Review Folder Proposal

To Review Users Group

March 10, 2003

Michael Cox, eRA Task Leader

* Presentation includes additional slides showing post-animation result, providing solution for PCs that don't support complex animation.

Presentation Outline

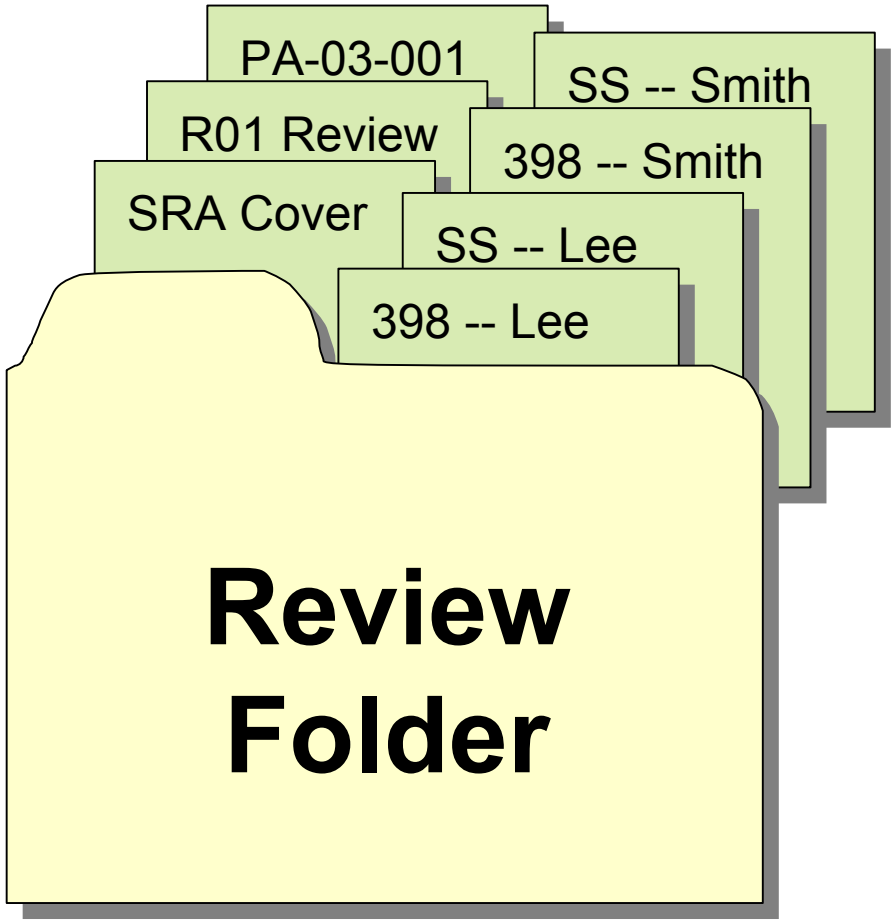
- Quickly Cover—
  - **Executive Summary of Review Folder**
  - **Content of CDs**
  - **Description of CD Problem**
  - **Policy Issues**
  - **CD Production Process**
  - **More description of Review Folder**
- Demo of Review Folder
- Next steps

Review Folder Overview

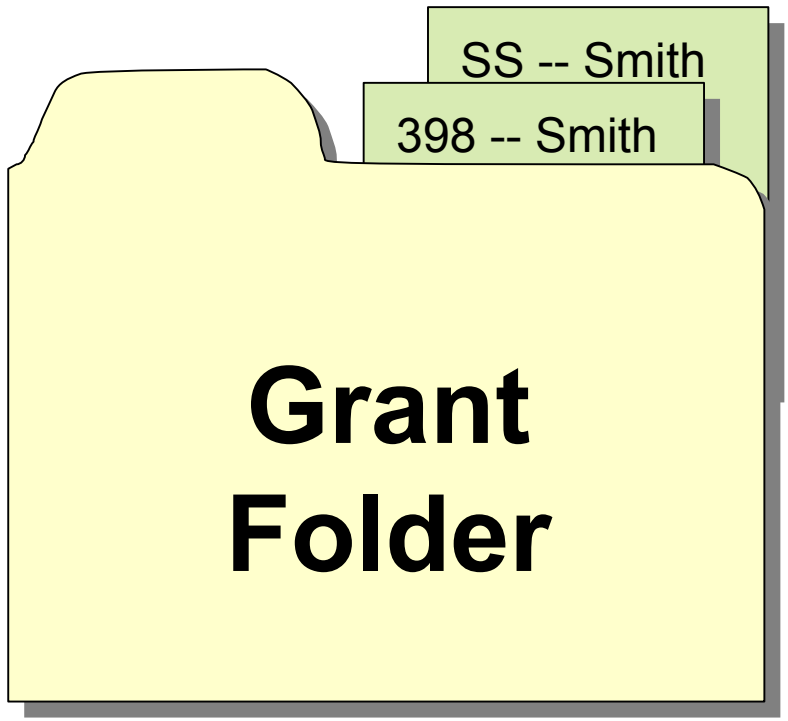
- Review Folder is an electronic collection of all documents a reviewer would normally receive in preparation for meeting, as prepared by SRA/GTA.
- General meeting information (e.g., SRA cover letter)
- General Review Guidelines
- Specific Review Guidelines
- PAs and RFAs
- Grant Applications
- Prior Summary Statements
- Other application materials (e.g., post-submission
- info)
- Other document types are possible.

Review Folder vs. Grant Folder

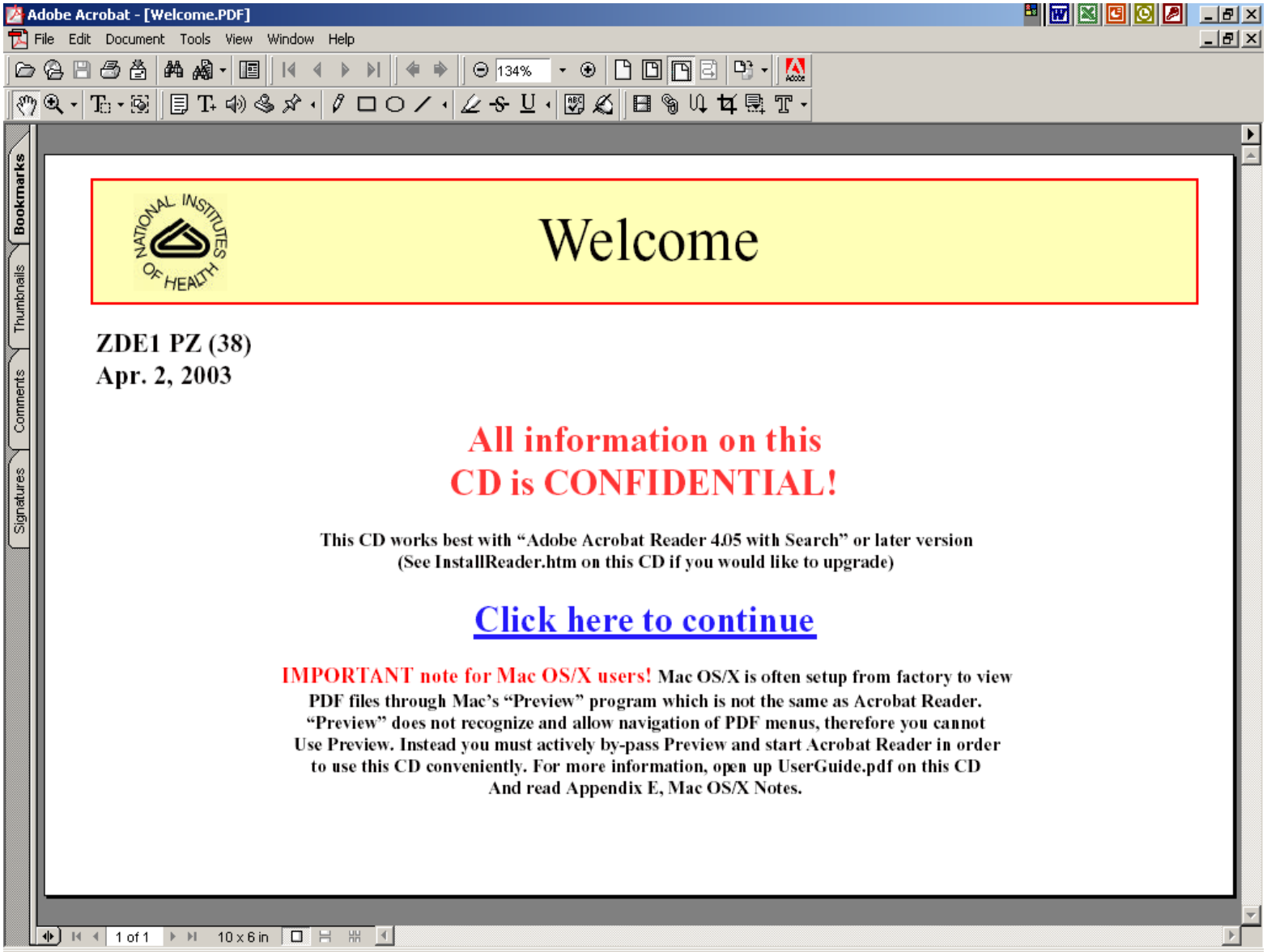
Documents for entire review



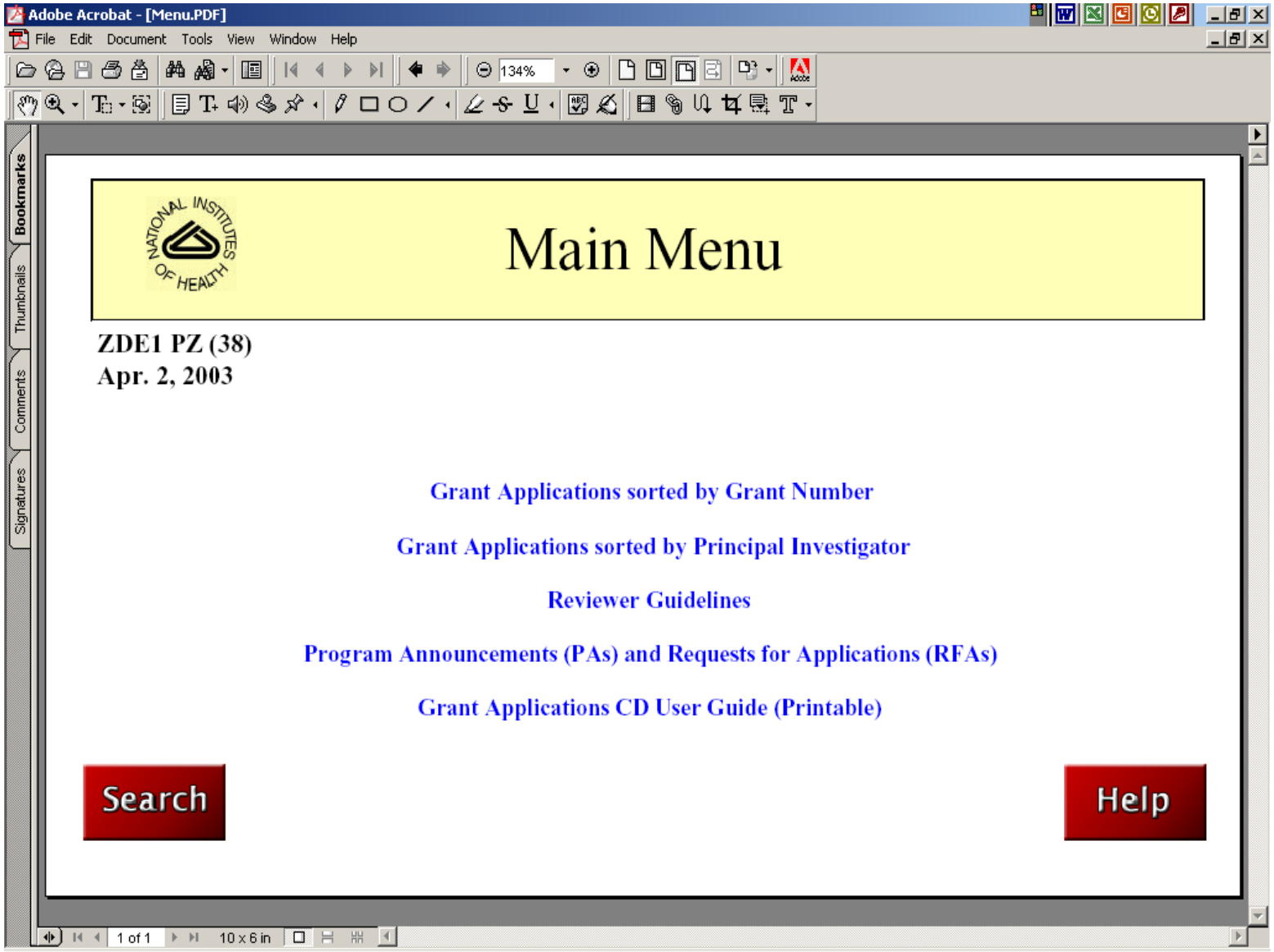
Documents for one applicant



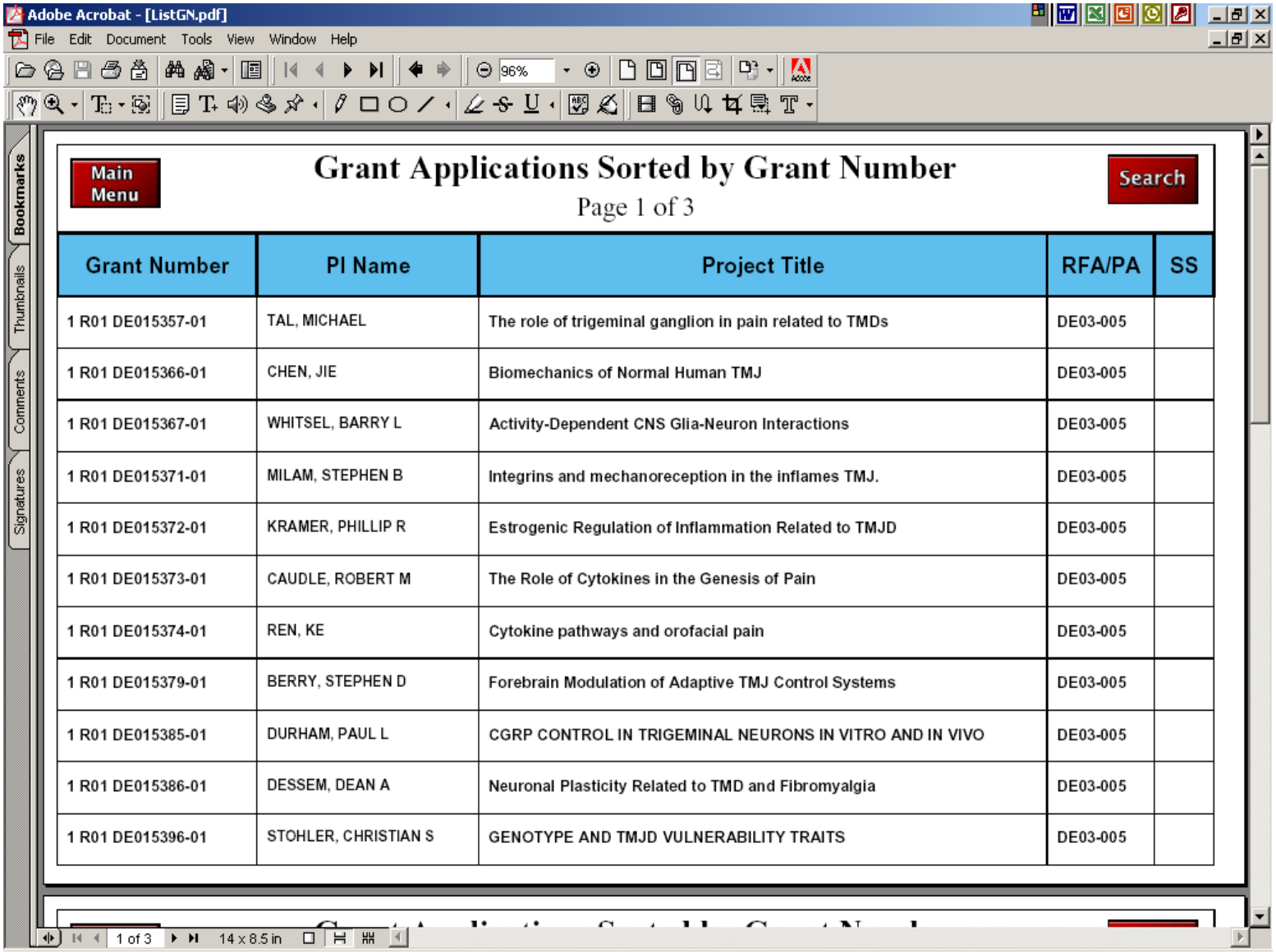
CD User Interface



CD User Interface

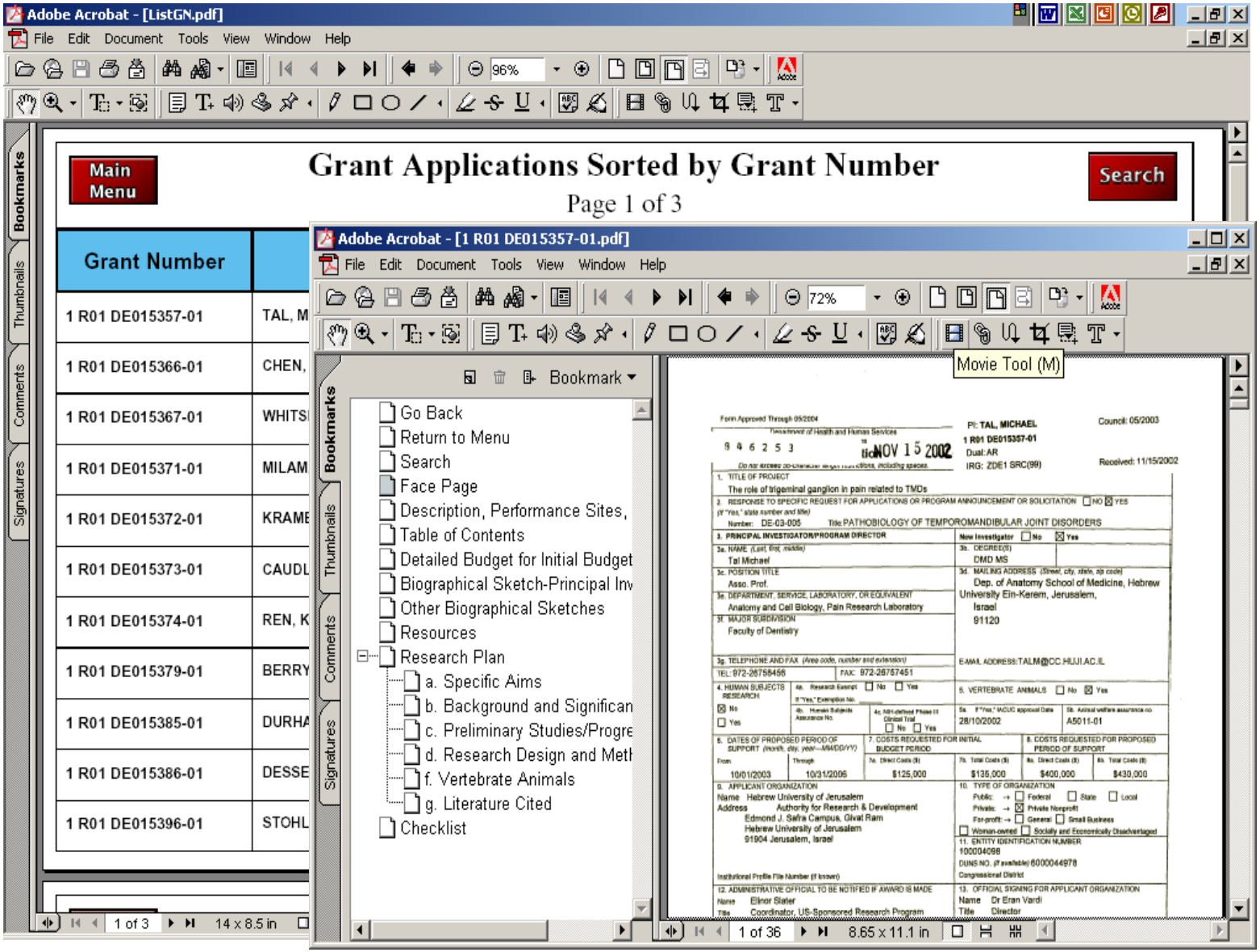


CD User Interface

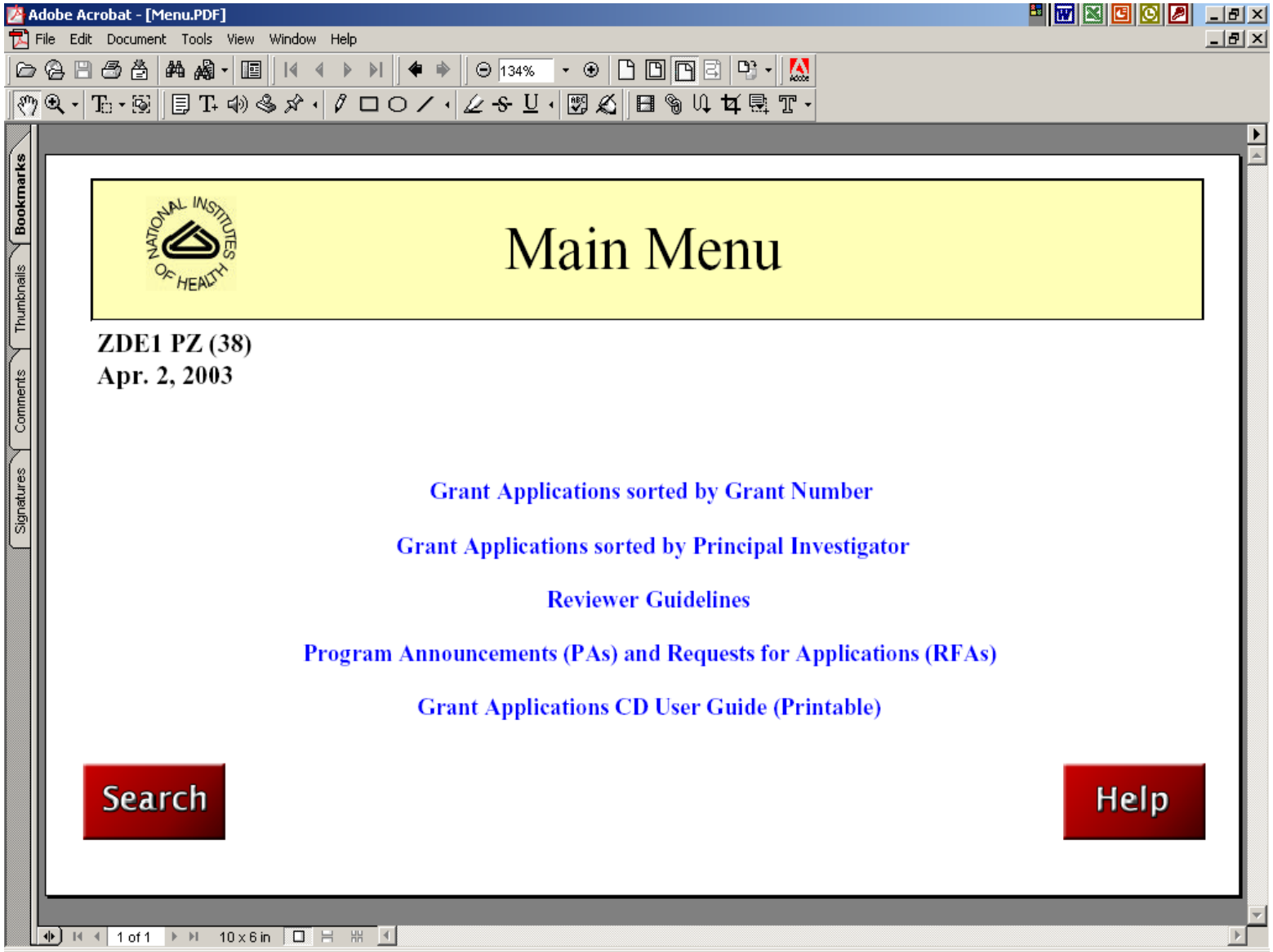


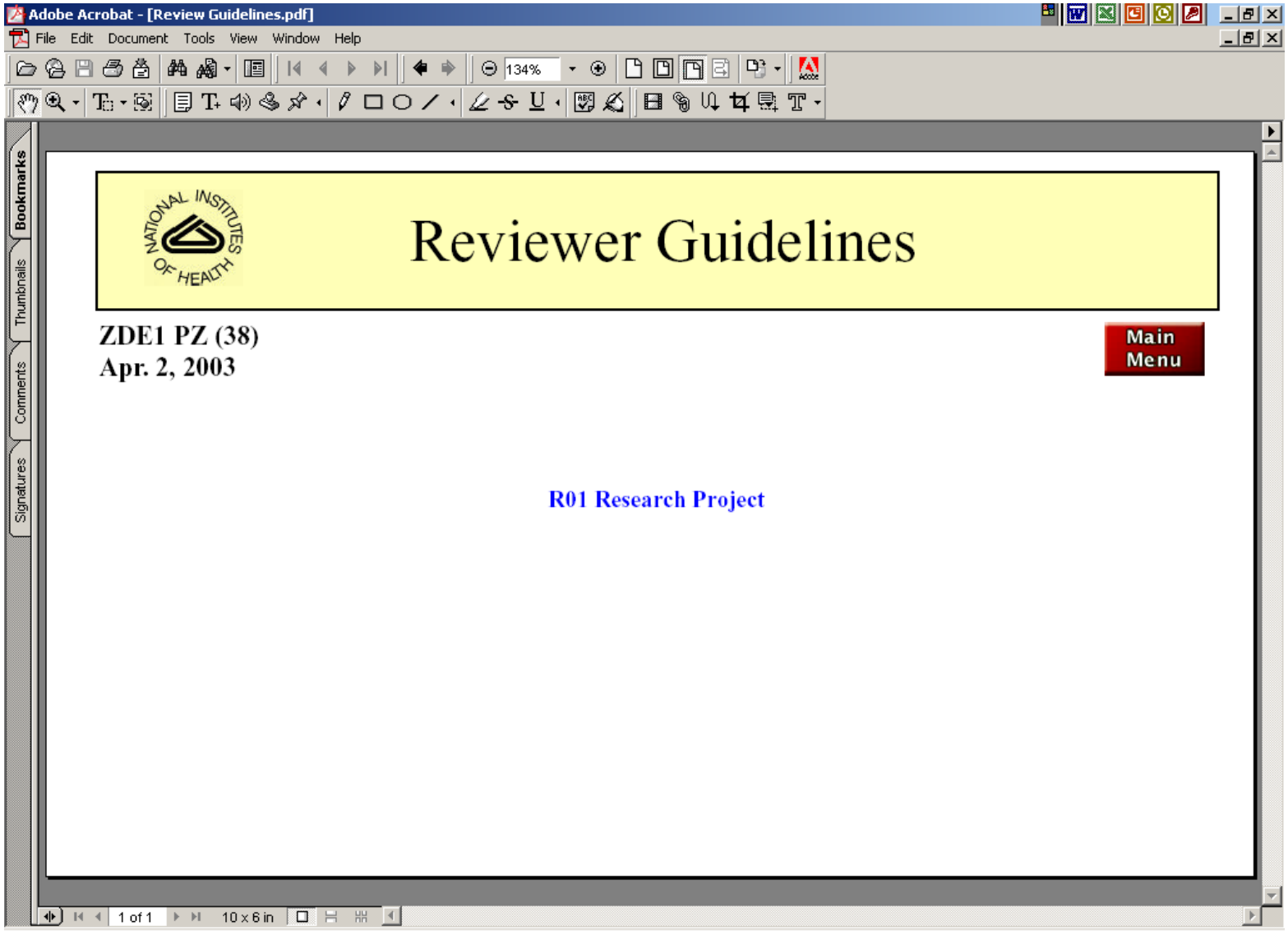
Grant Number	PI Name	Project Title	RFA/PA	SS
1 R01 DE015357-01	TAL, MICHAEL	The role of trigeminal ganglion in pain related to TMDs	DE03-005	
1 R01 DE015366-01	CHEN, JIE	Biomechanics of Normal Human TMJ	DE03-005	
1 R01 DE015367-01	WHITSEL, BARRY L	Activity-Dependent CNS Glia-Neuron Interactions	DE03-005	
1 R01 DE015371-01	MILAM, STEPHEN B	Integrins and mechanoreception in the inflames TMJ.	DE03-005	
1 R01 DE015372-01	KRAMER, PHILLIP R	Estrogenic Regulation of Inflammation Related to TMJD	DE03-005	
1 R01 DE015373-01	CAUDLE, ROBERT M	The Role of Cytokines in the Genesis of Pain	DE03-005	
1 R01 DE015374-01	REN, KE	Cytokine pathways and orofacial pain	DE03-005	
1 R01 DE015379-01	BERRY, STEPHEN D	Forebrain Modulation of Adaptive TMJ Control Systems	DE03-005	
1 R01 DE015385-01	DURHAM, PAUL L	CGRP CONTROL IN TRIGEMINAL NEURONS IN VITRO AND IN VIVO	DE03-005	
1 R01 DE015386-01	DESSEM, DEAN A	Neuronal Plasticity Related to TMD and Fibromyalgia	DE03-005	
1 R01 DE015396-01	STOHLER, CHRISTIAN S	GENOTYPE AND TMJD VULNERABILITY TRAITS	DE03-005	

CD User Interface



CD User Interface




Adobe Acrobat - [Review Guidelines.pdf]
File Edit Document Tools View Window Help
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Signatures
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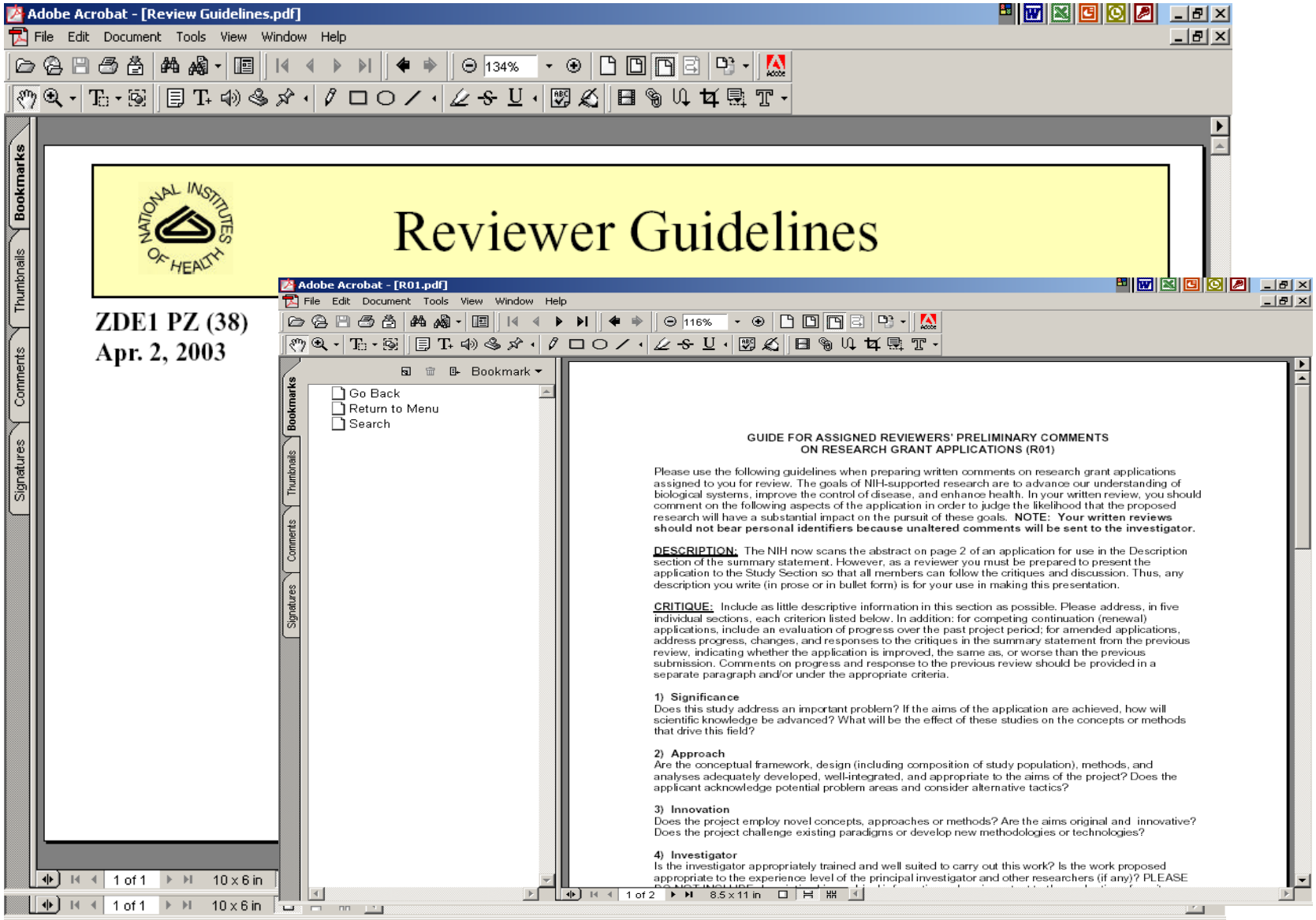
Reviewer Guidelines
ZDE1 PZ (38)
Apr. 2, 2003
Main Menu
R01 Research Project
1 of 1
10 x 6 in

CD User Interface



CD Contents

- General Review Guidelines
- Specific Review Guidelines
- PAs and RFAs
- Grant Applications
- Prior Summary Statements

(Also CD User Guide, Adobe Reader Install Guide, Reader Install Program, other miscellaneous data and files.)

Content Quality Problem

- Review Guidelines are not always available in time for CD production.
- ICs were supposed to provide a Web page of Review Guidelines for CD contractor to retrieve. Only three ICs have complied: CSR, NIDA, and NIDDK.
- Some SRAs have reported that a complete set of PA/RFAs is not always placed on the CD.
- Apparently PA/RFAs are not always reported on Grant Application, therefore IMPAC II data does not indicate need for PA/RFA. Also, perhaps it is possible that PA/RFA is sometimes not correctly recorded in IMPAC II.
- There are indications that some ICs maintain PA/RFAs outside the NIH Guide.

Review Policy Issues

- Reviewers should only receive approved Review Guidelines.
  - **SRAs sometimes distribute unapproved or obsolete guides.**
  - **Additional sensitivity regarding human subjects.**

- Reviewers should only receive approved PA and RFAs.
  - **SRAs sometimes distribute PA/RFAs that are not currently in the NIH Guide.**
  - **The NIH Guide is the "approved" set of PA/RFAs.**

CD Order Process

REVIEW MODULE

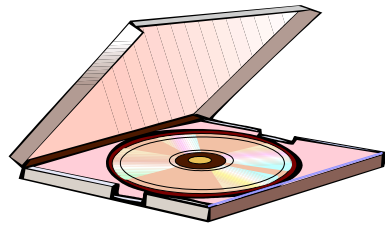
Meeting Info.

CD Order Info.

CD Order

CD Creation Process

CD Delivery



SRA /GTA

Order Confirmation

Additional Guides

Additional PA/RFAs

Other Attachments

398s graphics appendices etc.

Courier for scanning

CD Tech. (QAI)

Peer Reviewer

CD Order Process

*Post-animation result

REVIEW MODULE

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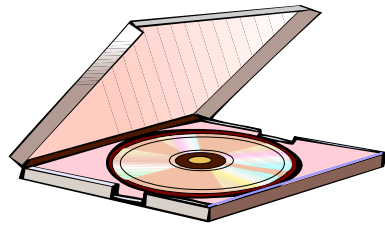

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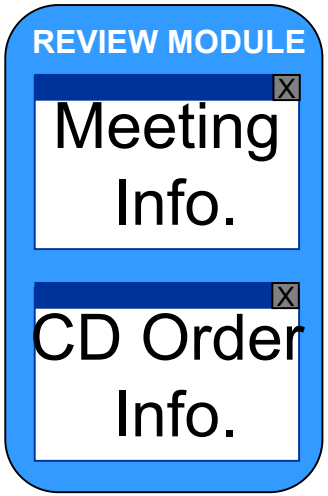

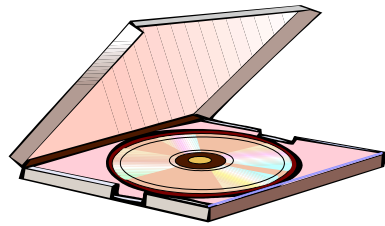

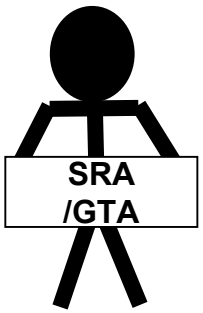

- Too much communication after order submission.
- Delays CD delivery time.
- Susceptible to error.
- Added cost.
- Inefficient!

CD Order Process

REVIEW MODULE

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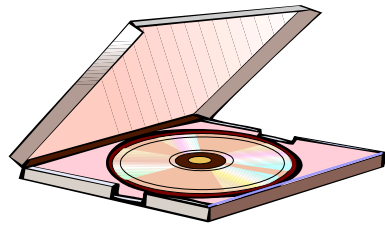

SRA /GTA

Ord mation

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Process Improvement

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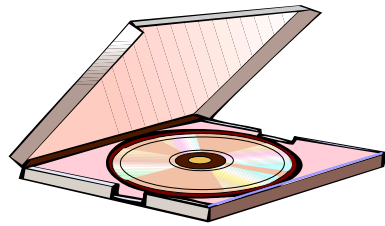

SRA /GTA

Review Folder

Peer Reviewer

Process Improvement

*Post-animation result

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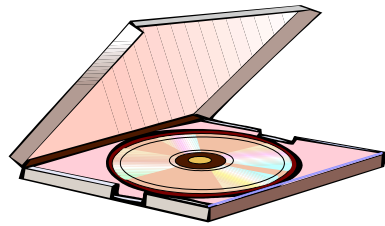


SRA /GTA

Review Folder

Peer Reviewer

Review Folder Concept

- Review Folder is an electronic collection of all documents a reviewer would normally receive in preparation for meeting. The SRA can edit the collection to assure it is accurate and complete.
- Review Folder allows only approved Review Guidelines and PA/RFAs. ICs will have flexibility to control and provide their own approved versions.
- Review Folder can be placed in IAR for online access by reviewers. This will set stage for eventual obsolescence of CDs.
- Review Folder can serve as a new interface to the CDs, providing SRAs and Reviewers with same UI no matter if CD or Internet.

Process *Innovation*

REVIEW MODULE

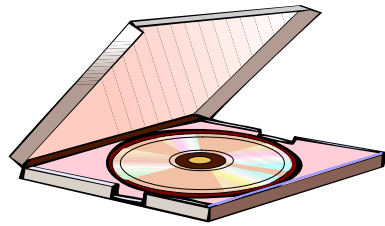
Meeting Info.

CD Order Info.

CD Order

CD Creation Process

CD Delivery



IAR

SRA /GTA

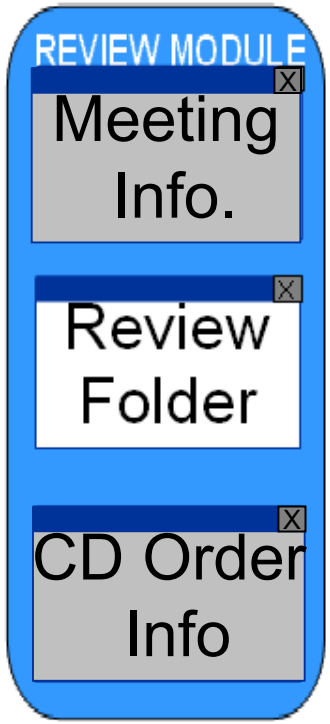
Folder on CD

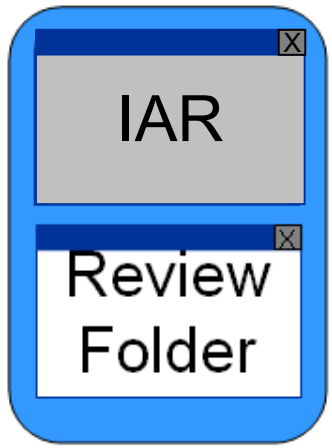
Same user interface for all media.

Review Folder

Process *Innovation*

*Post-animation result





Folder in Review Module
Collect all review documents.

Folder in IAR
Electronically distribute all documents to reviewers.

Folder on CD
Same user interface for all media.

Review Folder

Demo by Browser

Demo by PowerPoint

Sample Demo next 6 slides:

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Peer Review

Select Meeting

Meeting Query Parameters

Council YYYY/MM	SRG	SRG Flex	SRA Designator	SRA Flex	Group	
2003/05	ZRG1		SRB			Search

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Meeting Query Parameters

Council YYYY/MM	SRG	SRG Flex	SRA Designator	SRA Flex	Group	
2003/05	ZRG1		SRB			Search

List of Meetings 101- 200 of **999**

Council	SRG / Flex	Grp	Ext	SRA NAme	WG #	# of Appls	FACA	WG
2003/05	ZRG1	52	R	EILEEN BRADLEY		30	Yes	No
2003/05	ZRG1	51	R	EILEEN BRADLEY		37	Yes	No
2003/05	ZRG1	54	R	EILEEN BRADLEY		1	Yes	No
2003/05	ZRG1	53	R	EILEEN BRADLEY		9	Yes	No
2003/05	ZRG1	50	R	EILEEN BRADLEY		1	Yes	No

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Review Folder Summary

Council Date: 2003/02 **Study Section:** SAT Surgery, Radiology and Bioengineering IRG
SRA: Everett E. Sinnett, Ph.D. **Meeting Date:** Feb. 20, 2002

General Meeting Information Upload a Document

Dr. Everett E. Sinnett's Cover Letter	Remove
Directions and Map to Meeting Location	Remove
Hotels, Transportation, and other Accommodations	Remove

General Review Guidelines

General Review Procedures for Scientific Review Group Meetings
Guidelines for Reviewers
Streamlined Review Procedures used in CSR
Guidelines for Study Section Chairs
NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects
Review of Modular Research Grant Applications

Specific Review Guidelines

Review Guide	Grant Mech.	Awarding IC	RFA/PA Numbers	Date Created	Actions
K08 PA-00-003 Mentored Clinical Scientist Development Award [PDF Format]	K08		PA00-003	01/01/03	List Apps
K23 Mentored Patient-Oriented Research Career Development Award [PDF Format]	K23			01/01/03	List Apps
R01 Research Grants	R01			01/01/03	List Apps
R01 New Investigator Research Grants	R01			01/01/03	List Apps
R01 Template for Critique Preparation by Reviewers	R01			01/01/03	List Apps
R21: other ICs - Pilot Projects or Feasibility Studies	R21			01/01/03	List Apps

RFA and PAs

PA-00-003: MENTORED CLINICAL SCIENTIST DEVELOPMENT AWARD (K08)	List Apps
PA-00-004: MENTORED PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARD (K23)	List Apps
PA-01-129: INNOVATIVE AND EXPLORATORY RESEARCH IN DIGESTIVE DISEASES AND NUTRITION	List Apps
PA-02-011: BIOENGINEERING RESEARCH GRANTS	List Apps
PA-96-026: MOLECULAR PHARMACOLOGY OF ANESTHETIC ACTION	List Apps
PA-98-102: NEW DIRECTIONS IN PAIN RESEARCH: I	List Apps
PA-99-021: BIOBEHAVIORAL PAIN RESEARCH	List Apps

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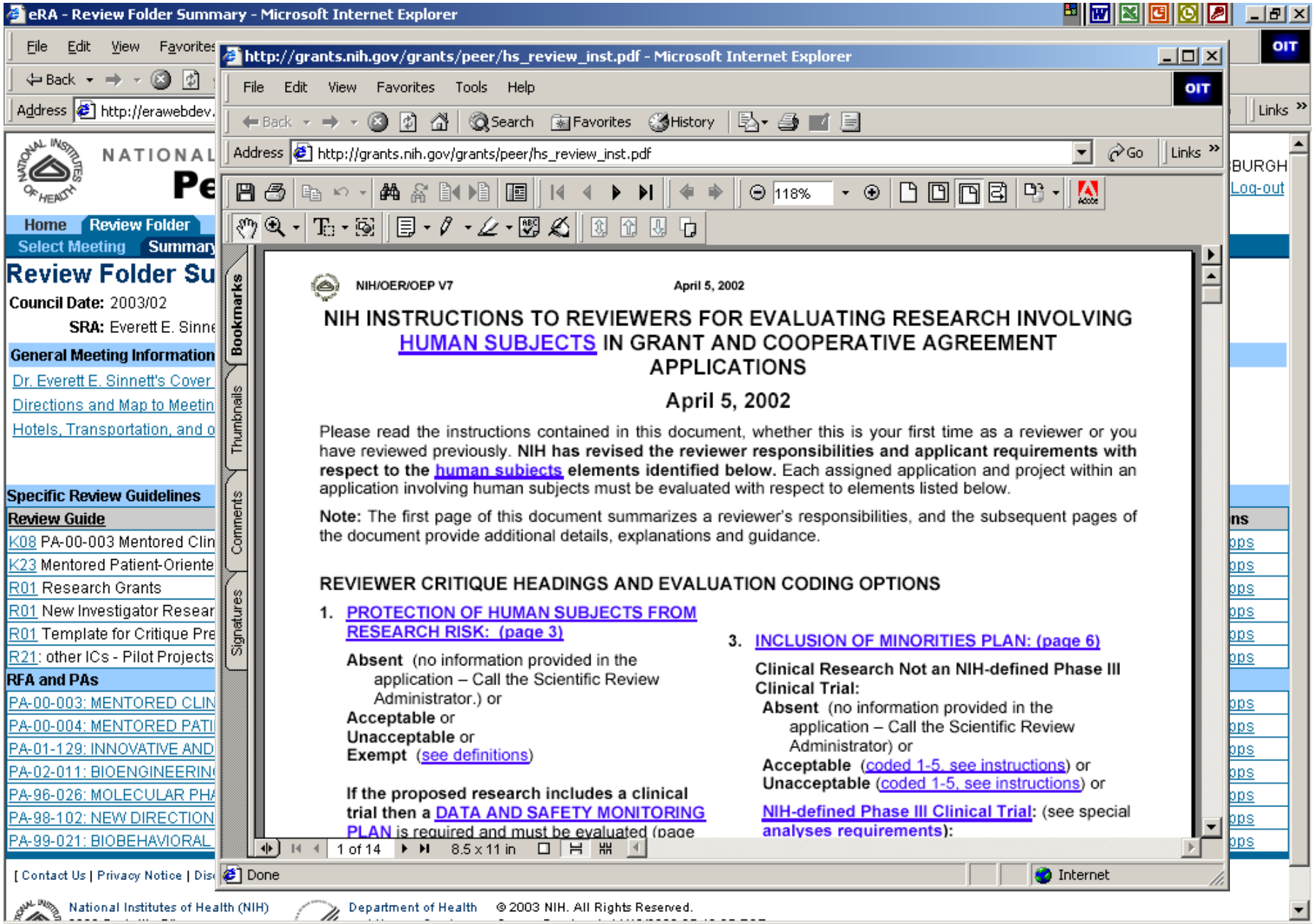
Internet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http://grants.nih.gov/grants/peer/hs_review_inst.pdf - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Address http://grants.nih.gov/grants/peer/hs_review_inst.pdf
Home Review Folder
Select Meeting Summary
Review Folder Su
Council Date: 2003/02
SRA: Everett E. Sinne
General Meeting Information
Dr. Everett E. Sinnett's Cover
Directions and Map to Meetin
Hotels, Transportation, and o
Specific Review Guidelines
Review Guide
K08 PA-00-003 Mentored Clin
K23 Mentored Patient-Oriente
R01 Research Grants
R01 New Investigator Resear
R01 Template for Critique Pre
R21: other ICs - Pilot Projects
RFA and PAs
PA-00-003: MENTORED CLIN
PA-00-004: MENTORED PATI
PA-01-129: INNOVATIVE AND
PA-02-011: BIOENGINEERIN
PA-96-026: MOLECULAR PHA
PA-98-102: NEW DIRECTION
PA-99-021: BIOBEHAVIORAL
Bookmarks
Thumbnails
Comments
Signatures
NIH/OER/OEP V7
April 5, 2002
NIH INSTRUCTIONS TO REVIEWERS FOR EVALUATING RESEARCH INVOLVING HUMAN SUBJECTS IN GRANT AND COOPERATIVE AGREEMENT APPLICATIONS
April 5, 2002
Please read the instructions contained in this document, whether this is your first time as a reviewer or you have reviewed previously. NIH has revised the reviewer responsibilities and applicant requirements with respect to the human subjects elements identified below. Each assigned application and project within an application involving human subjects must be evaluated with respect to elements listed below.
Note: The first page of this document summarizes a reviewer's responsibilities, and the subsequent pages of the document provide additional details, explanations and guidance.
REVIEWER CRITIQUE HEADINGS AND EVALUATION CODING OPTIONS
1. PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: (page 3)
Absent (no information provided in the application – Call the Scientific Review Administrator.) or
Acceptable or
Unacceptable or
Exempt (see definitions)
If the proposed research includes a clinical trial then a DATA AND SAFETY MONITORING PLAN is required and must be evaluated (page
3. INCLUSION OF MINORITIES PLAN: (page 6)
Clinical Research Not an NIH-defined Phase III Clinical Trial:
Absent (no information provided in the application – Call the Scientific Review Administrator) or
Acceptable (coded 1-5, see instructions) or
Unacceptable (coded 1-5, see instructions) or
NIH-defined Phase III Clinical Trial: (see special analyses requirements):
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Peer Review

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Review Folder Details

Council Date: 2003/02 **Study Section:** SAT Surgery, Radiology and Bioengineering IRG
SRA: Everett E. Sinnett, Ph.D **Meeting Date:** Feb. 20, 2002

Grant Application Attachments View All 101- 200 of 999

Grant Number	PI Name	Title	App.	Other	SS	PA/RFA	Guide	Actions
2 R01 AI 42898 5	ABECASSIS, M.	SURGICAL STUDIES OF CMV REACTIVATION IN TRANSPLANTATION	YES	(1) (2)	YES	PA-00-004	(1) (2) (3)	Edit
1 R01 AI 52352 1	ALEGRE, M.	ROLE OF NF-KB ACTIVATION IN ACUTE ALLOGRAFT REJECTION	YES				(1) (2) (3) (4)	Edit
3 R01 AR 46513 03S1	ALLEN, P.	MOLECULAR & ENVIRONMENTAL FACTORS INFLUENCING MH			YES			Edit
2 R01 HL 58760 5	ANDRESEN, M.	CENTRAL BAROREFLEX MECHANISMS OF ANESTHETIC ACTION	YES		YES			Edit
1 R01 HL 70721 1	ARDEHALI, A.	CD8 LYMPHOCYTES AND CARDIAC ALLOGRAFT VASCULOPATHY						Edit
1 R01 GM 63898 01A1	AYALA, A.	REGULATORY MECHANISMS OF ACUTE LUNG INJURY			YES			Edit
1 R01 GM 66181 1	BAYLISS, D.	ANESTHETIC ACTION:CHANNELS SUBSTRATES & MECHANISMS	YES			PA96-026		Edit
2 R01 GM 50509 9	BOYCE, S.	MECHANISMS OF WOUND HEALING WITH CULTURED HUMAN SKIN	YES		YES			Edit
2 R01 DK 52920 6	BUMGARDNER, G.	IMMUNOLOGIC TOLERANCE FOR HEPATOCYTE TRANSPLANTATION	YES		YES	FPA96-026		Edit
2 R01 HL 62324 4	BURCKART, G.	P-GLYCOPROTEIN IN LUNG TRANSPLANT RECIPIENTS	YES		YES			Edit
1 R01 GM 63050 01A2	CARLSON, D.	MODULATION OF NEUROENDOCRINE FUNCTION IN SEPSIS	YES		YES			Edit
1 R01 AI 52464 1	CHONG, A.	MECHANISMS OF GRAFT REJECTION & ANTI-GAL ANTIBODIES	YES					Edit
1 R01 DK 58106 01A2	COLLETTI, L.	SCF IN LIVER REPAIR AFTER HEPATECTOMY OR TOXIC INJURY	YES		YES			Edit
2 R01 HL 62195 4	DALMASSO, A.	ACTIVATION OF XENOGENEIC ENDOTHELIUM TO RESIST INJURY	YES					Edit
1 R01 NS 44026 1	DERBYSHIRE, S.	FUNCTION-SPECIFIC BRAIN NETWORKS IN PAIN PROCESSING	YES			PA99-021		Edit
1 R01 AI 52124 1	GALILI, U.	PREVENTION OF XENOGRAFT REJECTION BY ANTI-GAL SCFV	YES					Edit
1 R01 DK 62313 1	GELLER, D.	L-ARGININE/NO IN LIVER TRANSPLANT PRESERVATION INJURY	YES					Edit
1 K08 GM 64051 01A1	GERNER, P.	DEVELOPMENT OF SENSORY/PAIN-SELECTIVE LOCAL ANESTHETICS	YES			PA00-003		Edit
1 R01 GM 62136 01A2	GRANDO, S.	REGULATION OF KERATINOCYTE MIGRATION BY ACETYLCHOLINE	YES					Edit

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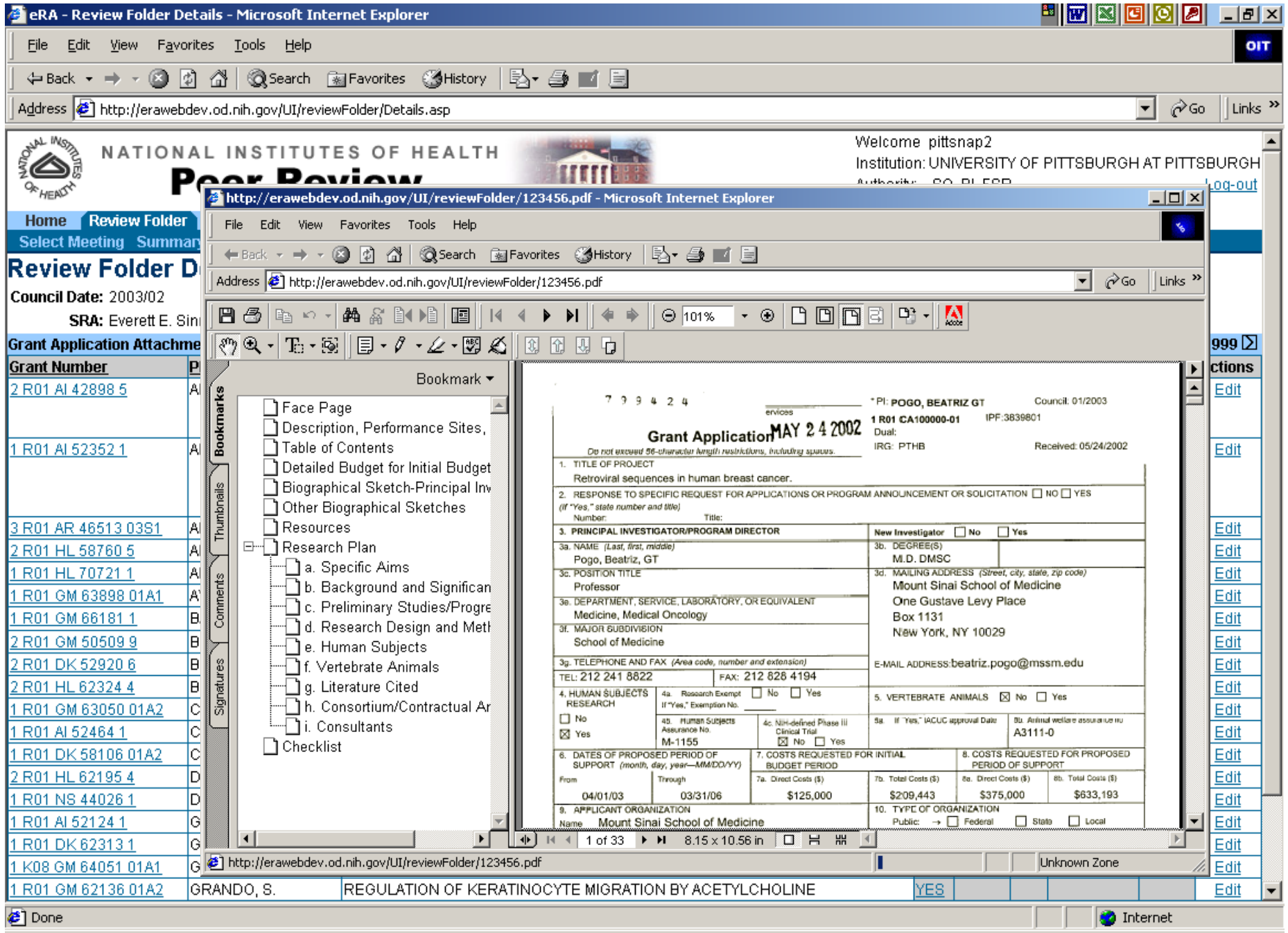
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Council Date: 2003/02
SRA: Everett E. Sin
Grant Application Attachme
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Grant Number
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2 R01 AI 42898 5
1 R01 AI 52352 1
3 R01 AR 46513 03S1
2 R01 HL 58760 5
1 R01 HL 70721 1
1 R01 GM 63898 01A1
1 R01 GM 66181 1
2 R01 GM 50509 9
2 R01 DK 52920 6
2 R01 HL 62324 4
1 R01 GM 63050 01A2
1 R01 AI 52464 1
1 R01 DK 58106 01A2
2 R01 HL 62195 4
1 R01 NS 44026 1
1 R01 AI 52124 1
1 R01 DK 62313 1
1 K08 GM 64051 01A1
1 R01 GM 62136 01A2
GRANDO, S.
REGULATION OF KERATINOCYTE MIGRATION BY ACETYLCHOLINE
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Detailed Budget for Initial Budget
Biographical Sketch-Principal Inv
Other Biographical Sketches
Resources
Research Plan
a. Specific Aims
b. Background and Significan
c. Preliminary Studies/Progre
d. Research Design and Meth
e. Human Subjects
f. Vertebrate Animals
g. Literature Cited
h. Consortium/Contractual Ar
i. Consultants
Checklist
7 7 9 4 2 4
* PI: POGO, BEATRIZ GT
Council: 01/2003
Grant Application
MAY 2 4 2002
1 R01 CA100000-01
IPF:3839801
Dual:
IRG: PTHB
Received: 05/24/2002
Do not exceed 56-character length restrictions, including spaces.
1. TITLE OF PROJECT
Retroviral sequences in human breast cancer.
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION NO YES
3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR
New Investigator No Yes
3a. NAME (Last, first, middle)
Pogo, Beatriz, GT
3b. DEGREE(S)
M.D. DMSC
3c. POSITION TITLE
Professor
3d. MAILING ADDRESS (Street, city, state, zip code)
Mount Sinai School of Medicine
One Gustave Levy Place
Box 1131
New York, NY 10029
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Medicine, Medical Oncology
3f. MAJOR SUBDIVISION
School of Medicine
3g. TELEPHONE AND FAX (Area code, number and extension)
TEL: 212 241 8822
FAX: 212 828 4194
E-MAIL ADDRESS: beatriz.pogo@mssm.edu
4. HUMAN SUBJECTS RESEARCH
No
Yes
4a. Research Exempt No Yes
If "Yes," Exemption No.
4b. Human Subjects Assurance No.
M-1155
4c. NIH-defined Phase III Clinical Trial No Yes
5. VERTEBRATE ANIMALS No Yes
5a. If "Yes," IACUC approval Date
5b. Animal welfare assurance no.
A3111-0
6. DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YY)
From 04/01/03
Through 03/31/06
7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD
7a. Direct Costs ($) $125,000
7b. Total Costs ($) $209,443
8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT
8a. Direct Costs ($) $375,000
8b. Total Costs ($) $633,193
9. APPLICANT ORGANIZATION
Name Mount Sinai School of Medicine
10. TYPE OF ORGANIZATION
Public: Federal State Local
1 of 33
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Project Plan

- RUG and Review Advocate approval
- RPC review
- Cost estimate
- eRA Project Approval: cost, schedule, priority
- Approximately three JADs:
  - **Users, Analyst, Developers, Testers, Tech Writer**
  - **Business rules, document types, policy**
  - **User interface and data requirements**
- CDR
- Develop
- Deployment Plan: Pilot? Full deployment? Phase?
- Final RUG review
- Deploy: October 2003

Transition Plan

- Develop transition plan
- Possible RPC policy announcement regarding plan
  - **(Especially if any CD product or service is required to scale back)**
- Develop Web site for approved review guides
- Possible patch release for CD order download file (e.g., include more data for ID of guides.)