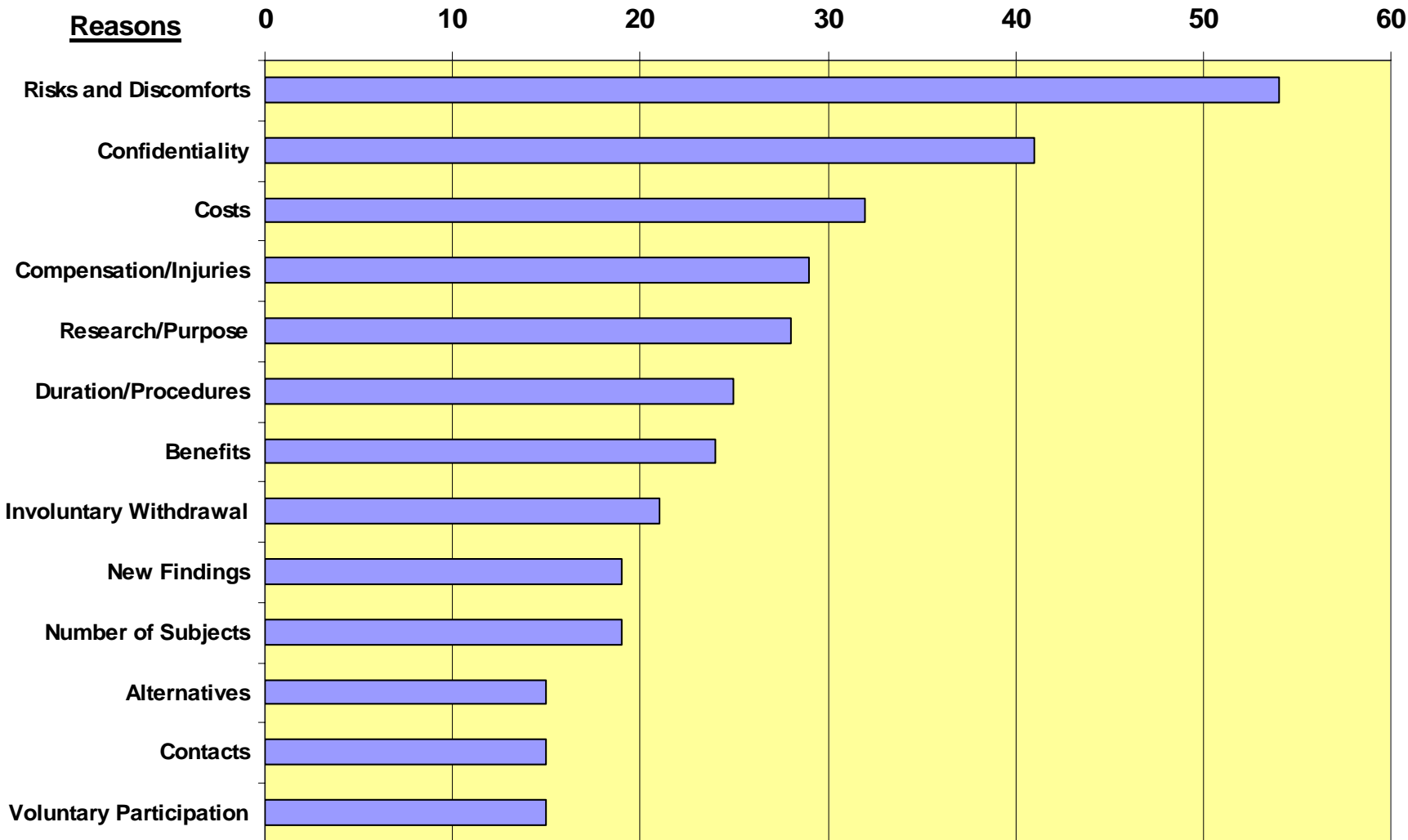
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# AACTG Second Quarter 2004

- 265/367 (72%) Approved
- 68/367 (19%) Disapproved
- 14/367 (4%) Paused
- 20/367 (5%) Open

# AACTG Jan-June 2004 Disapprovals

Number of Consents Disapproved for These Reasons



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# Inaccurate Information

- Risks
- Confidentiality
  - International: No Certificate of Confidentiality
- Costs
  - International: Standard of Care
- Compensation

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# Math 101 (The 3 V's)

- Volumes
  - International Sites
- Visits
- Versions

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# Number of Subjects

- International
- National
- Site

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# The Research Related Injury Statement

- Treatment Available
- Where
- Who to Contact and How
- Compensation for Injury

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# Basic and Additional Elements

- Essential Parts of the Informed Consent
  - 45 CFR 46
- Based on Federal Regulations
  - FDA: 21 CFR 50 for IND studies, OHRP, and DAIDS requirements
- Missing or Incorrectly Described Elements Cause Protocol Registration Disapproval

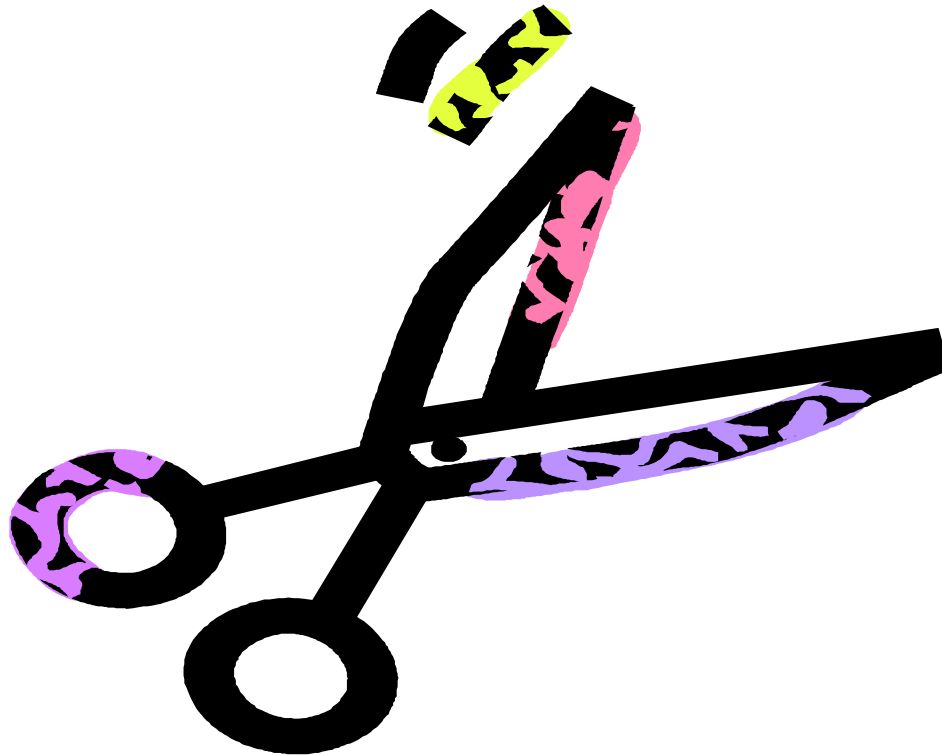
# How to Avoid Frustration



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# Informed Consent Tips

1. Cut and paste from the DAIDS Sample IC



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# To Avoid Inaccurate Information

- Check the following carefully:
  - Risks
  - Voluntary Participation
  - Research/ Purpose

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# Provide Supporting Documentation

- Birth Control Policy
- Specific IRB Requirements
- HIPAA
- Specific Populations (Men, Women, Children)
- International Populations
- Please refer to the Protocol Registration Manual (6/2004)

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# Required R's

- Risk
- Rights (Voluntary)
- Reason (Purpose)

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# Compulsory C's

- Confidentiality
- Compensation/ Payment
- Costs
- Contact (Injury/Questions/Rights)

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# Necessary N's

- New Findings
- Numbers Enrolled

# DO NOT:

- Omit Basic or Additional Elements
- Most commonly omitted for the AACTG are:
  - Risks
  - Rights (Voluntary)
  - Research/Purpose



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# Site Specific Considerations

- IRB may mandate changes to the consent
- Authorship
- So, the RCC would like you to provide justification.....

# Informed Consent Checklist

Protocol:	VERSION #:		
	Yes	No	ESSENTIAL Element Reference
<b>Content Review based on CFR Essential Elements {45 CFR46}</b>			
<b>Study involves research</b>			1
<b>Purpose: <i>If more than one listed, all must be listed</i></b>			1
<b>Expected duration of subject's participation</b>			1
<b>Accurate description of <i>all</i> procedures</b>			1
<b>Explanation that procedures are experimental</b>			1
<b>Description of risks and discomforts<sup>1</sup></b>			2 <sup>2</sup>
<b>Description of benefits</b>			3
<b>Description of alternative procedures</b>			4
<b>Confidentiality statement/ FDA inspection of research records</b>			5
<b>Injury /Compensation statement<sup>3</sup></b>			6
<b>Whom to contact for questions (with contact information)</b>			7
<b>Voluntary participation with no loss of benefit</b>			8

# Informed Consent Checklist

Protocol:	VERSION #:		
	Yes	No	Basic Element Reference
<b>Content Review based on CFR Essential Elements { 45 CFR 46 }</b>			
<b>Study involves research</b>			1
<b>Purpose: <i>If more than one listed, all must be listed</i></b>			1
<b>Expected duration of subject's participation</b>			1
<b>Accurate description of <i>all</i> procedures</b>			1
<b>Explanation that procedures are experimental</b>			1
<b>Description of risks and discomforts<sup>1</sup></b>			2 <sup>2</sup>
<b>Description of benefits</b>			3
<b>Description of alternative procedures</b>			4
<b>Confidentiality statement/ FDA inspection of research records</b>			5
<b>Injury /Compensation statement<sup>3</sup></b>			6
<b>Whom to contact for questions (with contact information)</b>			7
<b>Voluntary participation with no loss of benefit</b>			8

<b>Content Review based on CFR Additional Elements {45CFR46}</b>	<b>Yes</b>	<b>No</b>	<b>ADDITIONAL Element Reference</b>
<b>Risk(s) of particular treatment(s)</b>			<b>1</b>
<b>Involuntary termination</b>			<b>2</b>
<b>Cost to subject</b>			<b>3</b>
<b>Withdrawal/ orderly termination</b>			<b>4</b>
<b>New findings</b>			<b>5</b>
<b>Number of subjects enrolled</b>			<b>6</b>

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# Questions for AACTG Sites

- Who develops the consent for your site?
  - Principal Investigator
  - Site Coordinator
  - Research Nurse
  - Pharmacist
  - Outsourced
  - Other

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## Questions for AACTG Sites (Cont'd.)

- Do you cut and paste from the sample?
- If not, why not?
- How often does your IRB/EC meet?
- Who translates your consents (if applicable)? Is this person certified?
- In what specific area(s) you would like additional training?

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# Contact Information

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