



## Quick Reference Sections

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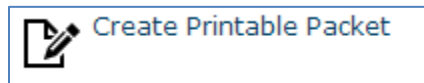
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### Overview

The Create Printable Packet activity assists IRB staff with organizing materials for review. Completing this activity will generate two files for further formatting (if needed), one snapshot of the SmartForm and one pdf of all attachments. **This activity can only be conducted by IRB staff and Committee Members.**

### Steps to Create a Printable Packet

1. Select the “Create Printable Packet” activity in the workspace.



2. A pop up window will appear during processing and will close automatically
3. View the “History” tab on the workspace to find the created files. Attachments which could not be converted will also be indicated here (*example text: “File: Recruitment Flier (attachments) of an unsupported format”*).

Activity	Author	Activity Date
Created Printable Packet	Administrator, System	3/14/2014 11:07 AM PDT

Smartform Pages as of Fri Mar 14 11:07:38 PDT 2014  
 Attachments for IRB14-0060 Fri Mar 14 11:07:42 PDT 2014

4. Click on each file to view and/or save to a separate space for further formatting.
- Important Note:** The files which are created and available on the history represent the submission at a single point in time and are not updated when the SmartForm is updated.



## SmartForm Pages File Detail

### Contents

When clicking on the file entitled “Smartform Pages...” the user will see the following:

- Initial Submissions: All pages of the main study SmartForm
- Modifications: Only the submission type (Modification or Continuing Review / Study Closure) and modification information SmartForm pages
- Continuing Review: Only the submission type (Modification or Continuing Review / Study Closure) and continuing review SmartForm pages
- Reports of New Information: RNI SmartForm pages

### Conversion

1. Click on the file entitled “Smartform Pages...” to view the contents.
2. Click “Print” at the upper right side of the displayed information.



3. In the print window, choose ‘print to pdf’ or ‘save as pdf’ to convert this to a file which can be saved to a computer.  
**Note:** There is no default filename provided, so you may want to record the information needed to name the pdf before opening the print window.
4. Click “Close” when printing or saving is completed.

## Attachments File Detail

### Contents

When clicking on the file entitled “Attachments for...” the user will see all attachments in the following order (as applicable):

- Continuing Review: All attachments to the Continuing Review SmartForm in the order they are attached
- Reports of New Information: All attachments to the RNI SmartForm in the order they are attached
- Base SmartForm Submissions
  - Initial Submissions: All attachments on the main study SmartForm
  - Modifications (any type): All attachments on the modification “Draft Study”  
*Note: If the modification scope is limited to one type or the other, all attachments will still appear in the attachments set.*

### Document Order

1. Protocol Attachments
2. External Site Attachments



3. Drug Attachments
  - a. Attachments for each Drug
  - b. IND Attachments
  - c. Other Drug Attachments
4. Device Attachments
  - a. Attachments for each Device
  - b. Other Device Attachments
5. Consent Forms, Assent Forms, HIPAA Authorization Materials
6. Supporting Documents, sorted by Category:
  - a. Ancillary Approvals/Permissions
  - b. Data use agreements or other Agreements
  - c. Debriefing Materials
  - d. External Site Information (*if attached to the Supporting Documents page of the SmartForm, rather than the External Site page of the SmartForm*)
  - e. Federal Department Requirements Checklists
  - f. Financial Interest Disclosure Form
  - g. Foreign Language Documents
  - h. Funding Source Attachments
  - i. Individual Investigator Agreement (IIA)
  - j. IRB Authorization Agreement (IAA) Request
  - k. Other
  - l. PI's Current CV (ICH-GCP E6 Only)
  - m. Protocol Attachment (*if attached to the Supporting Documents page of the SmartForm, rather than the Study Scope page of the SmartForm*)
  - n. Radiation Safety Form
  - o. Recruitment Materials/Advertisements
  - p. Sponsor Protocol including DHHS-approved protocol
  - q. Study Instruments/Tools
  - r. Translation Attestation Form
7. Study Personnel Forms (including any attached CITI documents)

### Conversion

1. Click on the file entitled "Attachments for..." to view the contents.
2. Save the file and use Adobe features to apply bookmarks or notes  
*Note: Adobe Pro and Reader Function Help is [available online](#)*
3. Upload the formatted packet for review to the IRB-specified location in ESTR