# Agenda for CWG Meeting January 8, 2003



- 1. eRA Project Status John McGowan
- 2. Clinical Research/IRB Business Process John McGowan/Steve Dowdy
- 3. Commons 2.0 Tim Twomey
  - Status of development/deployment
  - Plans for future releases
    - eSNAP
    - X-Train
    - Other new functionality
  - Outreach/Training
- 4. Internet-Assisted Review Dan Hall

# Agenda for CWG Meeting January 8, 2003



- 5. CGAP Datastream Approach and Models JJ Maurer
- Update on the SBIR eRA Initiative
- Progress on Streamlining the Competitive Grant Application Process – David Wright, George Stone
- Other Issues
  - NIH eRA Commons Implementation Planning at CWG Institutions



# 1. Status of the eRA Project

# JJ McGowan eRA Project Manager



JJ McGowan eRA Project Manager



# Tim Twomey eRA Commons Coordinator

### Commons 2.0 Functionality



- New GUI Interface
- Registration authentication using IPF#
- Accounts Administration
  - Account creation authentication
  - Account maintenance
- IPF (Institution Profile)
  - Maintain general IPF information
  - Assurances/certifications
  - Full user-defined organizational hierarchy
  - Maintain e-mail addresses (NGA, Notifications)
  - Assignment of applications to hierarchy(coming)

# Commons 2.0 Functionality



- PPF (Person Profile)
  - Create and maintain profile information
  - User-defined integration of organizational hierarchy within profile
- Grant Status
  - View status information
  - Full NIH contact information
  - Link to study section information
  - Link to NGA, Summary Statement, Abstract
  - Availability of pre-populated forms for renewals
- Demo Facility
  - Fully functional demo version of the system (partial)
- Single Point of Ownership for PPF and IPF

### Commons 2.0 Functionality



- eNotification
  - Notices to PI and Organization Officials on pending progress reports, FSR, other (coming)
- FSR
  - Submit new/revised FSR
  - View FSR status (due, late, received, etc.)
  - Replaces "dial-up" TSO system
- eSNAP See slide
- IAR See slides
- CGAP

# eSNAP Functionality



- Submission 45 days prior to anniversary
- No abstract updating
- Submission of Research Accomplishments
- Delegation of Submission to PI controlled by SO
- Reconfiguration of e-SNAP questions
- Presentation of Personnel Data Page

#### **Internet Assisted Review**



- Allows reviewers submit preliminary critiques and score prior to review meeting
- Facilitates meeting discussion and speeds up review process
- Integrates with NIH eRA Commons accounts

### Commons 2 Deployment Schedule



- Version 2.0.0.0 10/11/2002
- Version 2.1.0.0 11/01/2002
- Version 2.2.0.0 12/06/2002
- Version 2.2.1.0 01/10/2003
- Version 2.2.2.0 03/24/2003
- Version 2.3.0.0 07/12/2003



- Version 2.0.0.0 10/11/2002
  - Registration
  - Basic IFP/PPF

- Version 2.1.0.0 11/01/2002
  - eSNAP pilot (2 + orgs)
  - FSR pilot (2 orgs)



- Version 2.2.0.0 12/06/2002
  - "Push" registration
  - Bug fixes to eSNAP/FSR
  - Pilot release of IAR (internal testing)
  - FSR Pilot to CWG

As of 1/5/2003 67 Organizations registered 669 Active users 267 FSRs submitted



- Version 2.2.1.0 01/10/2003
  - Open registration (low key)
  - Basic screen/UI enhancements
  - Bug fixes/minor enhancements to eSNAP/FSR/IAR
  - FSR open to all registered organizations
  - IAR release to two study sections to pilot
  - eSNAP pilot to CWG (?)



- Version 2.2.2.0 03/24/2003
  - Enhanced demo/training facility
  - Improved account affiliation management
  - More UI enhancements for eSNAP
  - Expanded IAR pilot
  - Other fixes/enhancements



- Version 2.3.1.0 07/12/2003
  - X-Train Phase 1
  - Org hierarchy/grant assignment
  - Pop Tracking screens in eSNAP
  - eNotification for T5 progress reports
  - Other fixes/enhancements
  - IAR full production

#### X-Train 1.5 Status



- 23 grantee organizations participating
- 289 trainee appointments processed since Oct. 1, 2001
- Outstanding issue
  - PI (PD) delegation & notification to minimize unauthorized submissions
    - To be implemented with NIH eRA Commons 2.0 Release 2 (tentatively November 2002)
- 2.0 Deployment mid-FY2003 planned

# NIH eRA Commons Training and Outreach



- 1. On-line/content sensitive help
- 2. User guides (pdf)
- 3. "Cheat Sheets"
- 4. FAQs and other resources
- 5. Enhanced demo/training site
- 6. NIH eRA Commons support page <a href="http://era.nih.gov/commons">http://era.nih.gov/commons</a>

# NIH eRA Commons Training and Outreach



National/Regional Meetings FY 2003

February FRA IV
 New Orleans, LA

March NIH eRA Commons Workshop Houston, TX

April NIH Regional Seminar Palo Alto, CA

April NCURA Region 4 Cincinnati, OH

April SRA Northeast Section Providence, RI

June NIH Regional Seminar Baltimore MD

Others TBA

### Training/Outreach/Support



#### NIH eRA Helpdesk

866-504-9552 (Voice, Toll Free)

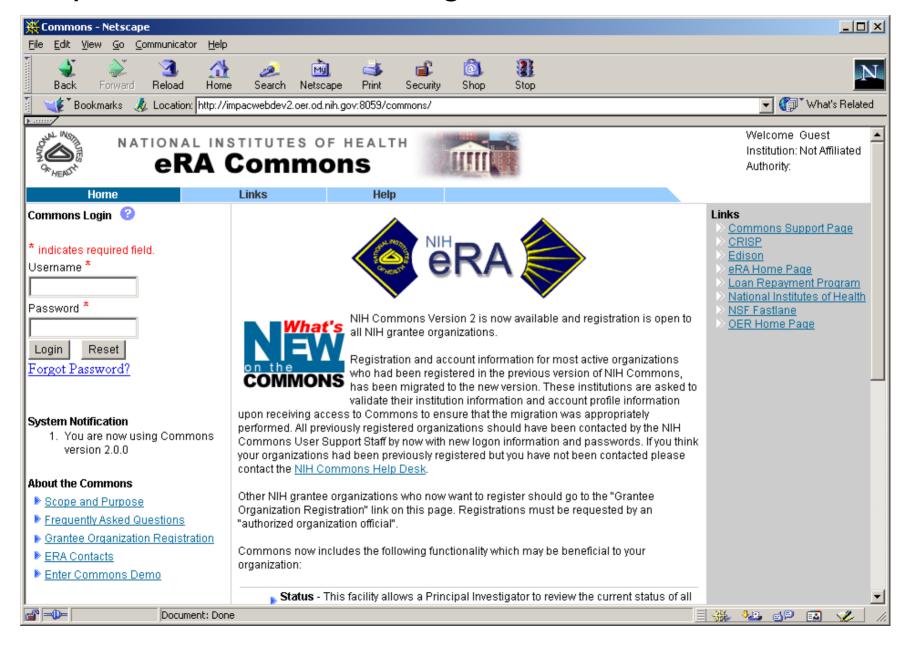
301-402-7469 (Voice - Local)

301-451-5675 (Fax)

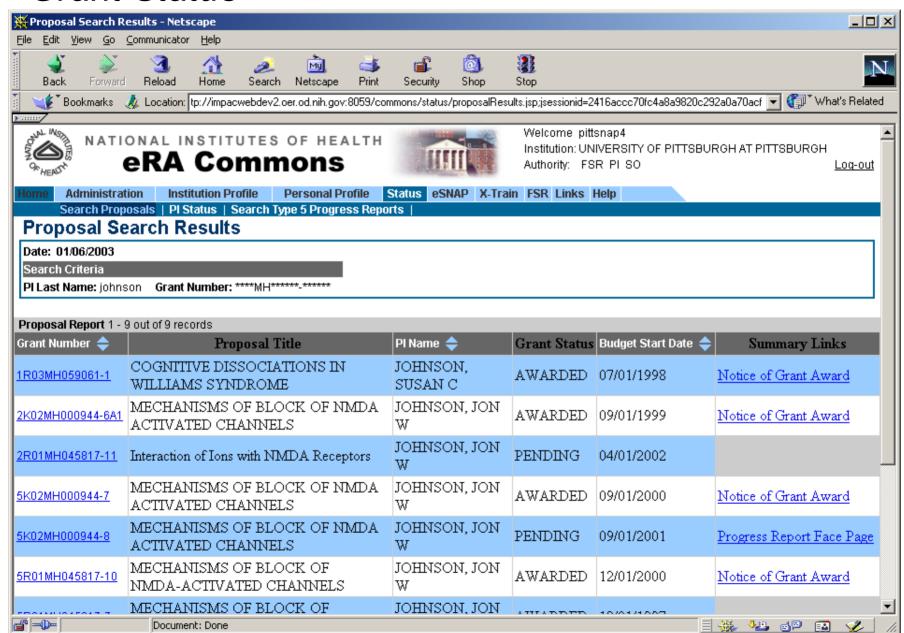
301-451-5939 (TTY)

commons@od.nih.gov

#### https://commons.era.nih.gov

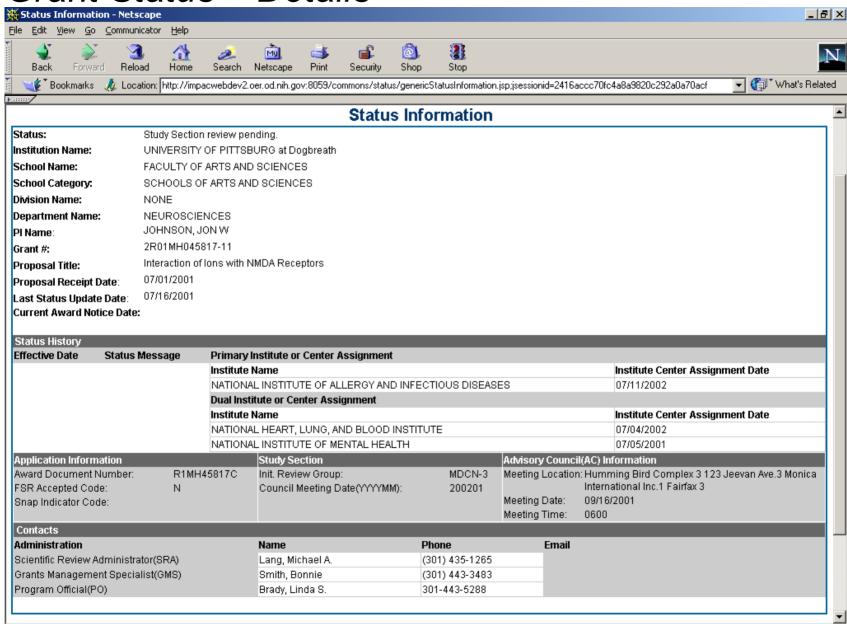


#### **Grant Status**



#### Grant Status - Details

Document: Done



# 4. Internet Assisted Review (IAR) and Institution Administration

Dan Hall
NIH eRA Commons Lead Analyst

# Internet Assisted Review (IAR)



#### **Internet Assisted Review**

Allows Reviewers to submit critiques and preliminary scores for applications they are reviewing for all to see.

- IAR was deployed on 12/6/2002
- Piloting two meetings (January March)
- Full production in July 2003

# IAR List of Applications





# NIH Requirements for IAR



- One UserID/Password
- Single sign-on with NIH eRA Commons
- Support both Affiliated and Unaffiliated Accounts (> 80% of Reviewers are PIs)

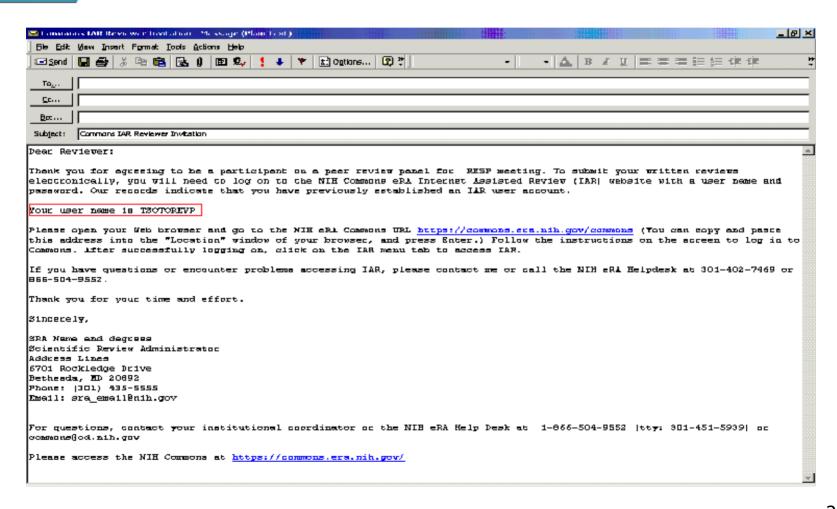
#### **IAR Account Creation Process**



- SRA initiates an invitation to a meeting
- If Reviewer has an NIH eRA Commons account:
  - An invitation to the meeting is sent
- If a Reviewer doesn't have an account:
   An email containing an account registration
   URL is sent

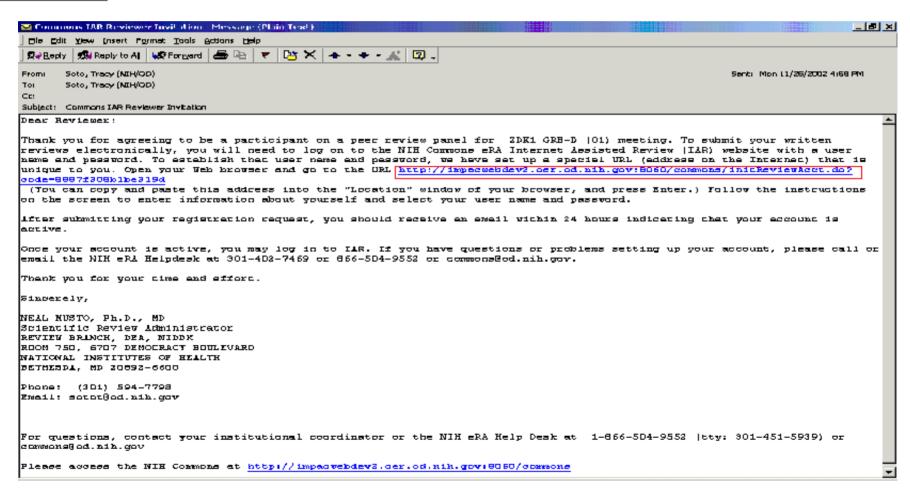
# Email for Reviewers with NIH eRA Commons Accounts



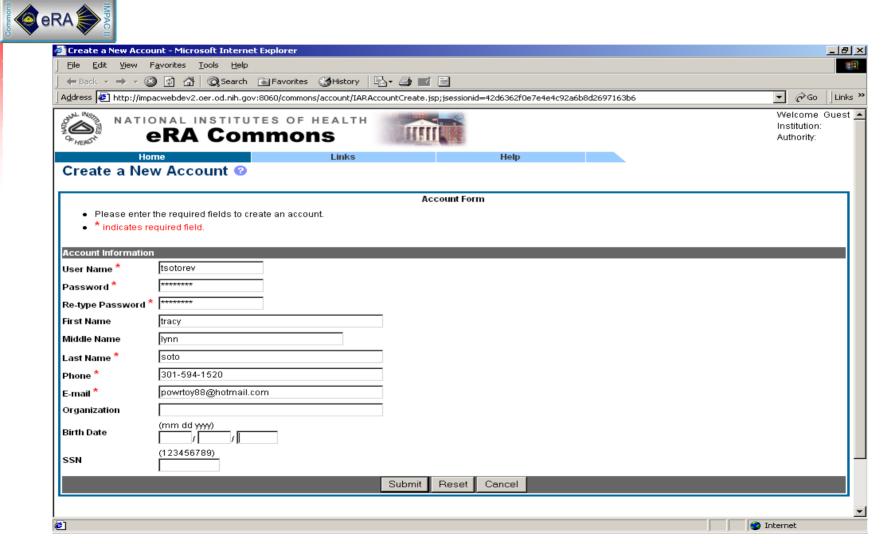


# Email for Reviewers without NIH eRA Commons Accounts

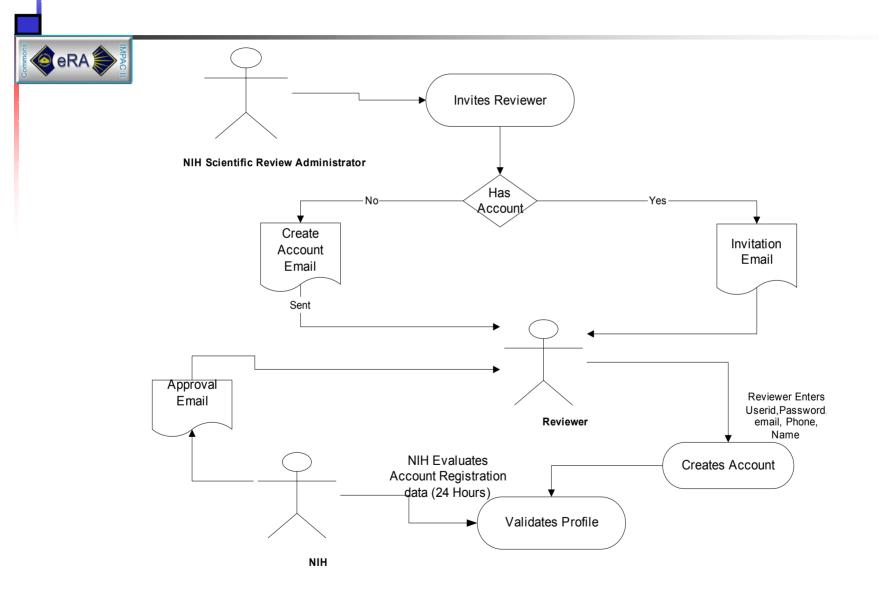




# Create Account Page



# IAR Account Registration

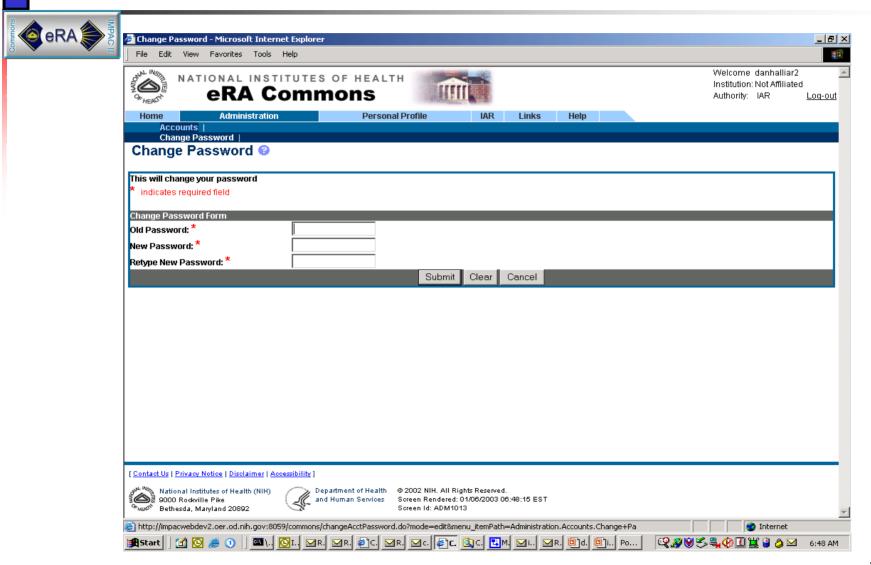


# How this Affects Institution Administrators (SO, AO, AA)



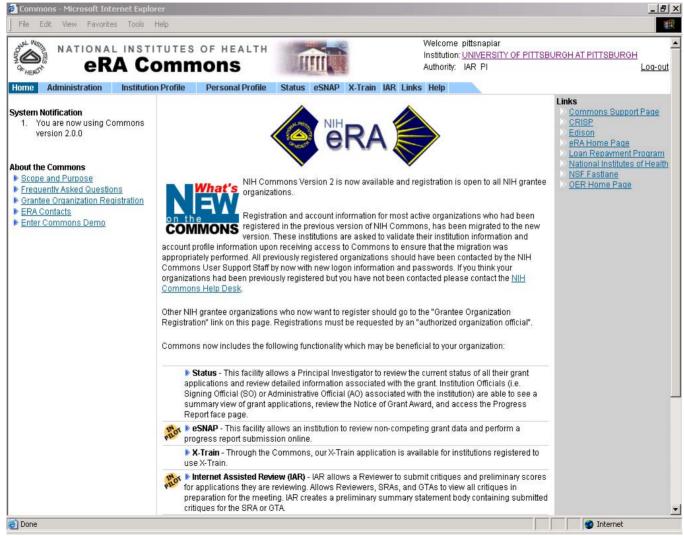
- Two states of an IAR account:
  - Affiliated with an institution
  - Unaffiliated with an institution
- Institution administrators manage these states by:
  - Create the initial accounts in NIH eRA Commons or affiliate reviewers to their institution
  - Remove institution affiliation through "delete account" (IAR accounts are not deleted)

#### **Unaffiliated Reviewer**



#### **Affiliated Reviewer**





# Process for Affiliating Reviewer's Accounts

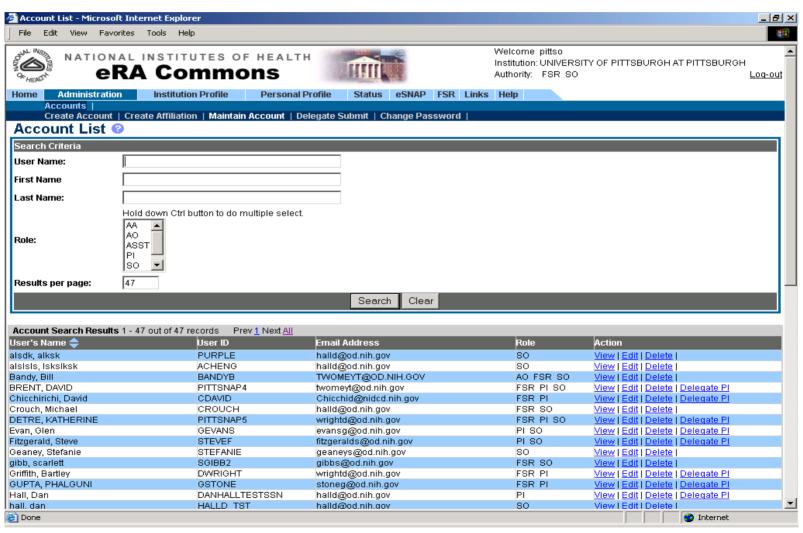


Today
 Requires NIH eRA Commons UserID and email

March 2003
 Integrated into "Maintain Accounts"

## Manage Institution Accounts







# 5. CGAP Data Stream Approach and Models

JJ Maurer eRA CGAP Lead Analyst

#### **Major Phases**



- Phase 1: Standard XML documentation, technology and application-receipt flow
- Phase 2: Application receipt and validation
- Phase 3: Business-to-government flow and interchange infrastructure
- Phase 4: Integration with bi-directional communications on IPF, PPF, FSR and potentially other requests

# Phase 1: Applications Only



- Analyze and document the e-application standard
- Submit for comments
- Define the technical architecture for
  - Receiving
  - Storing
  - Integrating e-apps into the NIH business flow
- Define the business flows to process e-Apps

# Phase 2: Receipt of e-Applications



- Define and implement the transaction receipt and format validation
- Prototype and TEST the receipt function with external partners
- Define downstream impact of e-Applications
- Integrate feedback from comments and tests

## Phase 3: Applications and B2B



- Define the business-to-government interchange
- Define and prototype error and change processing for e-Applications
- Define and prototype acceptance and referral by NIH
- Define and prototype registration, delegation of authority, security
- TEST the application receipt
- PILOT a limited set of live applications

# Phase 4: PPF, IPF integration



- Implement changes in business processes downstream from Receipt and Referral
- Define and implement PPF, IPF bi-directional transactions
- Define a receipt stream for FSR, e-SNAP
- Construct the production quality systems for e-Applications
- TEST exchange with external partners
- Prepare for production release of CGAP
- PILOT with gradual increase in volume

# **Target Timetable**



- Phase 1: Now to end of January 2003
  - Standard XML documentation, technology and application-receipt flow
  - Inception, tech architecture and analysis
- Phase 2: February April 2003
  - Application receipt and validation
  - Build and test the receipt of XML stream
- Phase 3: May July 2003
  - Business-to-government flow and interchange infrastructure
  - Complete design and build business-to-government exchange
  - Pilot
- Phase 4: August November 2003
  - Integrate with bi-directional communications on IPF, PPF, FSR and potentially other requests
  - Build out the integrated system for e-Applications: Test and gradual introduction

#### **Short-Term Actions**



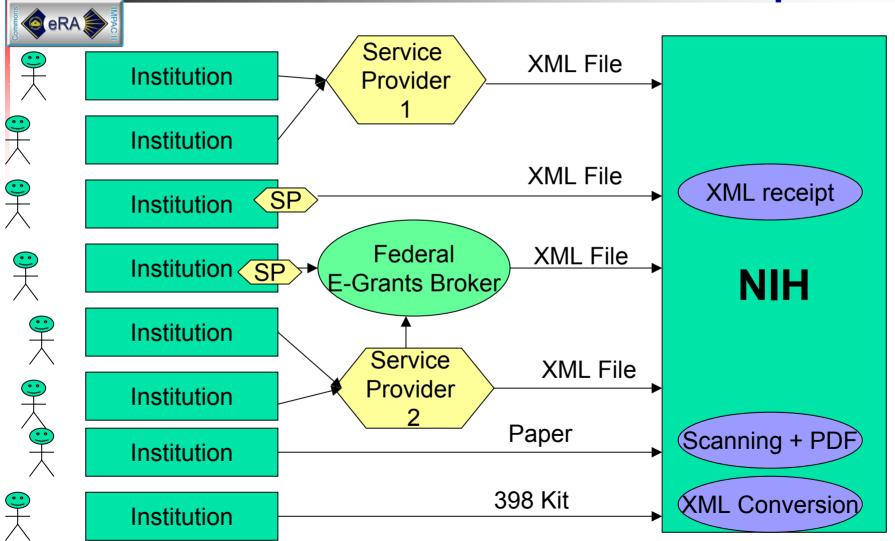
- More detailed plan under development
- Activated focus group for e-Receipt and Referral
  - List internal issues to be addressed
- Activated the SBIR listserv and communicate approach
- Technical solution for packaging, transport and storage of XML + docs started
- Resources assigned
- Test hardware procured, received, to be configured

# Receipt and Exchange Models

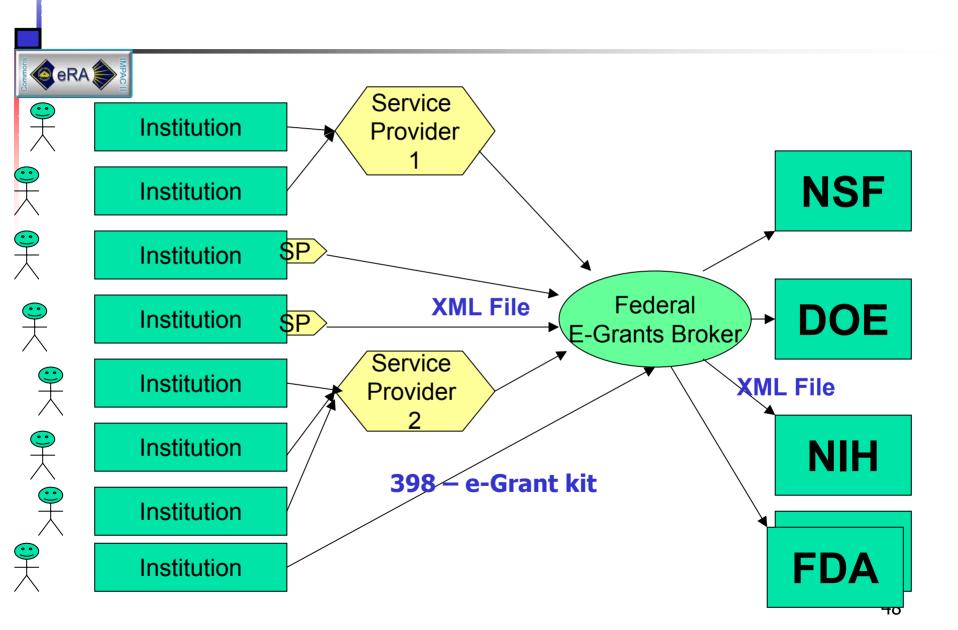


- Receipt Sources
  - Current model
  - Future model
- Exchange architecture
  - One-way communications versus
  - Exchange protocol
- Critical architectural decision

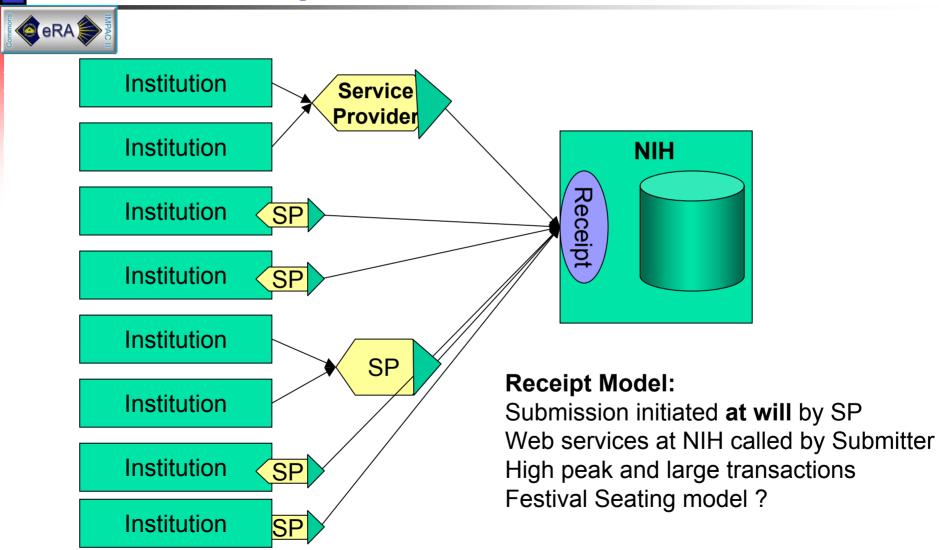
# **Current: Multi-Source Receipts**



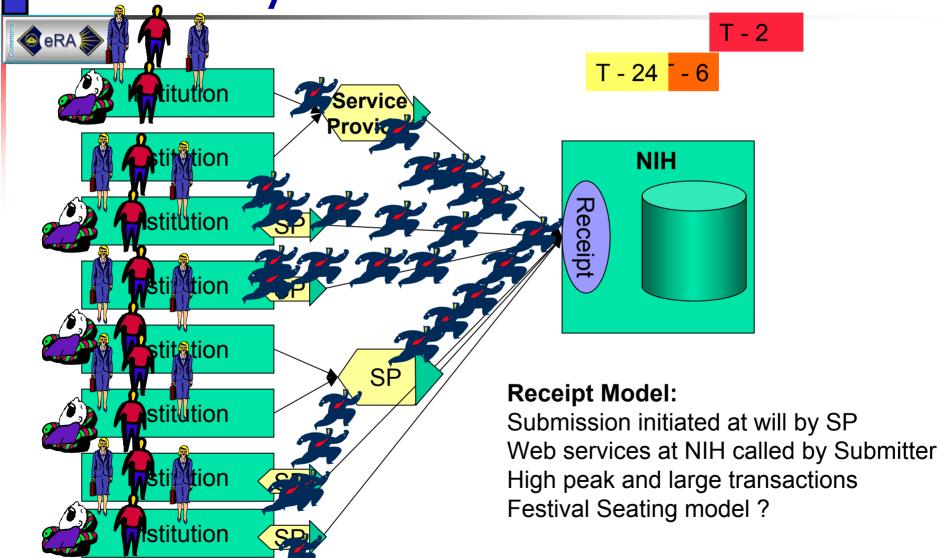
## Single Source Receipt for NIH



### **One-Way Communications**



#### **One-way Communications**



#### "Ticket" Process



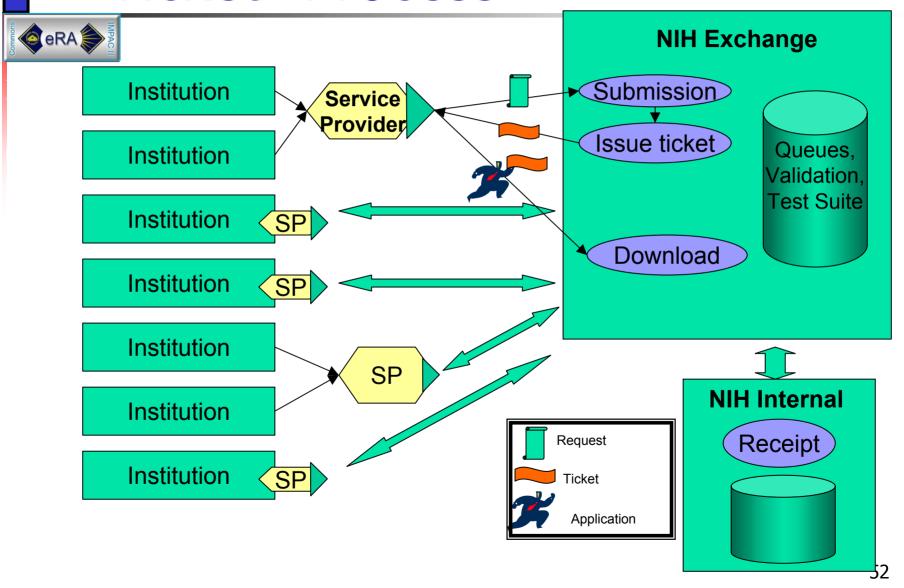
#### **Submission**

- Request for submission issued with application identifier and file characteristics
- NIH issues an accession number and a place in queue
- NIH records submission request and file characteristics

#### Later

- NIH signals for download
- SP sends file or NIH gets it
- NIH processes file

#### "Ticket" Process



#### "Ticket" Model T + 12 T - 24 @eRA **NIH Exchange** Institution Submission Queues, Issue ticket Validation, stil Test Suite Download stitation stitution sti **NIH Internal** stitation Receipt stitution SP Request Ticket Application

## Exchange



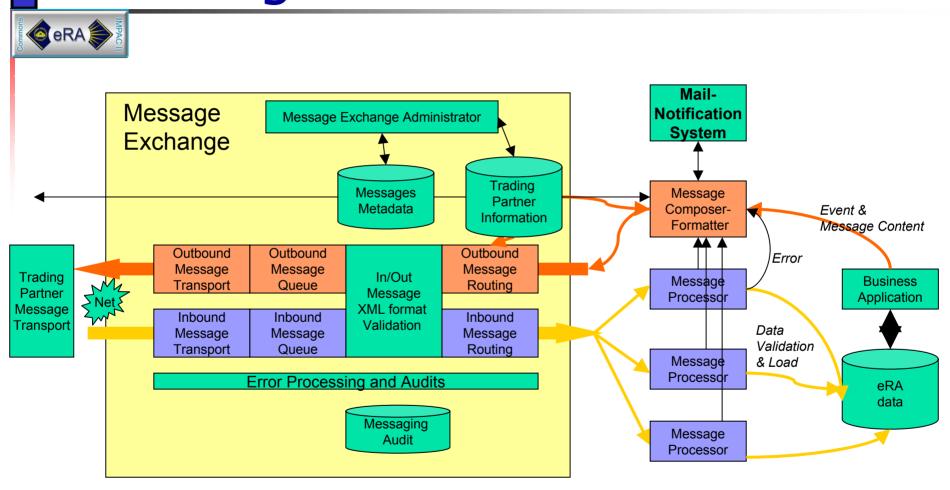
- Two-way communications
- A protocol to send and receive messages
- A "handshake" computer to computer
- Controlled transfer of the large transaction

#### Messages—Web Services



- A message is an XML file sent and received by a computer
- A message may have attachments
- Each message type has its own XML schema and workflow paths
- Example message types are:
  - Form 398 with PDF project plan and CV attachments
  - Appendices to a Form 398
  - Request for submission of 398
  - Queue ticket
  - Notification of receipt of XML file
  - Notification of acceptance of application by NIH
  - Notification of IRG and IC assignment
  - FSR, E-SNAP, Profile Submission
  - Protocols
  - and so on

# Functional Components of the Exchange



#### Components



- Trading partner agreement
- Message transport
- Message queues
- Message validation
- Message metadata
- Trading partner database
- Message content processors
- Notification, audits, error processing

#### **Issues**



- Approach not validated with E-Grants
- Each service provider must have a listener
- Each service provider must write the interfaces to their own systems and NIH exchange
- Standards may change
- Protocol and technology not defined
  - SOAP with attachments ?
  - ebXML? Or JAX APIS, COTS product?

## Major Tech Drivers



- Avoid a huge peak a few times a year
- Minimize footprint at the serviceprovider site
- Pick a standard that may be stable
- Look ahead for B-2-G interchanges and other transactions

# Advantages of Exchange



- Commercial models exist
- Lots of standard components exist
- No huge peak load problem to solve
- Generalized interface suitable for streamlining all exchanges
  - Post-receipt processes can be automated
- Could be kept relatively simple and nimble

#### Questions to Audience



- Is it feasible?
  - Can NIH send a message, computer to computer, to an institution or service provider and expect an answer (not e-mail) ?
  - Will institutions or SP write interfaces in a specific protocol or using a set of web services?

# Question about <u>Applications</u> Transfers



- Model 1: Submitter says: Here it is, go get it when you are ready.
  - With submission Service Provider (SP) indicates where the file is. Later NIH initiates transfer.
- Model 2: NIH says: It's your turn, give it to me.
  - When place in queue is reached, NIH requests transfer and SP initiates transfer (synchronized).
- Model 3: Submitter asks: Is it my turn yet?.... OK, here it is.
  - SP polls the NIH exchange for place in queue, when green light then SP initiates transfer.

#### 6. eRA SBIR Initiative Status



- NIH issued RFA for eRA SBIR initiative on Jan. 29, 2002
- Six awards
  - ERA Software Systems, Inc.
  - Research and Management Systems, Inc.
  - InfoEd International
  - Cayuse, Inc.
  - Clinical Tools, Inc.
  - Formatta Corporation
- Initial meeting with awardees to establish initial milestones took place on Nov. 13, 2002
- Program Contact: Dr. Amy Swain, NCRR <SwainA@NCRR.NIH.gov>



## 7. Streamlining the CGAP

Progress on CWG-derived Action Items

# IPF, EIN, Congressional District



#### IPF/DUNS

- Critical for identification of submitting institution
- Provisions must be made for new institutions
- Electronic process requires this information (validated) for submission

#### EIN

- Required for award financials
- Associated with IPF
- Could be made part of the organizational hierarchy to relieve submission burden

#### Congressional District

- Used by NIH for reporting to Congress
- Validated by NIH according to zip code
- Submission requirement not necessary

#### Abstract: ASCII vs. Rich Text



- Used for Receipt and Referral & CRISP
  - Rich text to facilitate referral process
  - ASCII only to facilitate manual indexing for CRISP
  - Current auto-index pilot software requires ASCII
- Questions posed to reviewers/applicants with assistance from CSR
- How do we define "Rich Text"
  - Benefits for expression of Greek characters
  - Mathematical equations?
  - Other graphics?

# Addresses & Signatures



- Box 9 Applicant Organization
  - Basic requirement of IPF
  - No need for repeated submission
- Box 12 Administrative Official
  - Required: GMOs use as first point of contact for negotiations and awards
- Box 14 PI Signature
  - Required: legally binds PI
  - Precedent exists for electronic delegation, i.e., NSF
- Box 15 SO Signature
  - Required: legally binds Institution
  - Precedent exists for electronic delegation, i.e., NSF and iEdison

#### Percent Effort



- Required to determine if effort is reflective of scope (42CFR, 52h)
  - Can be provided in budget-justification narrative
- Required to support administrative regulations and cost principles (45 CFR, 74.25)
  - Provided via budget page
    - Allows for costs analysis and monitoring of reduction in effort relative to date of award
- Maintain narrative for determination of scope
- Submission as JIT for administrative regulations and cost principles

# **Budget and Other Support**



- Itemized Budget Information
  - Used by GMOs to assess liability of cost, assess reasonableness for scope of work – requires detail
  - Used by reviewers to assess reasonableness of scope of work – required minimal detail
- Other Support
  - Used to assess experience and expertise
  - Used by review and program to identify potential scientific & budgetary overlap
- Consider overall simplification consistent with modular applications

#### **Text-based Information**



- PDF will be standard file format for application materials
- Issues
  - Image/print quality
  - File conversion
  - PDF versioning
- Recommendation to develop conversion service
  - Ensure quality
  - Accommodate file conversion (Word, WordPerfect, ASCII text)
  - Model after/partner with NSF

# The Research Plan: Formatting the Submission

Research Plan

@eRA

- Sections A-D must be in a separate file to allow validation of formatting
- Others sections to be submitted as one or more separate files.
- Formatting validation rules to be determined and in place prior to submission
  - Validation of page limits and fonts
  - Adherence to data requirements and business rules
- Leniency with formatting violations
  - NIH to provide warning with time for correction

#### **Appendices**



- Streamlining of receipt via JIT submission directly to the SRA
- CSR to support receipt of paper-based appendix material directly to SRA after application assignment

#### Appendices...cont.



- Streamlining via submission of electronic documents
  - PDF documents
    - Converted files (MS Word, WordPerfect, text) once conversion service in place
  - Upload document through NIH eRA Commons Status module
  - Preference for submission of single, multi-component file
- Process must ensure receipt of "documents" by all relevant NIH staff
  - Reviewers, IC GMO, IC Program
- Potential for "push" notification to PI
  - Notification of application assignment, SRA contact information, due date of materials

#### **Biosketch & Citations**



- Content and format of biosketch
  - Support for standard content and format for ease of analysis by reviewers/GMO
  - Support for optional content and format to accommodate PIs to excerpt from c.v.
- Questions posed to reviewers/applicants with assistance from CSR

#### **Biosketch & Citations**



- Citation Options
  - Utility in PPF to select citations & download in PDF to embed in the stream
  - JIT upload via eRA Status interface when assignment has been made (similar to electronic appendix materials)
  - JIT association (via institutional or third-party software) via eRA Status interface when assignment has been made
  - Consider using number of citations rather than page length to standardize length