

REGISTRATION OF RESEARCH SUBJECTS

Clinical Research Policy/Procedure	
Approved: October 2008	Next Review: October 2009

Purpose

To establish a process for the proper registration of research subjects participating in clinical research studies at Swedish Medical Center (Swedish).

Responsible Persons

Research Coordination Staff.

Procedure

1. The Research Coordinator completes a Research Referral Form (RRF) in advance of a research subject's anticipated study visit. See RRF at Addendum 1. The RRF is available at T:\RSCH\Shared\FinMgmtTools\Research Registration.
 - **NOTE:** A separate RRF is required for each separate registration area involved in the subject's visit. See Addendum 2 for a list of registration areas and the departments (i.e., service lines) the registration areas serve.
 - a. **Instructions for RRF.** Complete the RRF in entirety.
 - (i) **Date:** Enter today's date.
 - (ii) **RRF Type:** This field is used to indicate the requested registration action:
 - One-Time: Sets up a one-time registration account for the study visit.
 - Recurring account: Sets up a recurring account for a series of study visits (e.g., recurring chemotherapy treatment).
 - Change: Requests a change to a previously-established registration account (e.g., change to reimbursement scenario).
 - Cancel Research Coverage – Requests cancellation of research coverage for a previously-established registration account (e.g., recurring account).
 - (iii) **Facility:** Specify the facility where the subject's study visit is scheduled.
 - (iv) **ATTN:** Identify the Patient Registration contact to whom the RRF should be delivered to. See Addendum 2, Swedish – [First Hill] [Cherry Hill] –

Research Registration Contacts, available at
T:\RSCH\Shared\FinMgmtTools\Research Registration.

- (v) **Patient:** Identify the research subject's name.
- (vi) **SSN:** Identify the research subject's social security number.
- (vii) **DOB:** Identify the research subject's date of birth.
- (viii) **Physician:** Identify the physician referring/ordering the scheduled service.
- (ix) **Date of Service:** Enter the scheduled date of service.
- (x) **Diagnosis / Procedure.** Enter a descriptor/code for the research subject's diagnosis and scheduled procedure. If possible, use appropriate Dx codes, CPT codes, DRG codes, etc.
- (xi) **Research Program:** Identify the relevant Swedish Research Program. The Swedish Research Programs include:

Administration - Unknown
Cardiovascular Research
Clinical Trials Unit
Neuroscience Research
Perinatal Research
SCI – Comm – Medical Oncology
SCI – Comm – Radiation Oncology
SCI – Fed – Medical Oncology
SCI – Fed – Radiation Oncology

→ **NOTE:** The electronic RRF form includes a dropdown menu in the Research Program field.

- (xii) **Project ID:** Enter the Project ID # assigned by Swedish Research Administration.
- (xiii) **Trial #:** Identify the sponsor of the research study and the study's sponsor-assigned protocol number using the following convention: <Sponsor Name>/<Sponsor's protocol number>. For example, a research study sponsored by Amgen with protocol # AMG162-08 should be notated as "Amgen/AMG162-08".
- (xiv) **Reimbursement Scenario:** Select the reimbursement scenario that corresponds with the scheduled study visit.
 - (a) **COMBO – Insurance is primary to research.** Select this option when the planned procedures for the scheduled study visit involve a *combination* of both procedures that are standard of care that should be billed to insurers, and, procedures that will be covered by Swedish Research.
 - **NOTE:** Provide a note on the RRF or send an email to the Clinical Trials Budget & Claims Analyst with instructions as to how the bills should be split.

- (b) **Inpatient/Outpatient – 100% Research funded.** Select this option when all of the planned procedure(s) will be covered entirely by Swedish Research and should not be billed to insurers or external payors. Indicate whether the procedures are scheduled for an inpatient or outpatient setting.
- (c) **Routine Clinical Service Provided in Research – 100% Patient funded.** Select this option when all of the planned procedure(s) are required by the research study protocol and are routine clinical services (i.e., standard of care) that will be billed to insurers.

For more information about reimbursement scenarios, see Clinical Research Policy/Procedure: CLINICAL RESEARCH BUDGET AND COVERAGE ANALYSIS.

- (xv) **Notes:** Enter any specific notes or instructions, etc.
 - (xvi) **Study Coordinator Name; Phone:** Identify the study coordinator completing the RRF and a convenient phone number for follow-up as necessary.
2. Fax the RRF(s) to the appropriate Patient Registration contact. See Addendum 2, Swedish – [First Hill] [Cherry Hill] – Research Registration Contacts, available at T:\RSCH\Shared\FinMgmtTools\Research Registration.
 - ➔ **NOTE:** An RRF may be faxed in advance of a scheduled study visit, however, do not fax an RRF more than thirty (30) days in advance.
 3. Send the RRF as an attachment with an email to the same Patient Registration contact with “RRF for <Patient Name> faxed today” in the subject line of the email. A message in the body of the email is not required. Copy the Clinical Trials Reimbursement Analyst and the Patient Registration contact’s supervisor (if identified) on the email. See Addendum 2, Swedish – [First Hill] [Cherry Hill] – Research Registration Contacts, available at T:\RSCH\Shared\FinMgmtTools\Research Registration.

Forms

- ◆ Research Referral Form

Supplemental Information

Clinical Research Policy/Procedure: CLINICAL RESEARCH BUDGET AND COVERAGE ANALYSIS

Expert Consultants

Clinical Trials Budget & Claims Analyst

Author

Peter Kim, Research Education & Compliance Officer

Regulatory Requirement

N/A

References

N/A

Addenda

1. Research Referral Form
2. Swedish –Cherry Hill – Research Registration Contacts
3. Swedish – First Hill – Research Registration Contacts

pk:Registration of Research Subjects – v. 2.0.doc (10/13/08)

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ADDENDUM 1

Research Referral Form (RRF)

Research Referral Form (RRF)

Please scan this form into the "Additional Info" folder in EPIC

Date:		RRF Type:	<input type="checkbox"/> One-Time	<input type="checkbox"/> Recurring Account	<input type="checkbox"/> Change	<input type="checkbox"/> Cancel Research Coverage
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Facility:	<input type="checkbox"/> FH	<input type="checkbox"/> CH	<input type="checkbox"/> BAL	<input type="checkbox"/> ISQ	<input type="checkbox"/> SPD	<input type="checkbox"/> Other - _____	ATTN:	
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Patient:		SSN:		DOB:	
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Physician:		Date of Service:	
Diagnosis:		Procedure:	
Diagnosis:		Procedure:	

Research Program:		Project ID:	[Input to Insurance ID/group# field]
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Trial #:	
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Reimbursement Scenario:

COMBO – Insurance is primary to research

1° Payor: Patient Insurance
 2° Payor: Research
 Guarantor: Patient

Inpatient / **Outpatient – 100% Research funded**

1° Payor: Research
 2° Payor: None
 Guarantor: Research

Routine Clinical Service Provided in Research – 100% Patient funded

1° Payor: Patient Insurance
 2° Payor: Patient Insurance (if applicable)
 Guarantor: Patient

Notes:

Study Coordinator Name:		Phone:	
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REGISTRATION OF RESEARCH SUBJECTS
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ADDENDUM 2

Swedish – Cherry Hill – Research Registration Contacts

Swedish - Cherry Hill Research Registration Contacts

DEPARTMENT (SERVICE LINE)	REGISTRATION AREA	PATIENT REGISTRATION CONTACT	FAX	EMAIL	PATIENT REGISTRATION SUPERVISOR	EMAIL
Ambulatory Infusion Center	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Bronchoscopy	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Cardiovascular Wellness Center	Cardiovascular Wellness Center	JoAnn Pasek	320-4683	joann.pasek@swedish.org		
Cardioversions	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Cath Lab	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Chemotherapy	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Comprehensive Breast Center - Surgical	Comprehensive Breast Center	Gretchen Perez		gretchen.perez@swedish.org	Teresa Coluccio	teresa.coluccio@swedish.org
Comprehensive Breast Center - Imaging	Comprehensive Breast Center	Gretchen Perez		gretchen.perez@swedish.org	Cindy Lewis	cindy.lewis@swedish.org
Comprehensive Wound Healing Center	Comprehensive Wound Healing Center	Sally Munn	320-4073	sally.munn@swedish.org		
CT Scan	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Cyberknife	Cyberknife	Beverly Jones	320-4293	beverly.jones@swedish.org		
ECT (Electroshock Therapy)	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
ECHO (Echocardiogram)	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
ECHO (Bubble/Contrast/Stress Dobutamine)	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
EEG	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
ECG / EKG (Electrocardiogram)	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Executive Health Services	Executive Health Services					
Interventional Radiology - Outpatient	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Interventional Radiology - SDS	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Mother Joseph Clinic	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
MRI	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Myelogram	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Nuclear Medicine	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Occupational Therapy	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Oncology Professional Services (SCI Medical Oncology/Dr. Fer)	Oncology Professional Services	Richard Donato				
Permanent Pacemakers	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Physical Therapy	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Presurgical	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
PTCA	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Pulmonary Function	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Speech Therapy	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Stents	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Stress ECHO w/ Dobutamine	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Surgical - Inpatient	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Surgical - Outpatient	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
TEE (Transesophageal echo)	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
Ultrasound	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org
XRAY	Main Registration	Gina Umagat	320-3152	gina.umagat@swedish.org	Fred Henry	fred.henry@swedish.org

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ADDENDUM 3

Swedish – First Hill – Research Registration Contacts

Swedish - First Hill Research Registration Contacts

DEPARTMENT (SERVICE LINE)	REGISTRATION AREA	PATIENT REGISTRATION CONTACT	EMAIL	FAX	PATIENT REGISTRATION SUPERVISOR	EMAIL
Ambulatory Treatment Center	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Anticoagulation Clinic	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Bariatrics	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Blood Patch	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Blood Transfusions	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Cardiology Peds (EP Study / PVC Ablation)	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
CAT Scan (CT) (POS)	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Chemotherapy < 24hrs	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Circumcision	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
C-Sections	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Diabetes - Josin Center for Diabetes (POS)	910 Boylston					
ECG/ Electrocardiogram	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
ECHO/ Echocardiogram	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Emergency Dept.	Emergency Dept					
Epilepsy - Pediatric Inpatient	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
ESTT	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Eye Surgery	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
First Hill Diagnostic Imaging	1001 Boylston					
Gastro/Special Procedures	1221 Madison 5th Floor					
Gastroenterology	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Inductions - Gel or Medical	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Infant - Inpatient < 28 days old	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
International Patient Services	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Interventional Radiology	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Interventional Radiology (ASC)	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Medical Oncology - Swedish Cancer Institute	Arnold Bldg					
Medical Treatment Center (POS)	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
MRI	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Newborn	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
NST - Non Stress Test	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Nuclear Medicine	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Nuclear Medicine (ASC)	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Observation	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Obstetric Triage	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Occupational Therapy	1101 2nd Floor					
OLU	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Organ Transplant	1101 2nd Floor					
Pain Clinic	1101 2nd Floor	Lynn Sullivan-Lee				
Ped Rehab / OT Therapy	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org

Swedish - First Hill Research Registration Contacts

DEPARTMENT (SERVICE LINE)	REGISTRATION AREA	PATIENT REGISTRATION CONTACT	EMAIL	FAX	PATIENT REGISTRATION SUPERVISOR	EMAIL
Ped Rehab / Physical Therapy	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Ped Rehab / Speech Therapy	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Pediatric GNRH Stim Test (Growth Hormone Endocrine)NICU or PEDS unit	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Pediatric Specialty Care Clinic	?					
Peds ATC	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Peds Procedural Sedation / MRI	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Perinatal Medicine (POS)	Nordtrom, 7th flr					
PET CT Joint Venture	1221 Madison 1st Floor					
Physical Therapy	1101 2nd Floor					
Pre- Admit (OB)	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Preadmission Visit (PAV)	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Pulmonary Function	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Radiation Oncology - Swedish Cancer Institute	Arnold Bldg					
Radiology (1101 Madison)	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Radiology (X-RAY) (POS)	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Radiology Walk In	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Respiratory Therapy	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Speech Therapy	1101 2nd Floor					
Summit Club	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Surgical - Outpatient	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Surgical Inpatient	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Swedish Breast Care Center (POS)	1101 Madison, 3rd flr					
Ultrasound	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Ultrasound (ASC)	Main Registration	Marta Rivera	marta.rivera@swedish.org	386-2625	Diana Johnson	diana.johnson@swedish.org
Women's Diagnostic Imaging Center	1221 Madison Suite 520					