



Cultivating the Clinical Research Grant Environment

leveraging DOCR resources for grant administrators and the faculty they support

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Session Objectives

- Identify the 3 areas of focus for DOCR in order to help the Duke research community plan for and execute high quality studies
- State key questions to ask of faculty about obtaining appropriate cost estimates for their grant
- Verbalize potential resources available to research administrators



Duke Medicine – Facts and Figures



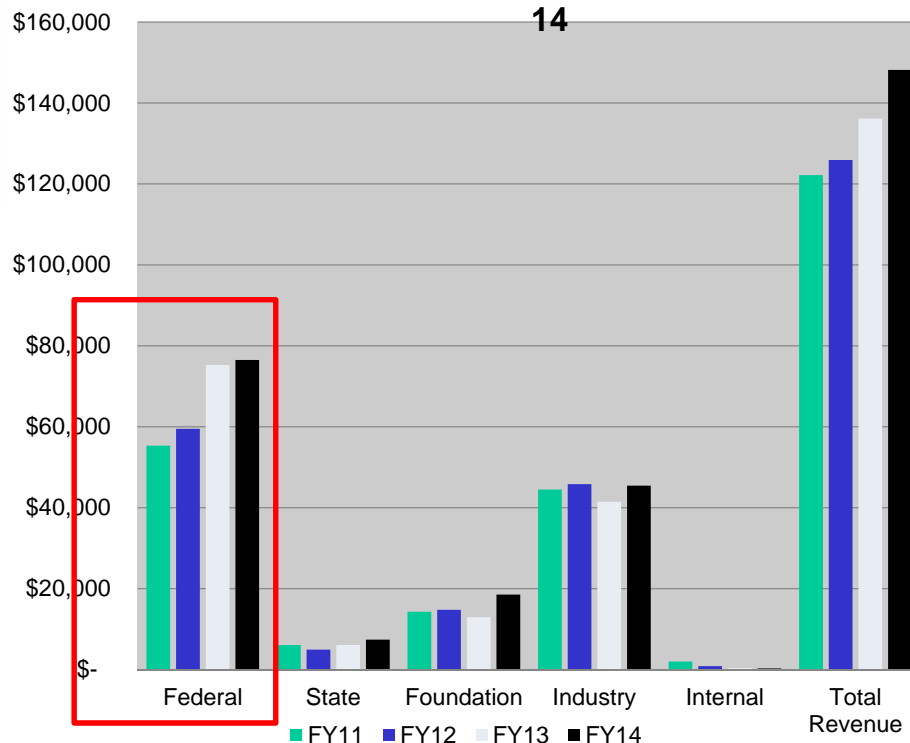
- 3 Integrated hospitals using Epic 2014
 - Duke University Hospital 924 beds
 - Duke Raleigh Hospital 186 beds
 - Duke Regional Hospital 369 beds
 - 16,318 employees
- 2013
 - Clinical revenues \$2.54B, 1.2m outpatient visits
 - 2013 Total research revenues - \$651m
 - 2013 NIH funding \$284m - ranked 10th
- 1115 investigators and 434 study coordinators in site based research
- About 4000 open IRB studies during FY14
- About 300 NEW clinical studies/year open at Duke University Hospital – another 900 new studies that do not bill
- ~1% of patients enrolled in clinical studies



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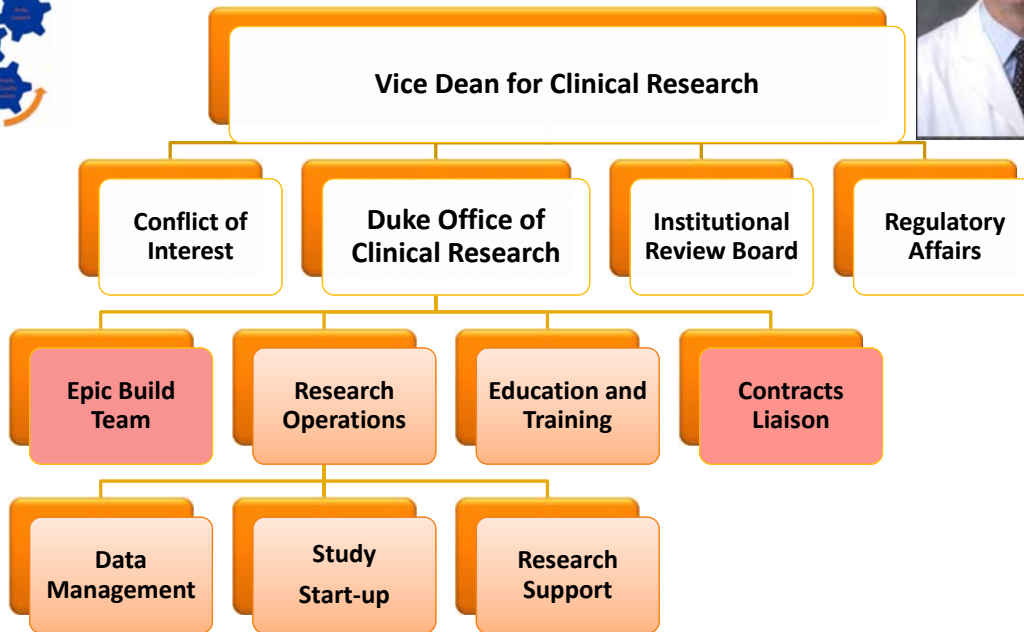
Clinical Research Revenue by Funding FY11-14



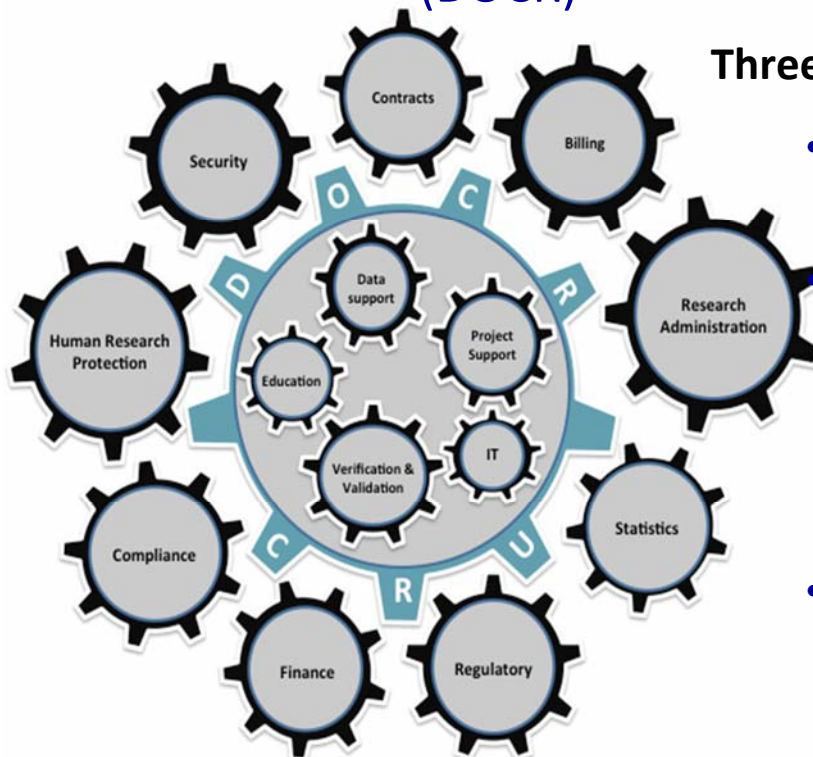
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Human Research Protection Program



The Duke Office of Clinical Research (DOCR)

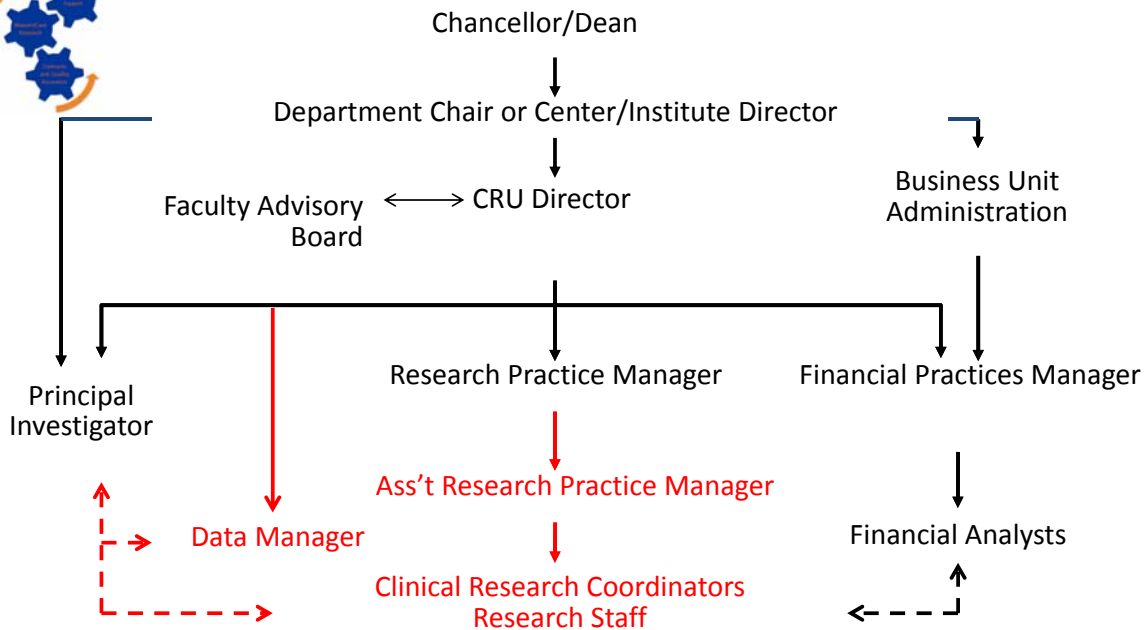


Three areas of focus:

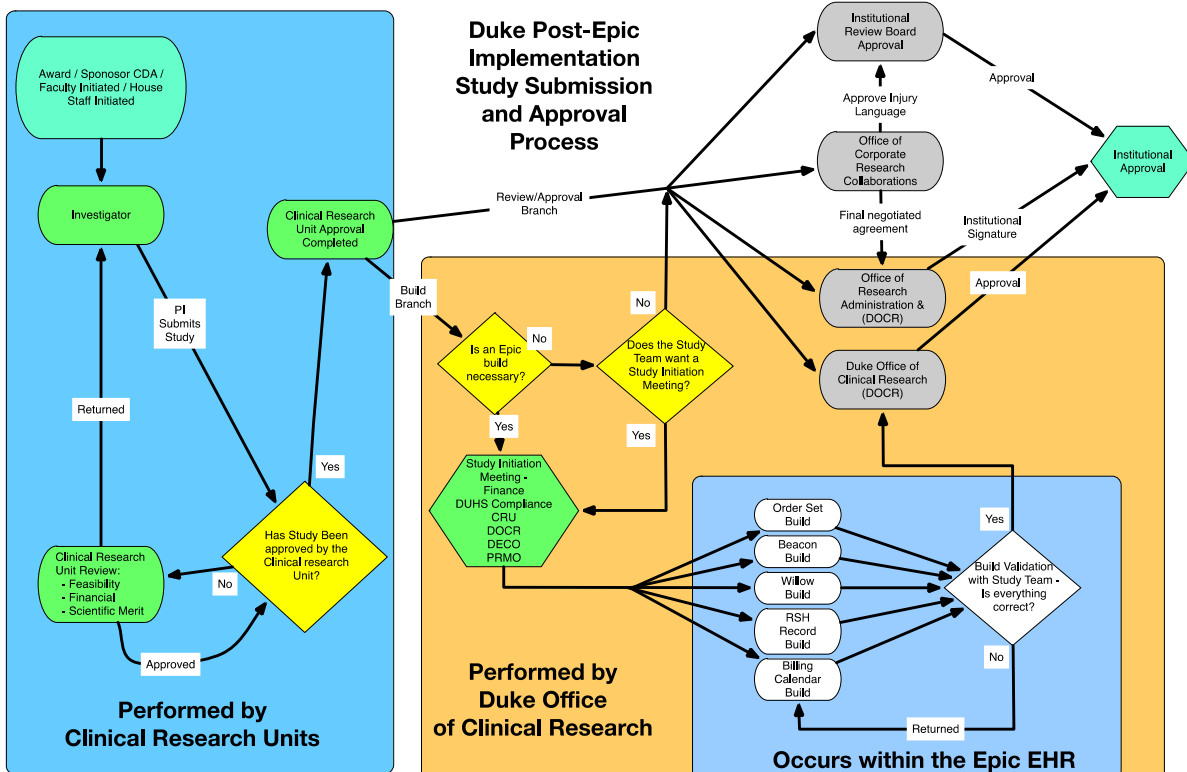
- **Education and Communication**
- **Research Study Support** - Research Management Team (RMT) data management and study coordination
- **Study Startup, Management and Closeout**



Clinical Research Unit Organizational Structure



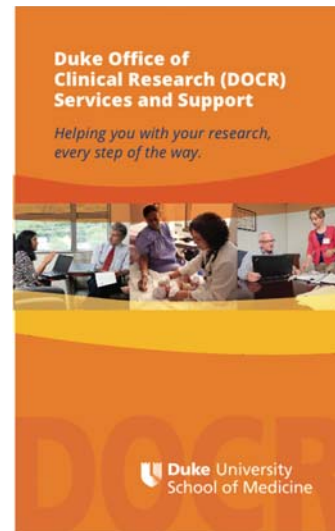
Day to Day Workflow





Education and Communication: FY2014

- **Human Subjects Research Training**
 - 1767 faculty/5122 staff
- **Direct training sessions**
 - 139 faculty/2909 staff 150 sessions
- **Research Wednesdays**
 - 34 faculty/1281 staff in 25 sessions
- **Clinical Research Update eNewsletter**
 - 8000+ subscribers to a monthly publication



docr.som.duke.edu/education/docr-course-descriptions



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Research Study Support: FY2014

Enhanced Research Management Team (RMT)

- Improve tracking of RMT work requests
- Added 2 data managers and 6 coordinators (including Associate Director)
- Managed 152 clients (faculty/staff); 203 total projects (133 data; 70 coordinator)

Residents, fellows, and medical students certificate training

- Partnered with GME to offer clinical research training series for residents/fellows
- Coordinated clinical research training for 3rd year medical students
- Allowed RMT to meet with them and jump start proposals

Institutional signature process

- Site-based industry sponsored contracts - institutional signature moved to DOCR (reduced to 1 business day)



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Let's Be Well RED

aims to help India fight the anemia crisis

Congratulations!

Gudness iron-rich nutritional bars to every anemic individual in India



Congratulations to Rajvi and Let's Be Well RED on winning \$55,000 at our Grand Finale! Read more about her team and our other finalists below.

RMT stepped in to help turn this into a research project ...

- Protocol development
- CRF design and REDCap build
- IRB setup and submission
- 80 hours
- Cost ~ \$3200



RMT Support: Let's Be Well RED

aims to help India fight the anemia crisis

- 9/17/13: DOCR and IRB consultants reviewed IRB requirements, DTAs, COI, training requirements, templates, logistics of submission to IRB in India and at Duke.
- 11/19/13: DOCR consultants reviewed draft protocol and made suggestions regarding protocol development, assessment tools and REDCap data base build.
- Krishna Udayakumar assists with Mumbai IRB application
 - Liz Burns provides statistical consultation
- 11/25/13: DOCR reviewed draft protocol and editions, drafted consent forms, and a mechanism for translation/backtranslations of ICFs and questionnaires.
- 12/17/14: IRB submission
- 1/8/14: CT.gov registry
- 1/24/14: Local and Duke IRB approvals
- 3/11/14: DOCR completes CRF edits
- 3/21/14: First protocol amendment!
- 4/7/14: DOCR completes Study Database



DHTS is currently working to fix access to documents (including DOCR policies and procedures) that are located behind the firewall on the DOCR website. In the meantime, please use [this link](#) to access these documents (will need VPN access if outside of Duke network). Alternatively, please contact DOCR.Help@dm.duke.edu if you are still having problems accessing the documents.

The Duke Office of Clinical Research (DOCR) is responsible for developing the "rules, tools, and training" for the conduct of clinical research in which Duke serves as an investigative site, and for fostering an identifiable, cohesive community of clinical investigators and research staff. DOCR's core values include flexibility, service, creativity, collaboration, quality and integrity.

Quick Links

- Contact Us
- DOCR Research Management Team Brochure

10,656 Users • 4 minute session avg • 3 pages per visit • 27% bounce rate

Follow us on the DOCR wiki...



Dashboard > DOCR

Dashboard ORI DTRI DTMI DOCR CRUs SOM

DOCR Create

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DOCR is housed within the Duke University School of Medicine, provides navigation, tools and training to support the conduct of clinical research in which Duke serves as an investigative site. These [services](#) and [tools](#) are available for faculty, staff, and trainees at Duke.

In FY2014, there were more than 4,000 active studies in the Duke IRB. Funding is approximately 1/3 industry, 1/3 federal, and 1/3 internal.

Spaces

- Duke Office of Clinical Research
- DOCR Internal
This is the internal space for DOCR collaboration.
- Maestro Care for Research
Knowledge base for Maestro Care for the research community.

Activity Stream Filter: OFF

Susan Budinger
Re: REDCap Survey links can be sent in MyChart (Duke Office of ...
We can show you how to create the REDCap link. The MaestroCare folks can help with creating a message to be sent with L... Reply
about 2 hours ago

Alexander Allori, M.D.
Re: REDCap Survey links can be sent in MyChart (Duke Office of ...
Wow! It's like you read my mind... How do we learn more about how to do this? Reply
about 2 hours ago

Denise Snyder

<https://ori.duke.edu/wiki/category/docr>



Operational plan/grant review

Focus:

- Approach
- Human Subjects
- Budget & Budget justification

Perspective:

- Study coordinator – operations EXPERT
- Finance manager
- (reviewer)

Reasons:

- Operational feasibility
- Compliance/regulatory
- Budget



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Operational plan – key questions

Participants

Identification & sample

- How/where
- Expected conversion rate
- Way to make more efficient?

Recruitment & retention

- Expected conversion rate
- Expected retention



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Operational plan – key questions

Data collection

Capture methods

Type – require special storage

Management – quality assurance, IT support

Access – who & how

Storage - where



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Operational plan

Put on coordinator/grant manager hat and review the budget justification

Staffing

- Coordinator time
- Data management time
- Other support staff time

Other expenses

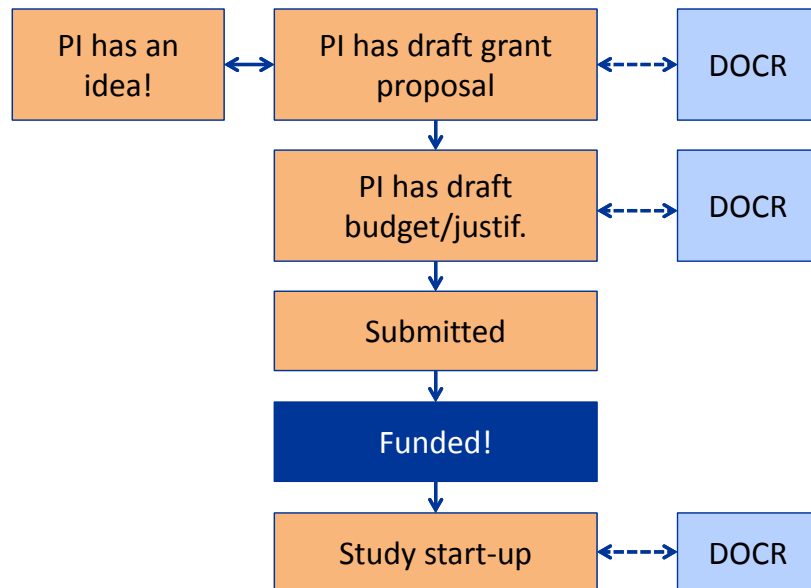
- Recruitment
- Travel (staff or investigator)
- Publication expenses
- Other?



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The plan in motion



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Study start-up offerings

Study initiation process

- Evaluated for all bill risk
- Offered for all
- Recommended for some
 - email
 - in-person (new, complex, issues in the past, etc.)

Study planning process

- All studies that fall outside of CRUs
- Offered and encouraged for those with no billing



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Study planning meetings

When

- prior to institutional approval

Who attends?

- study staff (PI, coordinator, others)
- DOCR staff

What happens

- Meet for ~1 hour
- Follow-up email with links/resources
- Satisfaction survey



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Study planning meetings

What is covered?

Training

- Human subjects (HSR, CITI)
- Informed consent/Data integrity and security/other DOCR classes
- Study-specific training, logs
- Financial – payment of participants, procuring goods (<http://finance.duke.edu/accounting/training/>)
- Clinical Research Update Newsletter & Research Wednesdays



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Study planning meetings

What is covered?

Regulatory

- Agreements
- Clinicaltrials.gov registration
- IRB communications
- Creation of regulatory binder
- Enrollment log, Delegation of Authority log, CVs / medical licenses of investigators and Key personnel
- Recommended resources (DECO)



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Study planning meetings

What is covered?

Study conduct

- Practices consistent with policies
- Recruitment – use DEDUCE/DISCERN?
- Consent – training, watermark, special populations
- Notice of Privacy Practices
- Subject payment
- Handling of specimens
- Mechanisms for reporting progress, escalation



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Study planning meetings

What is covered?

Keeping track of progress

- Enrollment target
- Milestone/alert levels



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Study planning meetings

What is covered?

Data management/QA/Analysis

- Data security (ISO)
- Data in-transit/mobile devices
- Data provenance
- Storage
- Data collection/management – think ahead to table shells
- Access to data – tracking and discontinuing
- QA, Analysis



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Study planning meetings

- Tailored to protocol
- Connect to internal resources
- Provides tools/templates
- Educate and link to additional education opportunities
- Constantly evolving as the research environment changes



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Thank you!



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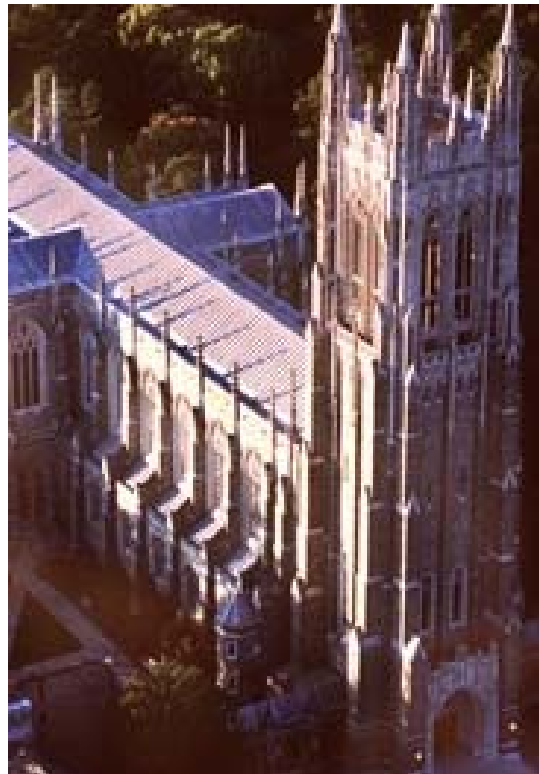
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