

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

<b>NAME</b> Lewis R. Goldfrank, MD	<b>POSITION TITLE</b> Professor and Chairman of Emergency Medicine New York University School of Medicine		
<b>eRA COMMONS USER NAME</b> LGOLDFRANK			
<b>EDUCATION/TRAINING</b> ( <i>Begin with baccalaureate or other initial professional education, such as nursing, and include</i> )			
<b>INSTITUTION AND LOCATION</b>	<b>DEGREE</b> ( <i>if applicable</i> )	<b>YEAR(s)</b>	<b>FIELD OF STUDY</b>
Clark University, <i>Worcester, Massachusetts</i>	B.A.	1959-1963	Chemistry
Johns Hopkins Medical School <i>Baltimore, Maryland</i>	--	1963-1964	Medicine
University of Brussels Medical School <i>Brussels, Belgium</i>	M.D.	1964-1970	Medicine

**A. Positions and Honors***Positions and Employment*

1971 – 1973 Residency in Internal Medicine, Montefiore Hospital Medical Center  
 1973 – 1976 Director, Emergency Services, Morrisania City Hospital, Bronx, New York  
 1976 – 1979 Director, Emergency Services, North Central Bronx Hospital, Bronx, New York  
 1977 – 1979 Director, Emergency Medical Services, Montefiore Hospital and Medical Center  
 1979- Director of Emergency Medical Services, Bellevue Hospital Center and New York University Medical Center  
 1979-2001 Associate Professor of Clinical Medicine, New York University Medical Center  
 1979- Associate Attending, Bellevue Hospital Center, New York University Medical Center and Manhattan VA Hospital  
 1985- Affiliate Clinical Professor of Clinical Pharmacy of St. John's University  
 1979- Medical Director of New York City Poison Control Center  
 2001- Professor of Clinical Medicine and Surgery, New York University School of Medicine  
 2003- Professor and Chairman, Emergency Medicine, New York University School of Medicine

*Other Experience and Professional Memberships*

1996- Member, Institute of Medicine National Academy of Sciences  
 1999-2002 Chairman, IOM Committee on Assessing Metropolitan Medical Response Teams: Preparedness for Terrorism  
 2002-2003 Chairman, IOM Committee on Psychological Consequences of Terrorism  
 2005- Chairman, IOM Committee on NIOSH Personal Protective Equipment in the Workplace  
 2006- Chairman, IOM Committee on Personal Protective Equipment in the Workplace During an Influenza Pandemic: Research and Policy Directions

**Honors**

1963 Phi Beta Kappa

**B. Publications (Selected Relevant)**

1. Goldfrank's Toxicologic Emergencies, Eighth Edition, Eds. Goldfrank LR, Flomenbaum N, Lewin NA, et al. McGraw-Hill Companies, New York 2006.

**Principal Investigator/Program Director (Goldfrank, Lewis R.)**

2. Ingall, TJ; O'Fallon WM, Asplund K, Goldfrank LR, Hertzberg VS, Louis TA, Christianson TJH, Findings from the reanalysis of the NINDS tissue plasminogen activator for acute ischemic stroke treatment trial. *Stroke*.2004;35:2418.
3. Stith Butler A, Panzer AM, Goldfrank LR. Editors. 'Preparing for the Psychological Consequences of Terrorism: A Public Health Strategy. Committee on Responding to the Psychological Consequences of Terrorism Board on Neuroscience and Behavioral Health. Institute of Medicine, National Academy Press 2003.
4. Kwon N, Raven MC, Chiang WK, Moran GJ, Carter RA, Goldfrank LR. Emergency Physicians' Perspectives on Smallpox Vaccination. *Acad Emerg Med* 2003;10:1-7.
5. Manning FJ, Goldfrank LR. Editors. Preparing for Terrorism: Tools for Evaluating the Metropolitan Medical Response System Program. Committee on Evaluation of the Metropolitan Medical Response System Program, Board of Health Sciences Policy. Institute of Medicine, National Academy Press 2002.
6. Jacobs DH, Tovar JM, Hung OL, Kim M, Ye P, Chiang W, Goldfrank LR. Behavioral Risk Factor and Preventive Health Care Practice Survey of Immigrants in the Emergency Department. *Acad Emerg Med* 2002;9:599-608.
7. D'Amore J, Hung O, Chiang W, Goldfrank LR. The Epidemiology of the Homeless Population and Its Impact on an Urban Emergency Department. *Acad Emerg Med* 2001;8:1051-1055.
8. Zachary MJ, Mulvihill MN, Burton WB, Goldfrank LR. Domestic Abuse in the Emergency Department: Can a Risk Profile Be Defined? *Acad Emerg Med* 2001;8:796-803.
9. Whiteman P, Hoffman RS, Goldfrank. Alcoholism in the Emergency Department: An Epidemiologic Study. *Acad Emerg Med* 2000; 7:14-20.
10. Dart RC, Goldfrank LR, Chyka PA, Lotzer D, et al. Combined Evidence-Based Literature Analysis and Consensus Guidelines for Stocking of Emergency Antidotes in the United States. *Ann Emerg Med* 2000; 36:126-132.
11. Hung O, Kwon NS, Cole AE, Goldfrank LR, et al. Evaluation of the Physician's Ability to Recognize the Presence or Absence of Anemia, Fever and Jaundice. *Acad Emerg Med* 2000: 7:146-156.
12. Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response. Member, Committee on R&D Needs for Improving Civilian Medical Response to Chemical and Biological Terrorism Incidents. Institute of Medicine, and Board on Environmental Studies and Toxicology Commission on Life Sciences. National Research Council. National Academy Press, 1999.
13. Goldfrank, LR. The Surgical Complications of Toxins. *J Emerg Med* 1999; 17:1055-1064.
14. Hoffman RS, Stringer JA, Feinberg RS, Goldfrank. Comparative Efficacy of Thallium Adsorption by Activated Charcoal, Prussian Blue, and Sodium Polystyrene Sulfonate. *J Toxicol Clin Toxicol* 1999; 37:833-837.
15. Goldfrank LR, Henneman PL, Ling LJ, Prescott JE et al. Emergency Center Categorization Standards. *Acad Emerg Med* 1999;6:638-655.
16. Simon JR, Dwyer J, Goldfrank LR: The difficult patient. *Emerg Med Clin NA* 1999;17:353-370.
17. Lee CH, Carter WA, Chiang WK, Williams CM, Asimos AW, Goldfrank LR. Occupational Exposures to Blood Among. Emergency Medicine Residents. *Acad Emerg Med* 1999; 10:1036-1043.
18. Vassallo SU, Delaney MD, Hoffman RS, Slater W, Goldfrank LR. A Prospective Evaluation of the Electrocardiographic Manifestations of Hypothermia. *Acad Emerg Med* 1999; 6:1121-1126.
19. Gordon JA, Goldfrank LR, Andrulis DP, D'Alessandri RM, Kellerman AL: Emergency department initiatives to improve the public health. *Acad Emerg Med* 1998;5:935-937.
20. Cahill-Morasco R, Hoffman RS, Goldfrank LR: The effects of nutrition on plasma cholinesterase activity and cocaine toxicity in mice. *Clin Toxicol* 1998;36:667-672.

**C. Research Support (Current)**

1. **Title:** Bioterrorism Preparedness Planning  
**Principal Investigator:** Lewis R. Goldfrank  
**Dates:** July 1, 2005 – June 30, 2006 (Extension)

**Principal Investigator/Program Director (Goldfrank, Lewis R.)**

\$600,000 – Effort 0%

The New York Center for Terrorism Planning and Preparedness (NYCTP) is a consortium of nine hospitals organized under the Federal Health Resources & Services Administration (“HRSA”) Hospital Preparedness Grant for the purpose of improving New York City Hospitals’ capacity to respond to bio-terrorist attacks as well as other public health emergencies.

**No. 16001**

2. **Title:** CDC Public Health Research: Health Protection Research Initiative Institutional Research Training Grant.

**Co-Principal Investigator:** Lewis R. Goldfrank

**Dates:** September 30, 2004 – September 29, 2007

Effort 10%

The major goal of this project is to develop scholars in public health and preparedness.

**CDC: 1-T010CD000146-01**

3. **Title:** Biodefense Training Grant from NYC Department of Health through HRSA.

**Principal Investigator:** Lewis R. Goldfrank

**Dates:** July 1, 2005 – June 30, 2006

\$500,000 – Effort 0%

The major goal of this project is to educate general hospital personnel in preparedness.

**05ET012/01R0X00**

4. **Title:** DHS Initiative for Preparedness Large Scale Emergency Readiness Proposal for 1,000,000 casualties incorporating efforts of New York University, School of Medicine, Law, Mathematical and Computational Sciences, Nursing, Dentistry, Social Services and Public Policy.

**Principal Investigator:** Lewis R. Goldfrank

**Dates:** January 1, 2005 – December 31, 2006

\$2,350,000 – Effort 20%

The major goal of this project is to investigate high consequence terrorist events.

**DHS: 2204-GT-TX-0001**

5. **Title:** Poison Center Stabilization and Enhancement Program. Bureau of Maternal and Child Health.

**Principal Investigator:** Lewis R. Goldfrank

**Dates:** September 1, 2001 – August 31, 2007

\$500,000 – Effort 0%

The major goal of this project is to enhance the quality of poison care.

**HRSA: H4NMC00085-04-00**

6. **Title:** Risk Management in the Healthcare Sector: What and Where are the Agents of Opportunity and Why?

**Principal Investigator:** Lewis R. Goldfrank

**Dates:** February 15, 2007 – February 14, 2010 (Renewal: February 15, 2008)

\$839,000 – Effort -- 20%

The major goal of this project is assess the risks posed to the community by materials typically useful in the hospital

**DOD: Log No. 06152016**

## BIOGRAPHICAL SKETCH

<b>NAME:</b> Teperman, Lewis	<b>POSITION TITLE:</b> Director of Transplantation Associate Professor of Surgery
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**EDUCATION/TRAINING** *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of Rochester, Rochester, NY	B.S.	1977	Biology
Mount Sinai School of Medicine, New York, NY	M.D.	1981	Medicine
Columbia Presbyterian Medical Center, New York, NY		1981-1984	Surgical Residency
Long Island Jewish Medical Center, Long Island, NY		1984-1986	Surgical Residency
University of Pittsburgh, Pittsburgh, PA		1986-1988	Fellowship Transplant Surgery

### A. Positions and Honors

#### Academic

1976 Instructor in Biopsychology, The University of Rochester, Rochester, New York  
 1978-1979 Lecturer in College Biology, The Bronx High School of Science, Bronx, New York  
 1980-1981 Lecturer, Mount Sinai School of Medicine, New York, New York  
 1996 Faculty Member, NATCO (North American Transplant Coordinators Organization)  
 1988-1989 Instructor in Surgery, University of Pittsburgh  
 1989 Assistant Professor of Surgery, University of Pittsburgh  
 1989-1999 Assistant Professor of Surgery, New York University School of Medicine  
 1999-present Associate Professor of Surgery, New York University School of Medicine

#### Hospital

1989-present Assistant Attending, NYU Hospitals Center  
 1989-present Assistant Attending, Bellevue Hospital, New York  
 1989-1994 Assistant Director, Transplant Surgery, NYU Hospitals Center  
 1989-present Director of Liver Transplantation, New York University School of Medicine  
 1995-present Director, Transplant Surgery, NYU Hospitals Center  
 1995-present Director, Mary Lea Johnson Richards Organ Transplantation Center, NYU School of Medicine

#### National

(2000 to present, earlier years available upon request)  
 2000 Counselor, Region 9, UNOS  
 2000 Member, Liver Disease Severity Score Committee, UNOS  
 200 U.S. Transplant Games Medical Spokesperson  
 2001-2 Hepatocellular Carcinoma (HCC) Subcommittee, UNOS  
 2001 Member, Board of Directors, UNOS  
 2002-5 Member, Program, Publication and Postgraduate Committee, AHPBA  
 2004 Member, Ad-Hoc Living Donor Committee, UNOS  
 2004 At-large Representative, Liver Committee, UNOS  
 2004 At Large Member, Liver & Intestinal Committee, UNOS  
 2005-2006 Chairman, Ad Hoc HCC Committee, UNOS  
 2005-2006 Member, Split Liver Sub Committee, UNOS  
 2007-present Member, Living Donor Committee, UNOS

#### Regional

(2000 to present, earlier years available upon request)  
 2000 Panel Member, Pre-operative Protocols and Surgical Team Communications, New York State, Department of Health  
 2000 President, NYODN  
 2000-3 Chairman, NYODN

2001-present	Member, New York State Transplant Council
2001	Chairman, NYS Peri-operative Living Donor Committee
2003-2005	Chairman, New York Center for Liver Transplantation, Inc.
2004-present	Member, NYS Task Force on the Use of Extended Donors
2004-present	Member, Medical Advisory Board, LOLA
2005-present	Member, Medical Advisory Board, National Kidney Foundation of Greater New York
2005-2006	Member, Search Committee for Medical Director, NYODN
2006-present	Chairman, PI Sub Committee of Medical Board, NYODN
2006-present	Member, NY State Transplant Council on Presumed Consent
2007-present	Chairman, Performance Improvement, Committee, NYODN
2007-present	UNOS Appointee Advisor, National Living Donor Assistance Center, HRSA Grant
2007-present	Interim Chair, Clinical Policy, NYCLT
2007-present	Police Surgeon (Hon.), New York Police Department
2007-present	Editorial Board, Journal of Critical Care

#### NYU Hospitals Center

1990	Member, Surgery Peer Review Committee Medical Board, NYU Hospitals Center
1993	Member, House Staff Committee, Department of Surgery, NYU School of Medicine
2000-present	Member, Peri-operative Service Committee, NYU Hospitals Center
2000-present	Member, Service Chief Committee, NYU Hospitals Center
2000-present	Member, Division Chief's Committee, NYU Hospitals Center
2004-present	Member, Executive Committee of the Medical Board, NYU Hospitals Center

#### Honors

(1998 to present, earlier years available upon request)

1998	Shirley Award
1998-present	The Best Doctors in New York, New York Magazine
1996	National Medical Award in Transplantation, National Kidney Foundation
1997	Triangle Award, Transplant Recipient International Organization (TRIO)
1998	Appointed Deputy U.S. Marshall (Hon.)
1999	Doctor of the Year Award, Latino Organization for Liver Awareness (LOLA)
2000	Doctor of the Year Award, Michael Carnivale Foundation
2005	Distinguished Service Award, New York Organ Donor Network

#### **B. Selected peer-reviewed publications (2002 to present).**

1. Fahmy, C. O'Mahony, H. Kaul, G. Morgan, D. John, T. Diflo, **L. Teperman**. Living donor liver transplantation (LDLT) is safe and effective for hepatitis C recipients. *American Journal of Transplantation*, 2004 May;4(8):355.
2. B. Koneru, **L. Teperman**, C. Manzarbeitia, M. Facciuto, K. Cho, D. Reich, D. Campbell, P. Scheiner, A. Fisher, M. Korogodsky, K. Noto. Are routine chest computed tomography and bone scan required in patients with hepatoma and cirrhosis undergoing liver transplant evaluation? A cooperative study by the hepatoma and liver transplantation (HALT). *American Journal of Transplantation*, 2004 May;4(8):438
3. Lee VS, Morgan GR, Lin JC, Nazzaro CA, Chang JS, **Teperman LW**, Krinsky GA. Liver Transplant Donor Candidates: Associations between Vascular and Biliary Anatomic Variants. *Liver Transplantation* 2004 Aug; 10(8):1049-59.
4. Lee VS, Krinsky GA, Nazzaro CA, Chang JS, Babb JS, Lin JC, Morgan GR, **Teperman LW**. Defining intrahepatic biliary anatomy in living liver transplant donor candidates at mangafodipir trisodium-enhanced MR cholangiography versus conventional T2-weighted MR cholangiography. *Radiology* 2004 Dec;223(3):659-666.
5. Chalsani N, Manzarbeitia C, Ferenci P, Vogel W, Fontana RJ, Voigt M, Riely C, Martin P, **Teperman L**, Jiao J, Lopez-Talavera JC. Peginterferon alfa-2a for hepatitis C after liver transplantation: Two randomized, controlled trials. *Hepatology*. 2005 Feb;41(2):289-298.
6. B. Koneru, **L. Teperman**, C. Manzarbeitia, M. Facciuto, K. Cho, D. Reich, D. Campbell, P. Scheiner, A. Fisher, M. Korogodsky, K. Noto. A Multicenter Evaluation of Utility of Chest Computed Tomography and Bone Scans in Liver Transplant Candidates with Stage I and II Hepatoma. *Annals of Surgery*. 2005 April;241(4):622-628.
7. Ken K. Washburn, **Lewis W. Teperman**, Thomas G. Heffron, David D. Douglas, Eli Katz, Carlos G. Fasola, Goran B. Klintmalm. Pharmacokinetics and Pharmacodynamics of 3-dose Daclizumab in Liver Transplant Recipients with Hepatitis C. *American Journal of Transplantation*. 2005 May;5(11):179.
8. Glyn R. Morgan, Bachir Taouli, Gary M. Israel, Michael Macari, D. A. Moses, Elizabeth Hecht, Vivian S. Lee, **Lewis W. Teperman**. Comprehensive Evaluation of Potential Right Lobe Liver Donors: Comparison of MRI with 3D MRCP and CT with CT Cholangiography. *American Journal of Transplantation*. 2005 May;5(11):209.

9. **Teperman, L;** Campbell, D; Morgan, G; Harper, A; Fahmy, A; John, D; Diflo, T; Tobias, H; West, B; Goldenberg, A. "Does the current MELD system disadvantage hepatoma patients?" *Liver Transplantation*, 2005 JUL;11(7):C62-C62.
10. **LW Teperman, MD,** T Diflo, MD, A Fahmy, MB, GR Morgan, MD, et al. "West Nile Virus Infections in Organ Transplant Recipients---New York and Pennsylvania, August---September, 2005." *MMWR Disptach of CDC* October 5, 2005: 54 (Dispatch); 1-3.)
11. Delmonico, Francis,... **Teperman, Lewis,**... et al. "Workgroup on Expanded Criteria Organs for Liver Transplantation: New York State Department of Health Workgroup." *Liver Transplantation*, Vol 11, No 10 (October), 2005: pp 1184-1192.
12. W. Kenneth Washburn, **Lewis W. Teperman,** Thomas G. Heffron, David D. Douglas, Steven Gay, Eliezer Katz, and Goran B.G. Klintmalm. "A Novel Three-Doses Regimen of Daclizumab in Liver Transplant Recipients With Hepatitis C: A Pharmacokinetic and Pharmacodynamic Study." *Liver Transplantation*, 12:585-591, 2006.
13. Fasola, C G., Heffron, T. G., Sher, L., Douglas, D. D., Brown, R., Ham, J., **Teperman, L,**... et al. "Multicenter Randomized Hepatitis C (HCV) Three Trial Post Liver Transplantation (OLT): A Preliminary Report." *Transplantation*. 78(2) Supplement 1: 146, July 27, 2004.
14. Benjamin Tsoi, M. Campbell, E. Lumeng, J. Ackelsberg, E. DeBernardo, R. Lanciotti, L. Peterson, M. Kuehnert, J. Sejvar, T. Smith, A. Fine, **L. Teperman.** "Transmission of West Nile Virus Through Solid Organ Transplantation, 2005." Presented at the 2006 EIS Conference.
15. **Lewis Teperman, MD,** Ahmed Fahmy, Glyn Morgan, Hillel Tobias. Transplant Surgery, NYU School of Medicine, New York, NY. "West Nile Virus A Looming Deadly Threat for Liver Transplantation." Supplement to American Journal of Transplantation and Transplantation, World Transplant Congress 2006. 251: 151. July 22-27.
16. Ahmed Fahmy, MD, Glyn Morgan, MD, Devon John, MD, Thomas Diflo, MD, Juan Del Rio Martin, MD, Tahiro Murakami, MD, Inbo Shim, MD, and **Lewis Teperman, MD.** Transplant Surgery, NYU Medical Center. "Multiple Duct Anastomoses in Adult Living Donor Liver Transplant (ALDLT)." Supplement to American Journal of Transplantation and Transplantation, World Transplant Congress 2006. 1931: 709. July 22-27.
17. Takahiro Murakami, MD, Ahmed Fahmy, MD, Devon G John, MD, Glyn R Morgan, MD, Thomas Diflo, MD, Hillel Tobias, MD, Lydia Petrovic, MD and **Lewis W Teperman, MD.** "The Use of Extended Criteria Donor and Recipient Risk in Liver Transplantation." Supplement to American Journal of Transplantation and Transplantation, World Transplant Congress 2006. 1000: 404. July 22-27.
18. Inbo Shim, Glyn Morgan, Thomas Diflo, Devon John, Ahmed Fahmy, Juan Del Rio Martin, Takahiro Murakami, **Lewis Teperman.** Surgery, New York University, New York, NY. "Survival Impact of Hepatic Enzyme Elevation After Liver Transplantation For Hepatitis C." Supplement to American Journal of Transplantation and Transplantation, World Transplant Congress 2006. 1411: 541. July 22-27.
19. S Rudich, A Harper, G Mazariegos, **L Teperman,** JM Millis, S. Horslen. "Refinement of National (UNOS) Policy of Adult Hepatic Status 1A Candidates: Initial Results." Supplement to American Journal of Transplantation and Transplantation, World Transplant Congress 2006. 612: 274 . July 22-27.
20. Charles Rogler, MD, Glyn Morgan, MD, Lewis Teperman, MD, Leslie Rogler, Hongchao Zhou, MD. Identification of hepatocytic and bile ductular cell lineages and candidate stem cells in bipolar ductular reactions in cirrhotic human liver in *Hepatology*, 2007; Vol. 45:716
20. Charles Rogler, MD, Glyn Morgan, MD, Lewis Teperman, MD, Leslie Rogler, Hongchao Zhou, MD. "Identification of hepatocytic and bile ductular cell lineages and candidate stem cells in bipolar ductular reactions in cirrhotic human liver." Manuscript has been accepted for publication in *Hepatology*, 2007.
21. **Lewis Teperman, MD,** "Considerations on the Impact of Hepatic Encephalopathy Treatments in the Pretransplant Setting". Manuscript has been accepted for publication in *Liver Transplantation*, 2007.
22. T Murakami, MD, **L Teperman, MD,** T Diflo, MD, C Hyudu, MD, "Portal Cavanoma as an Indication of Liver Transplantation". Manuscript has been accepted for publication in *Liver Transplantation*, 2007.
23. J Chapochnick, MD, **L Teperman, MD,** T Diflo, MD, G Morgan, MD, D John, MD, A Fahmy, MD, "Transplants for Patients Outside of Milan Criteria Can Yield Good Results". Manuscript accepted for publication in *Liver Transplantation*, 2007.
24. A Sebastian, J Arenas, L Sher, B Koneru, **L Teperman,** P Marotta, D Patel. "Spare-The-Nephron (STN) Trial in Liver Transplant Recipients: Interim Efficacy and Safety of Mycophenolate Mofetil/Sirolimus Maintenance Therapy After Calcineurin Inhibitor Withdrawal". Integris Baptist Medical Center, Oklahoma City, OK; Henry Ford Hospital, Detroit, MI; University of Southern California, Los Angeles, CA; University of Medicine and Dentistry of New Jersey, Newark, NJ; NYU School of Medicine, New York, NY; London Health Sciences Hospital, London, ON and Roche, Nutley, NJ. Manuscript accepted for publication in *American Journal Transplantation*, 2007.

## C. Research Support

Oct'04 – Dec'08

### **Phoenix/ Roche-Kendle**

### **H-11844 Teperman (PI)**

A Prospective, Randomized, Multi-center, open-label, Comparative safety and efficacy Study of Prophylactically administered Pegylated Interferon alfa-2a (Pegasys)Plus Ribavirin vs. No prophylaxis Following Liver Transplantation for Hepatitis C.

1. To study the impact of prophylactic administration of antiviral therapy (Prophylaxis Arm) as compared to initiation of antiviral therapy at the time of clinical recurrence of HCV infection (Observation Arm).
2. To compare the efficacy, tolerability and safety of antiviral therapy in post-transplant patients in the two arms.

May'04 – Dec'10

### **Sirolimus 2/Wyeth**

### **H-10373 Teperman (PI)**

A randomized, open-label, comparative evaluation of conversion from calcineurin inhibitor treatment to sirolimus treatment versus continued calcineurin inhibitor treatment in liver allograft recipients undergoing maintenance therapy.

To demonstrate the following in stable transplant recipients: a) Superiority of the sirolimus (SRL, rapamycin, Rapamune) conversion regimen over the calcineurin inhibitor (CI) continuation regimen with regard to the change from baseline in calculated glomerular filtration rate (GFR) at 12 months. The comparison will be performed on an intent-to-treat (ITT) basis. b) Non-inferiority of the SRL conversion regimen with regard to the rate of the first occurrence of graft loss or death at 12 months in the ITT population.

July'05 – Dec'09

### **STN ML18423/Roche-Covance**

### **H-12078 Teperman (PI)**

A prospective, open-label, multi-center, randomized trial of the efficacy and safety of a long term calcineurin inhibitor free maintenance regimen with mycophenolate mofetil and sirolimus in recipients of an orthotopic liver transplant.

To evaluate MMF + sirolimus as a calcineurin inhibitor-free regimen for preservation of renal function in recipients of an orthotopic liver transplant.

Jan'07 – Dec'10

### **GS-US-203-0107/Gilead**

### **H-06-776 Teperman (PI)**

A Phase 2, Open Label Randomized study to evaluate the efficacy and safety of the Combination product, Emtricitabine/Tenofovir Disoproxil Fumarate in the Presence of Absence of Hepatitis B Immunoglobulin (HBIG) in preventing recurrence of chronic Hepatitis B (CHB) Post-Orthotopic Liver Transplant (OLT).

The primary objectives of this study are: 1) to evaluate the efficacy of the combination therapy, emtricitabine/tenofovir disoproxil fumarate (DF), plus or minus hepatitis B immunoglobulin (HBIG) in preventing CHB recurrence post OLT (CHB recurrence is defined as confirmed HBV DNA levels  $\geq 400$  copies/mL). 2. To characterize the safety and tolerability of emtricitabine/tenofovir DF and HBIG for the prevention of CHB recurrence in subjects who have undergone OLT for CHB.

Nov06 – Dec'16

### **The Realm Study/Bristol-Myers Squibb**

### **H-06-860 Teperman (PI)**

Randomized, Observational Study of Entecavir of Assess Longterm Outcomes Associated with Nucleoside/Nucleotide Monotherapy for Patients with Chronic HBV Infection.

To assess the rate of the following: 1) malignant neoplasm (overall and non-HCC, in each case including carcinoma in situ [CIS] but excluding non-melanoma skin cancer, and HCC); 2) liver-related events of HBV disease progression; 3) mortality (all cause, liver-related).

Jan'07 – Dec'10

### **A463109/Bristol-Myers Squibb**

### **H-07-140 Teperman (PI)**

Study of the Antiviral Activity of Entecavir in Patients Receiving Liver Transplant Due to Chronic Hepatitis B Virus Infection.

To determine the proportion of patients who experience virologic recurrence of HBV at 72 weeks post-OLT (orthotopic liver transplant) as measured by HBV DNA by PCR  $\geq 50$  IU/mL (approximately  $\geq 300$  copies/mL).

Nov'06 – Dec'09

### **PROTECT/Schering Plough**

### **H-06-282 Teperman (PI)**

Pegylated Interferon alfa-2b and Ribavirin After Orthotopic Liver Transplantation: Efficacy in Hepatitis C Recurrence Therapy.

To determine the sustained virologic response (SVR) at the 24-week follow-up after treatment with PEG-IFN alpha-2B and Ribavirin in post-orthotopic liver transplant (OLT) recipients with recurrent HCV.

Jan'06 – Jan'09

**Rifaximin/Salix-Omnicare**

**H-05-251 Teperman (PI)**

A multi-center, randomized, double-blind, placebo-controlled trial to evaluate the efficacy, safety and tolerability of rifaximin 550 mg BID for 6 months in preventing hepatic encephalopathy.

The primary objective of the study is to compare the maintenance of remission from previously demonstrated HE as measured by Conn score and asterixis grade during 6 months of treatment with rifaximin at 550 mg BID or placebo.

April'07 – Dec'09

**Rifaximin/Salix-Omnicare**

**H-06-963 Teperman (PI)**

A Multicenter Open-Label Trial to Evaluate the Long-Term Safety and Tolerability of Rifaximin 550 mg BID in Subjects with a History of Hepatic Encephalopathy.

To evaluate the long-term safety and tolerability of rifaximin treatment (550 mg BID) in subjects with a history of HE.

May' 07 – Dec'10

**Maribavir/ViroPharma Inc.**

**H-07-288 Teperman (PI)**

A Randomized, Double-Blind Study to assess the Efficacy and Safety of Prophylactic Use of Maribavir Versus Oral Ganciclovir For the Prevention of Cytomegalovirus Disease in Recipients of Orthotopic Liver Transplants.

1. To compare the efficacy of the prophylactic use of maribavir vers oral ganciclovir when administered for up to 14 weeks for the prevention of cytomegalovirus disease in recipients of orthotopic liver transplant at high risk of developing CMV disease.
2. To compare the safety and tolerability of the prophylactic use of maribavir versus oral ganciclovir when administered for up to 14 weeks in this subject populations.
3. To evaluate the pharmacokinetics of maribavir in this subject population.

Oct'06 – Dec'08

**Living Donor/New York Center For Liver Transplantation, INC** **H-07-138 Teperman (PI)**

Increasing liver donation through peer-developed education: Baseline survey.

To collect baseline (i.e., pre-intervention) data on individuals awaiting liver transplant at The Centers for Liver Diseases and Transplantations.

Dec'06 – Dec'08

**TAP Project/ St. Luke's-Roosevelt Hospital Center**

**H-07-138 Teperman (PI)**

Drug Treatment for Transplant Patients

- 1) To develop a telephone intervention for transplant candidates with co-occurring addiction (TAP).
- 2) To develop and test adherence and competence rating scales for TAP.
- 3) To standardized "treatment as usual" (TAU) in order to assure comparable and measurable medical care for all study patients.
- 4) To evaluate the efficacy of TAP +TAU compared to TAU only in a randomized pilot study of 40 recent/current substance abusers who are candidates for liver or renal transplant.

Sep '04 - tbd

**Adefovir PK: Gilead, GS-02-531**

**H-11166 Diflo (PI)**

A Multi-center Phase II, Open-Label Study to Evaluate the Pharmacokinetics of Tacrolimus or Cyclosporine When Co-administered with Adefovir Dipivoxil 10 mg to Patients Post-Liver Transplantation

To evaluate pharmacokinetics of tacrolimus or cyclosporine when co-administered with Adefovir dipivoxil 10 mg once daily to patients post-liver transplantation.

Sep '04 - tbd

**Plasmapheresis**

**H-11732 Diflo (PI)**

Plasmapheresis and IVIg Infusion to Allow Transplantation in Crossmatch-Positive Donor-Recipient Pairs

To institute plasmapheresis and IVIg infusion therapy for crossmatch-positive donor-recipient pairs to allow kidney transplantation.

Jan '05 – Dec '09

**HLA**

**H-12077 Teperman (PI)**

The Influence of Human Leukocyte Antigens (HLA) on Recurrent Hepatitis C and Graft Survival in Liver Transplant Recipients.

1. To search for a correlation between carrying a specific HLA class I or Class II allele, and the severity of recurrent HCV liver damage and graft survival.
2. To search whether donor-recipient HLA mismatch is associated with a better prognosis in terms of recurrent HCV liver damage and graft survival

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Jan '05-tbd

**HALT-MD**

**H-12160 Teperman (PI)**

Hepatoma and Liver Transplant Multicenter Database

To collect data on a prospective basis of patients with the clinical diagnosis of HCC referred for liver transplantation.