

FAST-MAG Times

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Open Letter to Los Angeles County Paramedics from Dr. Sidney Starkman, Co-Principal Investigator

I am writing to tell each of you what a TERRIFIC job you are doing on the FAST-MAG Clinical Trial. You are recognizing the symptoms of stroke, performing the mLAPSS, and calling an enrolling physician – all in record time. The national and international pre-hospital communities call what’s happening in LA “The future of stroke care.”

More patients have been enrolled in this study in the first two hours from the onset of symptoms than all previous stroke studies combined; two-thirds are enrolled in under *one* hour. The sooner potential neuroprotective drugs like magnesium are administered, the greater likelihood they will be proven to work.

I would like to review a few points that may help expedite the accurate enrollment of these patients: 1) The only person authorized to obtain informed consent is a FAST-MAG enrolling physician. Our MDs are experts in stroke and follow specific guidelines to obtain consent over the telephone. 2) The paramedic’s job is to

determine the hospital destination, pull the English or Spanish consent for that hospital, and introduce the study to the patient using the script on the Quick Guide. 3) It is helpful if the paramedic monitors the patient/physician conversation as occasionally the doctor is saying, “Give the phone to the paramedics!” 4) When the consent process is complete, there should be only **one** signature on the consent: either the patient or the representative, not both. 5) Remember: the FAST-MAG doctor decides who signs the consent. 6) As shown on the photo, there are four labels on the drug kit that say: “**STOP! Open Only After Study Doctor Gives Order.**” This is a reminder that the drug kit is not opened

until you get a specific OK from the FAST-MAG doctor. As most of you now know, a percentage of these patients do not end up being enrolled, so please do not open the kit until the enrollment is a certainty.

This study is being conducted under the direction of the US Food and Drug Administration, the National Institutes of Health, and participating hospitals’ Institutional Review Boards. Federal and state laws mandate that *Continued on Page 2*



Fire Department Profiles

Long Beach Fire Department

Long Beach has grown from a popular seaside resort in the late 1800s to become the second largest city within the Los Angeles metropolitan area. The city maintains a thriving maritime theme to this day: it has one of the largest ports in the world (the second busiest in the United States), and is home to tourist attractions like the Queen Mary, once the fastest ocean liner in the world.



Long Beach Fire Department (LBFD), which was established in 1897, serves a population of over half a million people concentrated in 55 square miles. LBFD responds to around 70,000

emergency calls annually and incorporates 23 fire stations. There are 84 dedicated paramedics staffing nine ALS rigs and 11 paramedic assessment units.

The size, diversity and maritime element of Long Beach are mirrored in its fire department. LBFD emergency personnel enjoy the opportunity to diversify Captain Matt Gruneisen. Duties in their work, says EMS Coordinator range from performing fire rescue on boats to conducting Department of Homeland Security pilot programs. Long Beach is one of the few fire departments conducting such programs.

LBFD prides itself on maintaining high standards and good quality patient care via regular staff training and continued excellent liaison with local hospitals. Captain Gruneisen is proud to be part of the FAST-MAG team. "We are in support of anything that will help our citizens and create a positive outcome in our patients. Research like FAST-MAG is an important part of this process."

Open Letter to LA County Paramedics

Continued from Page 1

the protocol be followed. Types of protocol violations might include:

- Patient signing a consent form without speaking to the FAST-MAG doctor
- Study drug being started in the field without notification of the FAST-MAG physician
- Field dose being started after the patient's arrival in the ED (FAST-MAG is strictly a pre-hospital initiated study)
- Paramedics accepting an order to start the drug from an MICN or other base station personnel; the only person who can OK start of the study drug is the FAST-MAG enrolling MD.

The study is going very well, and all due to the diligence of

paramedics. While it is true that not every call results in an enrollment, every call counts toward improving stroke care. You have now enrolled more than 900 patients. Each enrollment gets us closer to the total needed to determine if magnesium benefits stroke patients. If it works as we hope, pre-hospital administration of magnesium will become the standard of care for stroke patients around the world. It's the paramedics of LA County who will get the well-deserved credit for this phenomenal work.

On behalf of the entire FAST-MAG team, I thank you for your efforts.

Judith Star Korman, MD

Meet Your FAST-MAG Nurse Coordinator

With her significant background as a neurology nurse at UCLA, native Angeleno **Kanika McCall, RN**, is perfectly suited to be a FAST-MAG study coordinator. A graduate of Mount St. Mary's College, Kanika joined FAST-MAG in July 2006.



"The variety is great," she says. "One day I'm teaching, the next day I'm doing patient visits, there's never a dull moment".

Teaching paramedics about stroke and answering paramedics' questions is an aspect of her work that Kanika really enjoys. She values obtaining feedback from paramedics about their study experiences. "I always like to thank the paramedics," she says, "without them there would be no study."

As a floor nurse, Kanika's role was to act as an advocate for the patient; as a research nurse, her role is to assess and collect information. Her desire to help patients remains unchanged, however. "Stroke education is pretty much at a turning point. People need to know that stroke is a medical emergency. With the help of the Emergency Medical Services and FAST-MAG, we are putting stroke at the forefront."

Kanika serves as the FAST-MAG liaison to LA County Fire Department Battalion 3 and the single-city fire departments of Long Beach, Vernon, Compton, Downey and Santa Fe Springs. She is the Site Nurse Coordinator for Long Beach Memorial Medical Center, Little Company of Mary San Pedro, St. Mary's Medical Center and St. Francis Medical Center.

PARAMEDIC HALL OF FAME

01/01/09	Barry Bell Eric Suarez	LA CO FD RS 54
01/01/09	Landon Rupright Jose Perez	LAFD RA 33
01/03/09	Brent Nunez Richard Ortega Michael Legere	Torrance FD RS 93
01/06/09	Brandon Vaughan Tom Crawford	Burbank FD RS 15
01/07/09	Robert Ponce Scott Anderson	LAFD RA 104
01/08/09	Chris Schenk George Gillen	LA CO FD RS 54
01/09/09	Charlie Hoff Brian Crosby Javier Marquez	Santa Monica FD RS 124
01/09/09	Patrick Hanrahan Kevin O'Hara Anthony Huynh Mike Garcia	LA CO FD RS 41
01/12/09	Darin Conant Todd Cloutier	LA CO FD RS 124
01/14/09	Bennett Rogers Mark Flot Pova Aguero	LAFD RA 5
01/15/09	Don Shiah Sam Chao Steve Lloyd Kevin Carey	Torrance FD RS 96
01/16/09	Robert Gates Sam Green	LA CO FD RS 31
01/18/09	Steve Guerrero Keith Carlson Phil Working Gene Rink	LA CO FD RS 88
01/19/09	Steven Keyes Ryan Lopez	Glendale FD RS 22
01/20/09	Renee Wilson-Hall William Prentice	LA CO FD RS 47
01/23/09	Ruel Cole Carlos Rodriguez	LAFD RA 86
01/26/09	Paul Rodriguez Jake Heflin	Long Beach FD RS 9
01/28/09	Shannon Olson Eric Wright	LA CO FD RS 106
01/29/09	John Wilson Enrique Ruelas Jeff Arnold	LAFD RA 102
02/01/09	Mario Gonzalez Jeff Bader	LAFD RA 87
02/03/09	Ken Johnstone Pat Armour Keith Smith	LA CO FD RS 111
02/03/09	Eric Arellano Larry Campbell Kevin Greenway	La Verne FD RS 62
02/07/09	Robert Miller Dimitrius Lynch	LAFD RA 26

02/07/09	Bob Fogelman Kevin Davis	LAFD RA 70
02/09/09	Octavio Corona Roger Peterson	LA CO FD 19
02/10/09	Kyle Boyd Jeff Mabery	LA CO FD RS 135
02/10/09	David Cato Darren Cureton	Long Beach FD RS 10
02/11/09	Robert Barocas Art Martinez Rafael Legido	LAFD RA 60
02/11/09	Richard Larson Danny Garrett	LAFD RA 86
02/12/09	Ted Saras Ron Castro	LA CO FD RS 45
02/13/09	Virgil Estrada Thomas Carlbollian	LAFD RA 84
02/13/09	Mathew Rutan David Hickman Ryan Mendivil	Torrance FD RS 95
02/15/09	Matthew Hennessy Scott Kwasigroch	LAFD RA 33
02/15/09	Chad Rolish Gregory Davis	LAFD RA 68
02/19/09	A.J. Ramirez Chris Venezuela Adolfo Perez	LA CO FD RS 39
02/20/09	Russell Arentzoff Bryan Howard	LAFD RA 19
02/27/09	Chase Coleman Aaron Guggenheim	LAFD RA 15
02/28/09	Michael Hartley Scott Hessing	LAFD RA 81
03/03/09	Mike Pellegrini Justin Morgan	LAFD RA 68
03/03/09	Shawn Agnew Frank Bish	LAFD RA 47
03/04/09	Emilio Heraldez Chris Reno William Power Justin Pagliuso	Pasadena FD RS 31
03/06/09	Shawn Hopkins Mike McGrady	LAFD RA 77
03/08/09	Daniel Altruz Robert Ortiz	LA CO FD RS 32
03/08/09	John Thomas Fred Carter	LA CO FD RS 92
03/09/09	Joe Thomas Wayne Habel	LA CO FD RS 107
03/20/09	Jeff Dodd Ryan Jones	LAFD RA 94
03/24/09	Tom Feingold Dana Crutchfield	LAFD RA 61
03/23/09	Tom Crawford Ted Hemphill Erick Clements	Burbank FD RS 13
03/30/09	Brian Morgan Scott Clark	LA CO FD RS 73

PARAMEDIC HALL OF FAME

04/03/09	Gary Marshall Tom Corbridge Rob Smith	Santa Monica FD 125
04/03/09	Mario Generoso Eric Shatee	LAFD RA 92
4/4//2009	David Cato Gary Starkenberg Scott Fukinaga	Long Beach FD RS 14
04/14/09	Roger Braum Mike Nagy	Culver City FD RS 1
04/14/09	Howard Pechter Thomas Lawson	LA CO FD RS 89
04/15/09	Matt Bandy Vincent Dipane	Redondo Beach FD 61
04/15/09	Gilbert Barela Andy Manzano	LA CO FD RS 40
04/18/09	Dave Bowman Brian Stevens	LA CO FD RS 124
04/19/09	Brian Fisk Tony Parra Bill Ardizzone	Long Beach FD RS 17
04/19/09	Ruben Ruvalcaba Edward Diaz	LA CO FD RS 28
04/20/09	Daniel Harris Cooper Kunath	LAFD RA 2
04/03/09	Richard Puels Henry Hsien	LAFD RA 4
04/21/09	Ethan Burlingame Warren Sutton	LAFD RA 37
04/21/09	Ivan Covin Bill Defeo	LAFD RA 94
04/22/09	Edward Hechanova Victor Khachatoorian	LAFD RA 55
04/27/09	Eduardo Perez Joon Hong	LAFD RA 7
04/28/09	Jerry Guzman Jason Centeno	LA CO FD RS 26
05/03/09	Carlos Dominguez Robert Ortiz	LA CO FD RS 154
05/05/09	Frank Vogel Matt Strittmatter Dave Mendiola	LA CO FD RS 84
05/07/09	Daniel Trevizo Joseph Murray	LA CO FD RS 182
05/13/09	John Barrera Ruben Ruvalcaba	LA CO FD RS 28
05/13/09	Dan Lievense Dan Dragotto Greg Barbera	LAFD RA 17
05/14/09	Gustavo Aguirre Ted Saraf	LA CO FD RS 45
05/19/09	Shawn Motes Daniel Trevizo Mike Chapman	LA CO FD RS 182
05/22/09	Lane Fenton Brian Hammond	LAFD RA 46
05/25/09	James Vancil Greg Shaw	Glendale FD RS 21

05/28/09	David Francis Ted Ecklund	Pasadena FD RS 31
05/29/09	Trent Western Elan Raber	LAFD RA 75
06/04/09	Bennett Rogers Fernando Vasques Doug Ahuero	LAFD RA 5
06/05/09	Eric Biefeld Mike Bennett	LA CO FD RS 49
06/05/09	Rich Ruelas Tony Soto Rich Sutherlin	LA CO FD RS 28
06/05/09	Phil Working Timothy Scott	LA CO FD RS 88
06/06/09	Pat Hanrahan Kevin O'Hara	LA CO FD RS 41
06/08/09	Jason Walker Jim Schier	Santa Monica FD 121
06/08/09	Rico Gross Jose Perez Dominic Marquis	LAFD RA 78
06/09/09	Victor Duran Eric Rodriguez Ryan Johnson	LA CO FD RS 29
06/10/09	Shawn Agnew Frank Bish	LAFD RA 47
06/13/09	Matt Stiffler Yvette Almaraz	LA CO FD RS 30
06/14/09	Tye Johnson Andrew Mehr Josh Rosenstein Jon Breedan	Long Beach FD RS 2
06/14/09	Joel DeGuzman Timothy Cummings Christian Johnson	Torrance FD RS 94
06/14/09	Jim Beach Todd Carb	LAFD RA 107
06/17/09	Ryan Johnson Tim Mehringer Dan Connes	LA CO FD RS 29
06/18/09	John Maccini III Rich Kramer	Santa Monica FD RS 122
06/26/09	Leo Harris John Matamoros	LA CO FD RS 163
06/29/09	Matt Eddington John Roe	LAFD RA 1
06/30/09	Robert Fogelman Vic Villa	LAFD RA 70
06/30/09	Victor Lazaryan Jessica Schuman Intern Adam Hamilton	Pasadena FD RS 33
07/01/09	Ken McCoy Nick Beljajev Chris Wronski Trainee Sonny Sarrell	LA CO FD RS 98
07/03/09	Rhion Morrone Jorge Ostrovsky	LAFD RA 69

PARAMEDIC HALL OF FAME

07/09/09	Anthony Ferro Tim Rocky Douglas De Young	LAFD RA 84
07/09/09	Mike Pelegrini Greg Davis	LAFD RA 68
07/12/09	David Rodriguez Jon Shibuya	LAFD RA 59
07/15/09	Matthew Edgington Abe Tapia	LAFD RA 1
07/18/09	Damon Grayson Sean Saunders Jamie Schlottmann	LAFD RA 34
07/19/09	Ron Wiggins Russ Chidley	Long Beach FD RS 14
07/21/09	Tad Friedman Angel Meza	Torrance FD RS 95
07/22/09	Nick Haiduc Omar Estorga	LA CO FD RS 3
07/22/09	Tom Rockey Jason Rios	LAFD RA 72
07/23/09	Joshua Tibbett Kevin Hardie	LA CO FD RS 134
07/24/09	Leyth Dauod Mark Metcalf	LA CO FD RS 20
07/26/09	Mike Jones Jeff Rich Ezikel Cabarallo	LA CO FD RS 49
07/27/09	Kevin Kemp Rod Jackson	LAFD RA 51
07/27/09	Jeff Simmons Ted Waldrup	Downey FD RA 642
07/28/09	Dane Broesel Mark Glenchur Pedro Lovzan	LAFD RA 81
07/28/09	David Bonanno Travis Moore Kevin Greenway	LA Verne FD RS 61
07/30/09	Richard Sutherlin Ricardo Ruelas	LA CO FD RS 28
07/31/09	Adam Van Gerpen Steve Marquez Joe Field	LAFD RA 98
08/01/09	Wayne Chisholm Ted Hemphill	Burbank FD RS 13
08/03/09	Christopher Sagara Stephanie Glass	LAFD RA 41
08/08/09	Ken Miller Mark Gocke Howard Pechter Chris Young	LA CO FD RS 89
08/12/09	Christopher Guerra Philip Olivas	LA CO FD RS 40
08/12/09	Jason Centeno Jerry Guzman	LA CO FD RS 26
08/14/09	David Moede Cameron Langhans Linsay Pellegrini	LAFD RA 102

08/15/09	Josh Richling Joe Silguero	West Covina RA 1
08/18/09	Mark Wheeler Mike Bennett	LA CO FD RS 49
08/18/09	Dean Comer Joseph Monzo	LAFD RA 78
08/20/09	Ryan Schleiger Sergio Zavala Josh Halbmaier	Downey FD RS 642
08/21/09	Jerry Perez Zach Cates	LA CO FD RS 3
08/26/09	Charles Brigance Thomas Cavanaugh Don Bailey	LA CO FD RS 37
08/26/09	Kevin Poole Ray Karstin	LA CO FD RS 134
08/30/09	Gustavo Aguirre Ron Castro	LA CO FD RS 45
08/31/09	Jeffrey Ochoa David Jaureguy	LAFD RA 60
08/31/09	Rick EGGLESTON Trey Glennon	LAFD RA 13
09/01/09	Tyler Ence Dave Chavez	LAFD RA 33
09/03/09	Darren Mallabon Gary Dailey Steve Hong	Redondo Beach FD RS 62
09/03/09	Brian Cross Grant Garrett	LAFD RA 85
09/05/09	Art Dominguez Mike Fera Abel Eligio	Pasadena FD RS 34
09/06/09	Manny Potter Eric Ingstad	LAFD RA 257
09/06/09	Rick Lestelle Jason Shelton	LAFD RA 38
09/08/09	Donn Cunnigan Mike Reddy	LAFD RA 95
09/08/09	John Denton Ed Wilson	LA CO FD RS 29
09/08/09	Jeff Rodriguez Louis Cerda Dennis Ohligschlagler	LAFD RA 62
09/10/09	Douglas DeYoung Carlos Rivera David Morales	LAFD RA 84
09/11/09	Spencer Armstrong Craig Hammond	Glendale FD RS 25
09/12/09	Mario Lemos Stuart Moore	LA CO FD RS 60
09/13/09	Chris DiValerio Dave Finger	LAFD RA 72
09/14/09	Ralph Pfeiffer Aaron Best Walt Bergman	LA CO FD RS 16

PARAMEDIC HALL OF FAME

09/16/09	Alan Anolin David Christian Marc Scott P.T. Robert Palma	LA CO FD RS 30
09/17/09	Art Dominguez Sun Choe Gary Hobbs	Pasadena FD RS 32
09/18/09	Frank Bish Mark Moyer	LAFD RA 47
09/19/09	Octavio Sotelo Joel Entreken	LA CO FD RS 147
09/20/09	John Terrusa Greg Sanderson	LAFD RA 90
09/20/09	Frank Correa Alex Gorme	LAFD RA 74
09/29/09	Javier Marquez Jason Walker Jason Wells Jim Schier	Santa Monica RS 121
10/02/09	John Dulmage Mike Wills James Falls Tyler Wade	Manhattan Beach FD RS 22
10/02/09	Victor Rossi Mike Bennetts	LA CO FD RS 154
10/03/09	David Finger Wes Manning	LAFD RA 107
10/04/09	Cherif Amin Elan Raber	LAFD RA 75
10/05/09	Andy Asari Steve Zaan	Long Beach FD RS 10
10/06/09	Brain Nelson Greg Metz	LA CO FD RS 116
10/09/09	John Britt Cole Stan Bakey	Arcadia Fire RS 105
10/09/09	Louis Contreras Gabriel Velez	LAFD RA 101
10/13/09	Daniel Apodaca Daniel Lee	LAFD RA 20
10/16/09	Mark Sutherland Jason Chapman	LAFD RA 91
10/18/09	Joel Purma Patrick Leonard	LAFD RA 68
10/18/09	Michael Murrey Rudy Mejia Jim Muth Tim Viselli	Manhattan Beach FD RS 21
10/18/09	David Rosa Joshua Hogan	Long Beach FD RS 11
10/23/09	Ryan Nasssar Bryan Hill Adam Van Gerpen	LAFD RA 75
10/23/09	David Jaureguy Jeff Ochoa	LAFD RA 60
10/23/09	James Duffy Andrew Schmaud	LAFD RA 66

10/27/09	Ronald Castro Ted Saraf Gavo Aguire	LA CO FD RS 45
10/30/09	Moises Gallardo Mike Fera Justin Pagliuso	Pasadena FD RS 34
10/30/09	Chris Lambert Sergio Gonzalez	LA CO FD RS 64
11/01/09	Sergio Gonzalez Rick Burk	LA CO FD RS 64
11/03/09	Danny Lopez Manuel Tenorio	LAFD RA 33
11/04/09	Kenneth Meyers Victor Khachatoorian	LAFD RA 55
11/05/09	Josh Rosenstein James Farley	Long Beach FD RS 2
11/05/09	Ted Saraf Gustavo Aguirre	LA CO FD RS
11/07/09	Dayton Calhoun Kyle Boyd Eric McNamara	LA CO FD RS 33
11/07/09	Nicholas Escobedo Chris Guerra	LA CO FD RS 40
11/08/09	Robert Fogelman Kevin Davis Timothy Baker	LAFD RA 70
11/09/09	Stacy Rios Gabe Zavala	LA CO FD RS 101
11/10/09	Dave Hernandez Michael Miller	LAFD RA 13
11/10/09	Daniel Trevizo Joseph Murray	LA CO FD RS 182
11/12/09	Emilio Heraldez Nicole Olsen	Pasadena FD RS 31
11/12/09	James Woods Joel Entreken	LA CO FD RS 49
11/12/09	Javier Honles Andy Schmad	LAFD RA 66
11/12/09	Jeff Wilk Robert Searls	LA CO FD RS 118
11/17/09	Joe Carvalho Kristian Lutz	LA CO FD RS 33
11/18/09	Mark Harris Javier Honles	LAFD RA 66
11/19/09	Mario Gonzalez Joseph Scamardo	LAFD RA 87
11/21/09	Alex Reyes Ryan Caines Brett Pearson	Pasadena FD RA 31
11/24/09	Mario Lemos Craig Bradford	LA CO FD RS 60
11/25/09	William Defeo Brian Quinn	LAFD RA 43
11/25/09	Ricky Herrera Michael McDonough	LAFD RA 36
11/27/09	Craig Larson Duke Snyder	Glendale FD RS 29

Assessing Facial Droop: Even the Textbooks Have It Wrong!

Facial droop is probably one of the most misunderstood aspects of a stroke assessment – even for health care professionals. In the FAST-MAG trial, a patient meets criteria for screening by a physician, even if their only deficit is a facial droop.

Remember: If you find droop and it seems to be on the opposite side of the grip or arm strength deficit, always call anyway. The reason is that droop can be confusing and we don't want to miss patients who might benefit from being in FAST-MAG.

The Los Angeles Pre-Hospital Stroke Screen (LAPSS) is a simple tool that correctly detects stroke 97 out of 100 times. It includes a three-item motor exam: facial smile or grimace (droop), hand grip and arm strength. In order to qualify for FAST-MAG, the patient must have a deficit in one of these three areas. Paramedics have demonstrated excellent ability to accurately assess grip and arm strength.

The most reliable approach to assess facial droop is during active smiling:

1. Ask the patient to smile or show their teeth
2. If the patient is unable to follow directions, mimic the action
3. The droop (or facial weakness/deficit) is on the *side that does not move* or moves less than the unaffected side

Which side are these droops on?



The woman has a **left-sided** droop. Notice how the right side of her face has more expression. The droop on the man is on the **right**. The tell-tale sign is that you see fewer teeth on the right side of his mouth.

When we review run sheets for stroke patients NOT enrolled in the study, one of the most frequent findings is that the patient had only facial droop. Oftentimes these facial weakness/droop patients have slurred speech or aphasia caused by an acute stroke. Sometimes these findings are just described as altered but, when looked for, the facial asymmetry/droop is evident.

Please remember that patients need only one motor deficit for you to call the enrolling physician.

RESTOCK SEASON BEGINS IN FEBRUARY

FAST-MAG drug kits expire February 28, 2010.
FAST-MAG coordinators will be restocking throughout the month.

UPDATES

Enrollments

884

(through November 27, 2009)

FAST-MAG Hospitals

The hospitals listed below are currently open for enrollment of FAST-MAG patients

Antelope Valley Hospital
Beverly Hospital
Brotman Medical Center
California Hospital Medical Center
Cedars-Sinai Medical Center
Citrus Valley– Intercommunity
Citrus Valley- Queen of the Valley
Encino Hospital Medical Center
Garfield Medical Center
Glendale Adventist Medical Center
Glendale Memorial Medical Center
Good Samaritan Hospital
Henry Mayo Newhall Memorial Hospital
Hollywood Presbyterian
Huntington Memorial Hospital
Kaiser – West LA
Kaiser – Sunset
Kaiser –Woodland Hills
LAC – Harbor-UCLA Medical Center
LAC – Olive View Medical Center
LAC – USC Medical Center
Lakewood Regional Medical Center
Lancaster Community Hospital
Little Company of Mary – San Pedro
Little Company of Mary – Torrance
Long Beach Memorial Medical Center
Marina Del Rey Hospital
Methodist Hospital of So. California
Mission Community Hospital
Northridge Hospital Medical Center
Olympia Medical Center
Pomona Valley Hospital
Presbyterian Intercommunity Hospital
Providence Holy Cross Medical Center
Providence Saint Joseph Medical Center
Providence Tarzana Hospital
San Dimas Community Hospital
Santa Monica – UCLA Medical Center
Sherman Oaks Hospital
St. Francis Medical Center
St. John's Health Center
St. Mary Medical Center
Torrance Memorial Medical Center
UCLA (Westwood) Medical Center
Verdugo Hills Hospital
West Hills Hospital & Medical Center
White Memorial Medical Center
Whittier Hospital Medical Center – AHMC

FAST-MAG
Clinical Coordinating Center
1072 Gayley Avenue
Los Angeles, CA 90024

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FAST-MAG

“Because Time is Brain”



RESEARCH 101: *Informed Consent Process*

The obligation to obtain informed consent for research comes in part from the unethical conduct of studies in the past. Imagine: A mentally disabled but otherwise healthy child is purposely infected with hepatitis to test the effect of gamma globulin. Poor, illiterate men with syphilis are denied the newly discovered penicillin because they are in a study to evaluate the progression of untreated syphilis. These practices led to the formulation of a set of principles to guide scientists and physicians in the ethical conduct of human research.

Informed consent is a legal and ethical process to ensure that a potential study subject understands fully what it means to participate. It is the responsibility of study investigators to provide complete information and to ensure that the decision to participate is voluntary. No study procedures can be done until consent is obtained.

The consent process must be in the subject's primary language. The consent form describes the study purpose, procedures and potential risks and benefits. It includes privacy protections and lists key contacts. Importantly, the consent form specifically states that the subject has the right to withdraw at any time. A key element of the process is that it cannot be coercive in any way. Special protections are required for vulnerable populations such as prisoners.

It is the investigator's responsibility to determine who provides consent. Patients do so if they are mentally competent to make decisions. If not, a legally authorized representative provides consent. The investigator ensures that the consent provider's questions are answered.

Consent for research differs from consent for emergency care. While emergency care can take place based on *implied* consent, research requires *explicit* consent. Each participating hospital has their own consent form, which includes authorization to release personal health information for research.

For the FAST-MAG Clinical Trial, the study investigator is the enrolling physician. Pages requiring a signature are green and are tagged with stickers. The person who speaks with the investigator signs and dates the green pages. The paramedic does not sign the consent form.

The enrolling physician signs the consent by fax and copies are placed in the patient's chart and given to the family. The original is filed with the patient's study chart at the Coordinating Center.

The FAST-MAG consent process occurs in parallel with field activity. This process is crucial to ensure that FAST-MAG is conducted ethically and with the greatest respect for the dignity and autonomy of patients.