

# Archiving Research Documents

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Purpose: To describe the activities involved with archiving research documents in the Center for Cancer Research (CCR)

### STEP 1: Obtain Approval to Archive Research Documents

1. Identify protocol documents to be archived.
2. Request protocol termination verification from the Protocol Review Office (PRO).
3. Request approval to archive protocol documents from protocol Principal Investigator.
  - Confirm the Principal Investigator's approval in writing or in email.
4. Verify records have been retained on site for 2 years before archiving:
  - After FDA approval was given for the drug for the indication for which it was investigated
  - If no application was filed, or the application was disapproved
  - The investigation was discontinued and the FDA was notified

### STEP 2: Obtain Archiving Materials

1. Place an order for archiving boxes with your purchasing officer or administrative officer:
  - Required NIH archiving materials must be used
  - Standard Record Box # 8115-00-117-8344 (size 14 3/4 in x 12in x 9 1/2in)
2. Prepare boxes and complete Standard Forms (135 and 135a) as per archiving guidelines:
  - <http://camp.nci.nih.gov/admin/oem/mab/record.htm>

### STEP 3: Prepare Research Documents

1. Locate and assemble the research documents identified for archiving.
2. Remove the documents from their binders and remove all non-official papers (e.g. post-it notes) from the documents.
3. Make an inventory list of each box including patient record ID numbers, the quantity and type of each document.
4. Place documents in the boxes; fill to 3/4 capacity each box.
  - Overfilled or bulging boxes will not be picked up.
5. Complete the SF 135 (and 135a if needed).

### STEP 4: Obtain Approval to Archive from the NCI Records Management Officer (RMO)

1. Send an email to the RMO (as of 10/2009, Karen Hubbard)
  - RMO email = [HubbardK@mail.nih.gov](mailto:HubbardK@mail.nih.gov)
  - stating you have records to archive
  - request an accession number:
  - OMA telephone: 301-496-6985
2. Attach a completed SF 135 and SF 135a to the email request.
  - This request can also be faxed to: 301-402-2188.
3. RMO will return a confirmation receipt of the request.
  - Contact the RMO if you do not hear from the officer in 24 hours.
4. RMO will email your approval to archive and include:
  - assigned accession number
  - eSF 135 with approval comment(s)
5. If modifications need to be made to your request, the RMO will:
  - Notify you via email or phone
  - Provide instruction on how to make corrections
  - The approval process may take up to 2 weeks

### STEP 5: Archive the Records

1. Follow the instructions in the approval email from the RMO.
2. Write the accession number on your SF 135 and SF 135a forms.
3. Place a hard copy of the approved SF 135 inside **Box # 1** on the top of the documents.
4. Place the boxes in the same location that you noted on the SF 135.
5. Mark boxes with a removable label stating:
  - "Approved for pickup on (date)".
6. The approval email will give you a timeframe for pick-up, but may take up to 2 weeks.
7. Someone must sign for the documents at time of pick-up:
  - A charge will be incurred for unsuccessful pick-ups when no one is available to sign or the boxes are filled over three-fourths full.

### STEP 6: Document the Process

1. Document the archiving process per branch policy or SOP.
2. Keep a copy of all completed SF 135 forms, archiving notes, and email correspondence for your records.
3. Locate and store the copies of the RMO's approval email, and SF 135 and 135A forms in a central location.
4. Notify the Principal Investigator in writing that the archiving process was successful.