

# *Inquiring Minds*

*News and notes from the Department of Clinical Investigation, WRAMC  
July/ August, 1999*

## *Important Notice Regarding Protocol Funding for Remainder of Fiscal Year 1999*

All newly approved protocols for the remainder of Fiscal Year 1999 (until 30 September 1999) that receive intramural funding will not have funds allocated for Fiscal Year 1999 but for Fiscal Year 2000. Investigators who have protocol applications currently "in the process" or who are about to submit a new proposal please consider this information when planning the research schedule.

In addition, supplies/TDY/publication expenditures are being held to a minimum until the end of Fiscal Year 1999 for protocols dependent on intramural funds. This measure is necessary because of the expected end-of-year shortage of funds. For emergencies or unique circumstances, please send your request (with justification) to Mr. Ed Garcia. This restriction does not apply to investigators with extramural sources of funds which are managed by WRAMC(eg, grants, gifts, CRDA accounts) or Foundations (eg, HMJF, Geneva, TRUE, etc.)

We regret any temporary inconvenience and appeal to your patience and cooperation. For further information call Mr. Ed Garcia, Chief, Research Administration Service at (202) 782-7859.

## *Next WRAMC Research Course, Sponsored by DCI, set for 9 September; Course is Required for Incoming Personnel Who Wish to do Research at WRAMC*

DCI is pleased to announce that the next presentation of the WRAMC Research Course will take place on Thursday, 9 September 1999, at the Holiday Inn Silver Spring, which is located at 8777 Georgia Avenue in Silver Spring. Please note that this is a new location for the Research Course. The hours of the course are 0800 to 1645, and parking is free at the hotel.

There is an important change regarding the WRAMC Research Course of which you should be aware. Previously, two modes of Research Courses have been offered; a "long course", lasting a day and a half, which has been required of all who are or wish to become a Principal Investigator (PI) on a WRAMC research protocol; and a "short course", a half-day session on research regulations and ethics which has been geared towards the experienced investigator or research supervisor.

However, beginning with the September course, both modes of instruction will be received in the one-day

## *IRB Calendar*

The following Institutional Review Board (IRB) meetings will be held in the months of August, September, and October, 1999:

### CLINICAL INVESTIGATION COMMITTEE (CIC):

03 August  
10 August  
07 September  
14 September  
05 October  
12 October

### HUMAN USE COMMITTEE (HUC):

24 August  
31 August  
21 September  
28 September  
19 October  
26 October

All meetings will begin at 1300 and will be held in the Fourth Floor Conference Room, Building 6, WRAMC.

course format. Personnel who are new to WRAMC who intend to perform research here, associate investigators who wish to become PIs, and PIs who have yet to receive the course are required to take the course in its complete form, from 0800 to 1645, on 9 September. However, experienced investigators (with appropriate waiver), medical monitors, and research supervisors are urged to attend the afternoon session of the Research Course, from 1300 to 1645 on 9 September, which is the equivalent of the old "short course".

The registration deadline is 31 August 1999, and the September course is normally well-attended, so please do not delay your registration!

Registration is available via the DCI Web page, via e-mail, and by calling Mr. Derrick Hunter at (202) 782-6389. Please watch your e-mail for further announcements regarding this event!

## *Farewell to MAJ R. Michael Tuttle, MC, Assistant Chief, DCI*

DCI is sad to report that MAJ R. Michael Tuttle, MC, Assistant Chief, DCI and Chief, Clinical Studies Service, DCI, will be leaving us in August, 1999. MAJ Tuttle will be leaving the Army to take a position at Sloan Kettering Memorial Medical Center in New York.

MAJ Tuttle came to WRAMC in July, 1995 from Madigan Army Medical Center. Upon his arrival at WRAMC, MAJ Tuttle was assigned to the Endocrine Service, Department of Medicine. During his time in Endocrine, MAJ Tuttle distinguished himself both as a clinician and as a prolific researcher.

In January, 1998 MAJ Tuttle was assigned to DCI, where he assumed his present duties. MAJ Tuttle's contribution to the Department has been extensive. As Chief, Clinical Studies Service, DCI, MAJ Tuttle has worked to ensure regulatory compliance for all WRAMC research, and has assisted numerous researchers in a wide range of issues. Additionally, MAJ Tuttle has served as Chair of the Clinical Investigation Committee, and as a substitute Chair of the Human Use Committee.

MAJ Tuttle's expertise, wit, and unending commitment to help WRAMC researchers succeed in their endeavors will be missed. We wish him all the best in his new position!

A luncheon will be held for MAJ Tuttle in Mologne House on Wednesday 11 August. If you would like to attend please call MAJ Stahl at (202) 782-7823.

## *Farewell to COL Louis Diehl, MC, Human Use Committee Chair*

We also wish to express our deep appreciation for another departing member of the WRAMC community who, although not a member of DCI, has worked very closely with us for several years, and for whose service we are all grateful.

COL Louis Diehl, MC, Chief, Department of Medicine, WRAMC, is retiring from the Army in August, 1999. For one year, COL Diehl served as a co-Chair of the Human Use Committee. His knowledge of research issues and regulations is encyclopedic in scope, and he has been a tremendous asset to the committee.

Additionally, for the last few years COL Diehl has presented a fascinating and insightful talk at the WRAMC Research Course, on the history of research regulations regarding human subjects. This has always been one of the most well-received parts of the course, and we hope that he will be able to join us in the future to present this talk.

We wish COL Diehl well in his future career at Johns Hopkins University.

## ***Bailey K. Ashford Award winners announced!!***

***We are proud to announce the winners in the 1999 Bailey K. Ashford***

***Clinical and Laboratory Award program:***

***Clinical Research Category:      Laboratory Research Category:***  
***MAJ Thomas J. Miner, MC, USA    MAJ Wanda L. Salzer, MC, USAF***  
***General Surgery Service    Pediatric Hematology-Oncology Service***

***Congratulations to the winners and their services!***

## Recently- approved protocols at WRAMC

Congratulations to the following principal investigators on their recently approved protocols.

Gulf War Health Center

8900-99Antibiotic Treatment of Gulf War Veterans' Illnesses

Engel, Charles C., LTC, MC 5/13/99

8901-99A Randomized, Multi-Center, Controlled Trial of Multi-Modal Therapy in Veterans with Gulf War Illnesses

Engel, Charles C., LTC, MC 5/13/99

Department of Medicine

Gastroenterology Service

1456-99 Long-Term Prevention of Recurrent Peptic Ulcer Hemorrhage in Patients Infected with Helicobacter Pylori: A Multi-Center, NIH Funded, Prospective, Randomized Double-Blind Study

Wong, Roy K.H., COL, MC 6/4/99

1457-99 Colorectal Neoplasia Screening with Colonoscopy in Asymptomatic Women at Regional Naval/Army Medical Centers: the CONCeRN Trial

Kikendall, James, COL, MC 6/15/99

Hematology-Oncology Service

1624-99A Multicenter Study of a 24 Hour Intravenous Infusions of HMR 1275 in Fludarabine-Refractory or Intolerant B-Cell Chronic Lymphocytic Leukemia

Byrd, John C., MAJ,MC 6/29/99

Pulmonary & Critical Care Medicine Service

1707-99Dose Formed Patient Asthma Education in NHLBI Guidelines Equate with Improved Morbidity and Mortality?

Kristo, David A., MAJ, MC 5/13/99

1709-99 Use of Impulse Oscillometry in Adult Bronchoprovocation Testing

Niven, Alexander, CPT, MC 7/14/99

Department of Nursing

7576-99E-mail as a Communication Tool in Army Nursing Management

Lasome, Caterina, MAJ, AN 6/9/99

Department of Pediatrics

6426-98Parent Decision-Making Process when Using Alternative Medicine for Their Child

Randall, Virginia F., COL, MC 6/9/99

Department of Pharmacy

3614-99Feasibility Study of Shortened Administration Schedule of Rituximab

Weickum, Ricke, LTC, MS 5/17/99

Department of Surgery

Anesthesia-Operative Service

2078A In Vitro Diagnosis of Malignant Hyperthermia With 4-Chloro-M-Cresol and Ryanodine

Bettencourt, Joseph A., LTC, MC 6/16/99

General Surgery Service

2080-99Alteration in Colonic Motility Secondary to Inflammatory Bowel Disease

Lawson, Stephen, CPT, MC 6/7/99

Organ Transplant Service

2635-99Monitoring for donor-specific hyporesponsiveness following renal and pancreatic allotransplantation

Kirk, Allan D, CDR, MC 6/23/99

2636-99Live Donor Renal Donation for Allotransplantation

Kirk, Allan D., CDR, MC 6/23/99

Otolaryngology-Head & Neck Service

2583-99The Laryngeal Mask Airway as an Alternative to Endotracheal Intubation for Prolonged Ventilatory Support in a Ferret Model of the Infant Airway

Mair, Eric A., LTC, MC 5/27/99

Peripheral Vascular Surgery Service

2131-99Is the Bacterium Chlamydia Pneumoniae a Possible Inciting Agent for the Development of Atherosclerosis of the Carotid or Coronary Arteries?

Gillespie, David L., LTC, MC 5/20/99

Urology Service

2884-99Randomized Prospective Study of Adjuvant Androgen Ablation in Radical Prostatectomy Patients at High-Risk for Disease Recurrence

McLeod, David G., COL, MC 5/26/99

## *DCI Passes Property, Supply Inspection*

The WRAMC Directorate of Logistics recently re-established its Command Supply Discipline Program (CSDP) Customer Assistance Visit program. CSDP is a priority logistics initiative for the Department of the Army and for NARMC. The goals of this program are to ensure that all of WRAMC's departments are in compliance with Department of the Army supply policies and procedures, to ensure that adequate systems are in place to monitor and track the flow of supplies and equipment within the department, and to resolve any special concerns that a department may have regarding its handling of supplies and equipment.

DCI was the first department at WRAMC visited by Directorate of Logistics personnel under this program. This was as a result of DCI having the largest manifest of property and equipment under handreceipt at WRAMC. For several hours, Logistics personnel met with key personnel in the Research Administration and Research Operations services, reviewing Army and WRAMC policies and procedures, inspecting DCI's property records, and interviewing DCI personnel as to the methodologies used to maintain compliance with Army and WRAMC policies.

Following the inspection, DCI received a very favorable review from the Directorate of Logistics. Specifically, the completeness and currency of our property records was commended. Also positively cited was the attention given to following the CSDP program guidelines, especially in the area of property security.

All of the DCI personnel who participated in the preparations for this inspection are to be complimented on a job well done. Special recognition goes to the Research Administration Service, the Research Operations Service, and the Office of the Chief.

Welcome to the following  
new DCI employee:

Sharon Hanopole--  
Clinical Studies Service

*Inquiring Minds* is published six times a year by the Department of Clinical Investigation, WRAMC, as a service to DCI employees and the WRAMC research community.

Any submissions or questions about content should be directed to the editors:

Mr. William Woodcock, (202) 782-7829  
MAJ Andrea Stahl, (202) 782-7823

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## *BMAR Calendar for August, September, and October, 1999*

In order to be fully compliant with JCAHO and WRAMC guidelines, all DCI personnel must be up to date in their BMAR training. BMAR will be held on the following dates in August, September, and October, 1999. BMAR is held from 0730-1200 in the Joel Auditorium, Building 2:

12 August  
26 August  
9 September  
23 September  
7 October  
21 October

The following DCI personnel have birthdays in the months of August, September, and October:

David Jackson  
Jesse Martin  
Elena Morris  
Robin Howard  
Diarmuid Nicholson  
Greg Rose  
SGT Smith  
Eleanor Bicknell  
Ed Garcia  
MAJ Stahl

Happy Birthday, but please don't forget to attend your BMAR training!!

## *Tuberculosis Skin Testing Tracking Begun for All Personnel*

WRAMC has a JCAHO requirement to track the TB skin test status on all personnel, both military and civilian. To that end, all personnel will need to bring their TB skin test status to currency. This means a TB skin test within the last twelve months.

To do this, personnel must either: 1) bring written documentation of a TB skin test done by your personal physician or other "outside" provider to the Occupational Health Clinic, 3rd Floor, Building 2, or 2) report directly to the Immunization Clinic with their blue stamp plate to have the TB skin test performed. If you do not have a blue stamp plate, you may obtain one in the patient records office, 1st floor, building 2.

## Recent WRAMC Publications

Congratulations to the following WRAMC investigators on their recently published papers. The list was compiled from a recent MEDLINE search of the literature. Listed articles have been cleared through DCI and the WRAMC Public Affairs Office. If you have recently published, and we have not included your publication, please let us know so we may list your publication in the next issue of the newsletter.

Bauer JJ, Zeng J, Weir J, Zhang W, Sesterhenn IA, Connelly RR, Mum SK, Moul JW. Three-dimensional computer-simulated prostate models: lateral prostate biopsies increase the detection rate of prostate cancer. *Urology* 1999; 53:961-7.

Braverman SE, Spector J, Warden DL, Wilson, BG, Ellis, TE, Bamdad, MJ, Salazar, AM. A multidisciplinary TBI inpatient rehabilitation programme for active duty service members as part of a randomized clinical trial [In Process Citation]. *Brain Inj* 1999; 13:405-15.

Byrd JC, McGrail LH, Hospenthal DR, Howard RS, Dow NA, Diehl LF. Herpes virus infections occur frequently following treatment with fludarabine: results of a prospective natural history study. *Br J Haematol* 1999; 105:445-7.

Conner WC, Gallagher CM, Miner TJ, Tavaf-Motamen H, Wolcott KM, Shea-Donohue T. Neutrophil priming state predicts capillary leak after gut ischemia in rats. *J Surg Res* 1999; 84:24-30.

Costabile RA, Spevak M. Oral trazodone is not effective therapy for erectile dysfunction: a double-blind, placebo controlled trial. *J Urol* 1999; 161:1819-22.

Desilets DJ, Davis KE, Nair PP, Salata KF, Maydonovitch CL, Howard RS, Kikendall JW, Wong RK. Lectin binding to human colonocytes is predictive of colonic neoplasia. *Am J Gastroenterol* 1999; 94:744-50.

Donnelly KM. Venous thromboembolic disease in the pediatric intensive care unit [In Process Citation]. *Curr Opin Pediatr* 1999; 11:213-7.

Engel CC, Jr., Ursano R, Magruder C, Tartaglione R, Jing Z, Labbate LA, Debakey S. Psychological conditions diagnosed among veterans seeking Department of Defense care for Gulf War-related health concerns [In process citation]. *J Occup Environ Med* 1999; 41:384-92.

Irby PB, Schwartz BF, Stoller ML. Percutaneous access techniques in renal surgery [In Process Citation]. *Tech Urol* 1999; 5:29-39.

Kikendall JW. [In Process Citation]. *J Clin Gastroenterol* 1999; 28:298-305.

Loube DI, Andrada TF. Comparison of respiratory polysomnographic parameters in matched cohorts of upper airway resistance and obstructive sleep apnea syndrome patients. *Chest* 1999; 115:1519-24.

Loube DI, Andrada T, Howard RS. Accuracy of respiratory inductive plethysmography for the diagnosis of upper airway resistance syndrome. *Chest* 1999; 115:1333-7.

Loube DI, Gay PC, Strohl KP, Pack AI, White DP, Collop NA. Indications for positive airway pressure treatment of adult obstructive sleep apnea patients: a consensus statement. *Chest* 1999; 115:863-6.

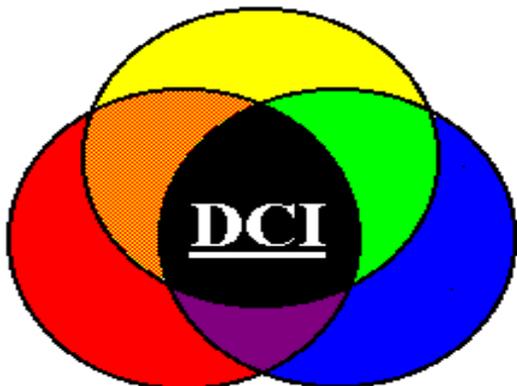
Miner TJ, Shriver CD, Jaques DP, Maniscalco-Theberge ME, Krag DN. Sentinel lymph node biopsy for breast cancer: the role of previous biopsy on patient eligibility. *Am Surg* 1999; 65:493-8; discussion 498-9.

Morse RW, Noe S, Carvalho J, Jr., Balingit A, Taylor AJ. Rest-redistribution 201-Tl single-photon emission CT imaging for determination of myocardial viability: relationship among viability, mode of therapy, and long-term prognosis. *Chest* 1999; 115:1621-6.

Moul JW, Connelly RR, Mooneyhan RM, Zhang W, Sesterhenn IA, Mostofi FK, McLeod DG. Racial differences in tumor volume and prostate specific antigen among radical prostatectomy patients [In Process Citation]. *J Urol* 1999; 162:394-7.

Moul JW. Angiogenesis, p53, bcl-2 and Ki-67 in the progression of prostate cancer after radical prostatectomy. *Eur Urol* 1999; 35:399-407.

Trakimas CA, Sperling LC. Temporal triangular alopecia acquired in adulthood. *J Am Acad Dermatol* 1999; 40:842-4.



## Research Technique Spotlight: High Performance Liquid Chromatography (HPLC)

by Maged Abdel-Rahim, Chief,  
Research Operations Service, DCI

Chromatography is a general term applied to a wide variety of techniques designed to separate two or more chemical substances. In general, chromatography techniques rely on the differential movement of these substances through a two-phase system (i.e.: gas-solid chromatography, liquid-solid chromatography). One phase is designated as the stationary phase and can be either a liquid or a solid. The second phase is the mobile phase and is either a liquid or a gas. Separation of substances occurs because each substance in the sample (typically miscible in the mobile phase) will move in a unique fashion through the stationary phase.

One of the most common, yet powerful techniques available for separation and identification of chemical substances involves a special type of chromatography called High Performance Liquid Chromatography, or HPLC.

In the past, liquid chromatography (the term liquid indicates that the mobile phase is liquid or that the sample is miscible in a liquid medium) was performed in large diameter glass columns under atmospheric conditions. While this method was sufficient for chemical separation, the analysis times were long and the entire procedure was very tedious. One limitation was the particle size of the stationary phase.

## A Guide to DCI Personnel and Services

Wondering where to go in DCI for help? Here's a phone listing. All numbers are commercial area code 202, and DSN 662-(last 4 numbers of listing):

### OFFICE OF THE CHIEF

Chief--COL Maria H. Sjogren, MC	782-6389
Assistant Chief-- MAJ R. Michael Tuttle, MC	782-7840
NCOIC-- SSG Timmie L. Merriwether	782-6391
Secretary to the Chief-- Derrick E. Hunter	782-6389

### RESEARCH REVIEW SERVICE

Chief-- Dr. Audrey S. Chang	782-7858
(Medical/Scientific Consultation and Emergency Clearances, also Chief of Biometrics section)	
Intramural Protocol Coordinator, Human Use Agenda	
Coordinator-- Verna A. Parchment	782-7828
Extramural Coordinator--Deborah Kessler	782-7880
Extramural and Oncology Group Protocol Coordinator--	
Irone "Marty" Green	782-7864
Addendums, APRs-- Michelle Porter	782-7861
Intramural Coordinator-- Cheryl Jackson	782-7848
Exempt Protocol Coordinator, IRB Recorder, Writer/Editor--	
Vicki Mis kovsky	782-7833
APR Coordinator-- Mary Jane Muchui	782-7856
Biostatistician-- Robin Howard	782-7878
Computer Support-- SGT Tarvin D. Smith	782-7102

### RESEARCH ADMINISTRATION SERVICE

Chief-- Eduardo L. Garcia	782-7859
(Overall Financial Manager, Intramural Funding Availability)	
Assistant Chief, Publication Clearances--	
MAJ Andrea M. Stahl	782-7823
Grants Manager, Extramural Funding Financial Manager--	
William Woodcock	782-7829
Clerk/Typist-- Audrey Franklin	782-7810
Supply Coordinator-- Wilfred Shelton	782-7820
Computer Specialist-- Greg Rose	782-7884
Computer Specialist (contract)-- Guy Durant	782-7889
Data Coordinator (HMJF)-- Daniel Rosen	782-7841

### RESEARCH OPERATIONS SERVICE

Chief-- Mr. Maged Abdel-Rahim	782-5997
Supply Coordinator-- Jesse Martin	782-8170
Chemistry Laboratory Section Leader--	
Dr. Diarmuid Nicholson	782-3472
Immunology Laboratory Section Leader--	
Ms. Yvonne Lukes	782-4501
Molecular Biology Laboratory Section Leader--	
Ms. Aneeta Patel	782-8167

### CLINICAL STUDIES SERVICE

Chief-- MAJ R. Michael Tuttle	782-7840
Research Associate-- Eleanor Bicknell	782-7830

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# Frequently Asked Questions (FAQ)

## Regarding CRDAs, Part 1

Cooperative Research and Development Agreements (CRDAs) have become an essential tool in military medical research. CRDAs are necessary whenever a federal physician (military or civilian) wishes to interact with the private sector, either directly or through the use of an intermediary (see the last issue of the newsletter for more on intermediaries) to perform a research project.

Here at WRAMC, we have seen a dramatic increase in the last couple of years in the amount of research which is being done in cooperation with the private sector, and thus require a CRDA. This and future articles will answer some common questions investigators have posed regarding CRDAs.

Do I need to do a CRDA for every protocol I write?

No, for protocols which rely solely on intramural resources, a CRDA is not needed. But, for protocols which will rely on extramural resources, such as funds for personnel, supplies, equipment, etc, a CRDA is needed.

Why do I need a CRDA?

A protocol application deals with the scientific and ethical aspects of the study. The CRDA focuses on the transfer of resources--including people, equipment, supplies, etc.--between the Government and the private sector.

What should I get approved first, the protocol or the CRDA?

The CRDA and protocol can be submitted at different times. One does not need to be approved first. However, both have to be approved before you can begin your research.

Who can do a CRDA?

CRDAs can be done by one of the research intermediary organizations (HMJF, FACT, TRUE, Geneva, etc.) Their personnel will assemble the pertinent facts of the resource transfer in the proper format and submit the CRDA document (also referred to as a "Statement of Work") to DCI.

What is the approval process for a CRDA?

All proposed CRDAs are submitted by the intermediary (HMJF, TRUE, FACT, Geneva, etc.) to Mr. Bill Woodcock in the Research Administration Service of DCI. Mr. Woodcock will work with the intermediary to ensure that the CRDA meets all applicable requirements. The CRDA is then routed through local approval (DCI and JAG) and is then sent to the Clinical Investigation Regulatory Office (CIRO). Following CIRO approval, DCI is notified of the approval, and the CRDA is forwarded to the Army Technology Transfer Office for their review. After this review, DCI is notified of the CRDA approval, and the Research Review Service, DCI generates an approval memorandum for the investigator. Then, work can begin on the project.

How long does the approval process take?

Typically, between 60-90 days between submission to DCI and final notification. This takes into account a required 30-day review period by the Army Technology Transfer Office.

I have an approved CRDA, and I need to hire someone to be paid from it. How do I do this?

Personnel matters on CRDA-supported research are handled by the intermediary (HMJF, TRUE, FACT, Geneva, etc.). They will guide you through this process. Please note, though, that personnel hired through CRDAs become employees of the intermediary; though the investigator may supervise them, they are not federal civilian employees.

A federal civilian employee in my service has put in overtime while working on CRDA-supported research. May I pay him/her overtime pay using CRDA funds?

No, federal civilian employee salary, base or overtime, may not be paid using CRDA funds.

Look for "CRDA FAQ part 2" in the next issue of the newsletter!

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## *Thank you to LTC Thomas Miller, AN, for IRB Service*

We would like to express our sincere thanks for the efforts of LTC Thomas Miller, AN, of the Nursing Research Service, Department of Nursing, for his participation on the Clinical Investigation Committee (CIC). LTC Miller's insight, wit, and wisdom on the CIC were respected and appreciated by his peers on the committee, and we wish him well in his future endeavors at his new duty station at Ft. Sam Houston, Texas.

## *Congratulations to MAJ Andrea Stahl, Clinical Research Associate, DCI*

DCI is proud to announce that on 1 July 1999, CPT(P) Andrea M. Stahl, MS, was promoted to the rank of Major. MAJ Stahl serves in DCI as a Clinical Research Associate, and also as Assistant Chief, Research Administration Service, DCI.

MAJ Stahl has been with DCI since December, 1997, following completion of her PhD program in Cellular and Molecular Physiology at Yale University. This is her second tour of duty at WRAMC, having previously served as an administrative officer in the Department of Surgery.

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