



MNTX 302

Confidential Phase 3 Clinical Study Report

16.1.3.1 List of IRBs/IECs

Site	IRB or IEC name and address
02	Schulman Associates Institutional Review Board 4290 Glendale-Milford Rd Cincinnati, OH 45242 Chair: Sharon Lynn Nelson, M.S.N., R.N., C.N.S.
03	Schulman Associates Institutional Review Board 4290 Glendale-Milford Rd Cincinnati, OH 45242 Chair: Sharon Lynn Nelson, M.S.N., R.N., C.N.S.
04	Schulman Associates Institutional Review Board 4290 Glendale-Milford Rd Cincinnati, OH 45242 Chair: Sharon Lynn Nelson, M.S.N., R.N., C.N.S.
05	Research Ethics Boards McGill University Health Centre 1650 Cedar Montreal (Quebec) Canada H3G 1A4 Chair: Committee A - Celeste Johnston, DEd, (Co-Chair), Lawrence Hutchison, MD, (Co-Chair) Committee B - Serge Gauthier, MD
06	Schulman Associates Institutional Review Board 4290 Glendale-Milford Rd Cincinnati, OH 45242 Chair: Sharon Lynn Nelson, M.S.N., R.N., C.N.S.
08	Schulman Associates Institutional Review Board 4290 Glendale-Milford Rd Cincinnati, OH 45242 Chair: Sharon Lynn Nelson, M.S.N., R.N., C.N.S.
10	University of British Columbia British Columbia Cancer Agency Research Ethics Board Vancouver Centre – Room 4571 Alcove 600 West 10 th Avenue Vancouver, BC V5Z 4E6 Chair: Dr. Joseph Connors
11	San Diego Hospice IRB 4311 Third Avenue San Diego, CA 92103 Chair: Linda Strause, PhD
12	University of Utah Institutional Review Board 20 North 1900 East 101 NREB Salt Lake City, UT 84132 Chair: John Hurdle, M.D., PhD
14	Henry Ford Health System Institutional Review Board CFP-Basement 046 2799 West Grand Blvd Detroit, MI 48202-2689 Chair: Timothy Roehrs, PhD

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16.1.3.1 List of IRBs/IECs - continued

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16	Schulman Associates Institutional Review Board 4290 Glendale-Milford Rd Cincinnati, OH 45242 Chair: Sharon Lynn Nelson, M.S.N., R.N., C.N.S.
17	Schulman Associates Institutional Review Board 4290 Glendale-Milford Rd Cincinnati, OH 45242 Chair: Sharon Lynn Nelson, M.S.N., R.N., C.N.S.
18	Human Subjects Protection Office The Penn State University/ The Milton S Hershey Medical Center 500 University Drive – PO Box 850 Hershey, PA 17033 Chair: Not Listed
19	City of Hope IRB 1500 E Duarte Rd Duarte, CA 91010 Chair: Not Listed
24	Schulman Associates Institutional Review Board 4290 Glendale-Milford Rd Cincinnati, OH 45242 Chair: Sharon Lynn Nelson, M.S.N., R.N., C.N.S.
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30	Schulman Associates Institutional Review Board 4290 Glendale-Milford Rd Cincinnati, OH 45242 Chair: Sharon Lynn Nelson, M.S.N., R.N., C.N.S.

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16.1.3.1 List of IRBs/IECs -continued

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33	Schulman Associates Institutional Review Board 4290 Glendale-Milford Rd Cincinnati, OH 45242 Chair: Sharon Lynn Nelson, M.S.N., R.N., C.N.S.
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16.1.3 List of Independent Ethics Committees (IECs)/Institutional Review Boards (IRBs) and Sample Consent Forms

Recruiting Sites and Corresponding IRBs - January 2013
Subject Consent May 23, 2011 Protocol Amendment #3
Subject Consent July 12, 2011 Protocol Amendment #4
Caregiver Consent May 23, 2011 Protocol Amendment #3
Caregiver Consent - July 12, 2011 Protocol Amendment #4

Protocols 3200K1-4000-WW (B2541005) & 3200K1-4001-WW (B2541006)

List of Investigators Sites and their Corresponding IRBs

Site No.	Site Address	Address for IRB
002	Richard Levene Hospice of Palm Beach County 5300 East Avenue West Palm Beach, FL 33407, USA	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
004	Chuck Wellman Hospice of the Western Reserve 300 E.185th St Cleveland, OH 44119, USA	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
006	Kumarasamy Sivakumar, Research Center for Clinical Studies-West, nc. 1314 West Avenue J Lancaster, CA 93534, USA	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
011	Jared Winston Senior Adult Specialty Research 3215 Steck Avenue Suite 202 Austin, TX 78757, USA	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
012	Richard Stephenson Hospice & Palliative Care Center 101 Hospice Lane Winston Salem, NC 27103, USA	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
013	Donna Zhukovsky M.D. Anderson Cancer Center Investigator Pharmacy Services 1515 Holcombe Blvd, Room B 1.4392 Houston, Texas 77030, USA	The University of Texas, MD Anderson Cancer Centre Institutional Review Board, Unit 1437,
014	David McGrew Hernando Pasco Hospice, Inc. 12107 Majestic Blvd Hudson, FL 34667, USA	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
016	Sloan Beth Karver H. Lee Moffitt Cancer and Research Institute Investigational Drug Services Pharmacy Department, Moffitt Cancer Center 12902 Magnolia Drive, Tampa, FL 33612, USA	Division of Research Integrity & Compliance 12901 Bruce B, Downs Blvd, MDC35 Tampa FL 33612-4799
018	Marcin Chwistek Fox Chase Cancer Center 333 Cottman Ave Philadelphia, PA 19111, USA	Fox Chase Cancer Centre Institutional Review Board, 50 Huntingdon Pike, Rockledge, PA 19046
020	Janet Bull Four Seasons Hospice and Palliative Care 571 S Allen Rd Flat Rock, NC 28731, USA	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
026	Maria Jakobsson Palliative Unit Vrinnevi Hospital Apoteket Vrinnevisjukhuset EA Att: Eva Malmberg Gamlavagen 25 601 82 Norrka ping Sweden	Regionala Etikprövningsnämnden i Linköping c/o Hälsouniversitetets kansli Sandbäcksgatan 7 581 83 Linköping ZIL
027	Gunnar Eckerdale ASIH Kungsbacka Narsjukhus Varbergs sjukhusapotek Att: Ulla Brattgayrd Traslavsvagen 68 432 81 Varberg Sweden	Regionala Etikprövningsnämnden i Linköping c/o Hälsouniversitetets kansli Sandbäcksgatan 7 581 83 Linköping ZIL

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028	Jose Gamez Galiz Research, LLC 201 Curtis Parkway Suite 304 Miami Springs, FL 33166, USA	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
033	Ana Casas Hospital Virgen del Rocio Edificio Hospital General Servicio de Farmacia Unidad de Ensayos Clinicos Avda. Manuel Siurot s/n planta semisotano Sevilla 041013 Spain	Ethics Committee CEIC. CSUB Ciutat Sanitaria Universitaria Bellvitge Dirección: Feixa Llarga, s/n - Edifici de Suport a la Recerca Localidad: Hospitalet de Llobregat CP: 08907
034	Pere Gascon Hospital Clinic i Provincial Agencia Ensayos Clinicos escalera 6B, sotano C/ Villarroel 170 08036 Barcelona Spain	Ethics Committee CEIC. CSUB Ciutat Sanitaria Universitaria Bellvitge Dirección: Feixa Llarga, s/n - Edifici de Suport a la Recerca Localidad: Hospitalet de Llobregat CP: 08907
036	Jose Espinosa Institut Catala d Oncologia Ser. Farmacia ICO 2nd Ptn. At. Marta Vat/Rosa Gomez av. Gran via s/n Km. 2,7 08907-Hospitalet del Llobregat SPAIN	Ethics Committee CEIC. CSUB Ciutat Sanitaria Universitaria Bellvitge Dirección: Feixa Llarga, s/n - Edifici de Suport a la Recerca Localidad: Hospitalet de Llobregat CP: 08907
040	Walter Cosolo John Fawkner Private Hospital HPS Pharmacies Brunswick 82 Moreland Road Brunswick, Vic 3086 Australia Vacluse Hospital 82 Moreland Road Brunswick Victoria 3056 Australia	Bellberry Limited 229 Greenhill Road, Dulwich, South Australia 5065
042	Presidio Ospedaliero "San Salvatore" Ospedale Civile San Salvatore Unita Operativa Complessa del farmaco Farmacia Ospedaliera Viale San Salvatore Coppito (l'Aquila)/ Italia, 6100 ITALY	Azienda Sanitaria Locale di Asti - ASL AT Sede Legale Via Conte Verde, 125 - 14100 ASTI Casella Postale 130 Centralino
043	Furlo Zucco Azienda Ospedaliera G. Salvini Unita' di Cure Palliative e Terapia del Dolore Viale Forlanini 121 Garbagnate Milanese Milano Italy 20020	COMITATO ETICO DELL'AZIENDA OSPEDALIERA GUIDO SALVINI DI GARBAGNATE MILANESE (MI) Viale Forlanini, 121 20024 GARBAGNATE MILANESE (MI)
044	Augusto Tommaso Caraceni Istituto Nazionale Tumori Fondaz. IRCCS 1st. Nazionale Tumori S. C. Farmacia Via Venezian, 1 Milano Italy 20133	COMITATO ETICO INDIPENDENTE DELLA FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI DI MILANO Via Giacomo Venezian, 1 20133 - MILANO
046	Richard Chye St Vincent's Hospital Linda Hotong Clinical Trials Pharmacist Pharmacy Store Victoria Street Level 2 Xavier Building Darlinghurst Australia NSW2010	St Vincent's Hospital Human Research Ethics Committee (HREC) "Research Office Level 6, de Lacy Building St Vincent's Hospital, 390 Victoria St Darlinghurst NSW 2010"

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050	Frank Elsner University of Aachen Med. Fakultät der RWTH Aachen Klinik fuer Palliativmedizin Pauwelsstr. 30 Aachen 52074 Germany	Ethik-Kommission an der Medizinischen Fakultät Technischen Hochschule Aachen, Pauwelsstrasse 30, 52074 Aachen
051	Thomas Jehser Gemeinschaftskrankenhaus Havelhoehe Zentrum fuer Schmerz- und Palliativmedizin Kladower Damm 221 Station 11 Berlin 14089 Germany	der Rheinisch-Westfalischen Muenchen Pettenkoferstrasse 8a 80336 Muenchen
054	Odette Spruyt Peter MacCallum Cancer Institute Pharmacy Department Peter MacCallum Cancer Centre St Andrew's Place East Melbourne Victoria 3002 Australia	Peter MacCallum Cancer Institute Locked bag 1 A'Beckett Street, Victoria, 8006
055	Bernard J Lapointe Hopital General Juif - Sir Mortimer B. Davis Main Pharmacy 3755 Chemin de la Cote Ste- Catherine Suite C-005 Montreal, QC H3T 1E2 Canada	The Jewish General Hospital Adele Cascini (Unit Coordinator) Clinical Research Unit Jewish General Hospital 3755 Cote St Catherine Road, Room: E: 872 Montreal, Quebec H3T 1E2
056	Bruno Gagnon Centre Universita de Santa McGill McGill University Health Centre Montreal General Hospital 1650 Cedar Avenue, C1 200 Montreal, Quebec H3G 1A4 Canada	The Jewish General Hospital Adele Cascini (Unit Coordinator) Clinical Research Unit Jewish General Hospital 3755 Cote St Catherine Road, Room: E: 872 Montreal, Quebec H3T 1E2
057	Standiford II Helm Pacific Coast Pain Management Center 24902 Moulton Parkway Suite 200 Laguna Hills, CA 92637	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
059	Paul Daeninck St. Boniface General Hospital 675 McDermot Avenue ON3114 Winnipeg, MB R3E 0V9 Canada	University of Manitoba Bannatyne Campus Research Ethics Board, P128- 770 Bannatyne Avenue, Winnipeg MB R3E CW3
062	Johan Menten UZ Leuven Apotheek Herestraat 49 Leuven B-3000 Belgium	Ethics Committee UZ Gasthuisberg E330, Herestraat 49, 3000 Leuven,
065	Guillemette Laval CH MICHALLON CHU GRENOBLE BP 217 High Ground Floor Grenoble Cedex 38043 France	Comité de Protection des Personnes - Sud Est V "C.H.U de Grenoble Comité de Protection des Personnes Service de Médecine Légale, R.C Haut - Hall Vercors, BP 217, 38043 Grenoble Cedex 9"

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067	Ragis Aubry Hopital Jean MINJOZ Unite de Soins Palliatifs Bd Fleming 5th Floor - wing north Besancon 25030 France	Comité de Protection des Personnes - Sud Est V "C.H.U de Grenoble Comité de Protection des Personnes Service de Médecine Légale, R.C Haut - Hall Vercors, BP 217, 38043 Grenoble Cedex 9"
068	Benoit Burucoa CHU BORDEAUX Hopital Saint Andre 1 rue Jean Burget 2nd Floor Bordeaux 33075 France	Comité de Protection des Personnes - Sud Est V "C.H.U de Grenoble Comité de Protection des Personnes Service de Médecine Légale, R.C Haut - Hall Vercors, BP 217, 38043 Grenoble Cedex 9"
069	Josyane Chevalier-Michaud HOPITAL SAINT-ELOI 80, avenue Augustin Fliche Ground Floor Montpellier 34295 France	Comité de Protection des Personnes - Sud Est V "C.H.U de Grenoble Comité de Protection des Personnes Service de Médecine Légale, R.C Haut - Hall Vercors, BP 217, 38043 Grenoble Cedex 9"
073	Sophie Laurent INSTITUT DE CANCEROLOGIE GUSTAVE ROUSSY Centre d'Évaluation et de traitement de la douleur et de soins palliatifs 39 rue Camille Desmoulins Ship DISSPO - 1rst Floor - Room 713 Villejuif 94804 France	Comité de Protection des Personnes - Sud Est V "C.H.U de Grenoble Comité de Protection des Personnes Service de Médecine Légale, R.C Haut - Hall Vercors, BP 217, 38043 Grenoble Cedex 9"
075	Beverley Hattersley St Peter's Hospital Pharmacy Dept. 88 Maplewood Avenue Hamilton, ON L8M 1W9 Canada	Hamilton Health Sciences 293 Wellington St. N. Suite 102 Hamilton, ON L8L 8E7
080	Paul Perkins Leckhampton Court Hospice Pharmacy Department Cheltenham General Hospital Sandford Road Cheltenham Gloucestershire GL53 7AN	London – Central MREC Level 7, Maternity Northwick Park Hospital Watford Road Harrow, HA1 3UJ
084	Louis Roy Hatel-Dieu de Quebec C.H.U.Q Pavillion Hotel-Dieu de Quebec 6, rue Mc Mahon, Room 0691 Quebec, Canada	CHUQ Research Ethics Committee Centre Hospitalier Universitaire de Quebec, 10 de l'Espinay Street, Room AO-124, Quebec, G1L 3L5
085	Ronald Schonwetter Lifepath Hospice ATTN; PHARMACY HPC Pharmacy 111 Kelsey Lane, Suite F Tampa, FL 33619	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
088	Gary Garner Rocky Mountain Clinical 1429 South 550 East Orem, UT 84097	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242

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091	James Cleary Rebecca Marnocha c/o Susan Johnston University of Wisconsin Hospital and Clinics Pharmaceutical Research Center 600 Highland Avenue E5/125-1530 Madison, WI 53792	Western Institutional Review Board 3535 SEVENTH AVE SW • OLYMPIA, WA 98502-5010
093	Michael Harris Aspen Clinical Research, LLC 1215 South 1680 West Orem, UT 84058	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
103	Walter Forman Lovelace Scientific Resources 2441 Ridgecrest Drive SE Albuquerque, NM 87108	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242
111	Sandra Serrano Hospital AC Camargo Rua Professor Antonio Prudente 211 1a sub solo Sao Paulo SP 01509-900	Comitê de ética em Pesquisa em seres Humanos da Fundação Antônio Prudente Hospital do Câncer – A.C. Camargo/ SP, Liberdade, São Paulo, SP 01509-900, BRAZIL
117	Deborah Thorpe Huntsman Cancer Hospital, Investigational Pharmacy Services Attn: Melissa Johnson 1950 Circle of Hope Room 2110 Salt Lake City, UT 84112	University of Utah Health Sciences Center Institutional Review Board Research Administration Building 75 South 2000 East Salt Lake City, Utah 84112
120	Sharon Watanabe Cross Cancer Institute Pharmacy Department Main Floor, Pharmacy 11560 University Avenue NW Edmonton, Alberta, Canada T6G 1Z2	Alberta Cancer Research Ethics Committee 308 Campus Tower, University of Alberta, 8625-112 Street, Edmonton AB T6G 1K8
125	Nora Godinez Eleccion Salud Dr. Jose Maria Vertiz #1097, Col. Vertiz Narvarte Delegacion Benito Juarez C.P. 03600 Distrito Federal, Mexico	Comité Bioético para la Investigación Clínica S. C. Puebla # 422 Despacho 4, Colonia Roma Sur. C.P. 06700.
1021	Victor Chang Dept. Of VA Affairs NJ Healthcare System 385 Tremont Ave. Hem/Onc (111), Rm 9-133 East Orange East Orange, NJ 07018	VA New Jersey Healthcare System 385 Tremont Avenue, East Orange, NJ 07018
1415	Mark Marilley 701 Doctors Drive Suite N Kinston NC 28501	Schulman Associates IRB 4290 Glendale Milford Road • Cincinnati, Ohio 45242