Appointment Processing for Clinical Fellows

Office of Postdoctoral Affairs

April 28th 2011, 9:00am – 11:00am

LK120

Agenda

- **Definitions**

- **Appointment Process and Paperwork**
  - Submissions and Deadline
  - Required Training
  - Occupational Health
  - Spectrum OTC

- **Funding and Paying**

What is a Clinical Fellow?

- A Clinical Fellow is a MD, MD/PhD **in advanced years of training** (year 4 or higher) with full or incidental patient contact for the <u>purpose of treatment</u>

  - ❏ includes ACGME programs (even during research-intensive years)
  - ❏ includes non-ACGME training programs

- Clinical Fellow appointments are set up in PeopleSoft with MF (Medical Fellow). That is the PS code for it.

- General appointment guidelines can be found on:
  http://postdocs.stanford.edu/admin/clinical_trainees.html

Appointing Clinical Fellows

Why Appoint Clinical Fellows through OPA?

Because OPA grants them an "Academic Affiliation" with SUMC.

To receive University affiliation, Clinical Fellow appointments require approval by the Office of Postdoctoral Affairs **AND** by the Graduate Medical Education Office (GME)

University affiliation allows charging funding to Training Grants (T32s) and permits the fellows to submit competitive fellowship applications (e.g., American Heart Association fellowships)

Visas for Clinical Fellows

- Stanford University (OPA) does not sponsor visas for foreign Clinical Fellows

- For Non-US MD trainees with patient contact for the purpose of treatment, J-1 visas approved by ECFMG, processed through GME

Guidance for Patient Contact <u>without</u> Treatment

- Check and initial the "May have incidental patient contact" on the Recommendation Form to Appoint Postdoctoral Clinical Fellows (Trainees)

- Medical Research:

  http://humansubjects.stanford.edu/research/medical/medical.html

- Nonmedical Research:

  http://humansubjects.stanford.edu/research/nonmedical/nonmedical.html

Required Appointment Forms for ANY clinical fellows appointed through OPA

(initial appointees as well as those who started at GME)

1. Recommendation Sheet for Clinical Trainees
2. Information Sheet
3. OPA offer letter
4. Current CV
5. Diploma(s) showing conferral of all degrees
6. Copy of CA Medical License

Offer letter is through Stanford University not SHC (OPA template)

Submission of Clinical Fellow Appointment Packet

- Submit appointment packet as PDF via email to postdocaffairs@stanford.edu

- Do NOT send a copy through ID Mail or by fax. This creates a duplicate file

- Partial submissions of paperwork WILL delay the review of your file.

- Process moving to PeopleSoft Web Forms in a few weeks.

Deadlines, Procedures and Forms

Appointment Start Date	Deadline to submit paperwork to OPA	OPA Notification Date*
July 1	May 10	May 16
August 1	June 10	June 20

- Decision notifications may be approval, or return to department for further/missing documentation.

A checklist of required OPA documents
http://postdocs.stanford.edu/admin/checklist.html

Use the updated forms at
http://postdocs.stanford.edu/admin/forms.html

Important New Paperwork Procedures

1. Department Administrators must submit the appointment paperwork that was approved by OPA along with the OPA email approval notice directly to GME.

2. OPA will not forward paperwork to GME.

3. Departments must submit immunization records directly to Occupational Health (as was the case last year also).

Appointment Processing

- OPA's responsibilities consist of:

    - Term Activation in PeopleSoft Student Administration
    - Creating Student ID (mailed to fellow and administrator)
    - Setting up a record in Clear Benefits

- Departments are responsible for:
    - <u>Aid-Year Activation and </u>GFS Aid entry
    - Monitoring the fellows to ensure completion of all required training and provide immunization data to relevant offices.

- Salary must be based on Stanford Hospital PGY scale
    - Can be a combination of SoM and SHC sources

Funding Policy for Clinical Fellows

- ALL Clinical Fellows must receive the PGY level support that's appropriate to them, whether they are appointed at OPA or at GME.

- If the clinical fellow is in a research intensive year or period in a clinical training program, the fellow must receive the appropriate PGY level of support; i.e., no reduction in pay is allowable because the clinical trainee is doing research.

- A combination of School and SHC/VA sources may be used towards the PGY support. All funding sources must be entered in GFS. Direct-paid SHC/VA funding must be entered as "info-only" lines.

Important Funding Guidelines

- Only funding that is paid towards support of the training program is counted as part of the PGY level. In other words, pay for moonlighting or other work at the clinics that is outside of the training program DOES NOT count towards the funding minimum required towards training.

- Include all special funding terms and conditions (e.g., clinic time, on-call expectations…) in the offer letter.

- Billing in the area of training is NOT ALLOWABLE.

Using GFS to Pay Clinical Fellows

- **After Aid Year Activation, pay lines can be entered in GFS using Aid Entry**

- **Clinical Fellows funding** must be supported either by Stanford grants and contracts, training grants, School or departmental funds, external fellowships, SHC clinical activity provided that it is part of the training program and is documented in the offer letter, or by a combination of these sources (administered in GFS).

- **Assist Salary Tab**
  - Use Assist Type RAF if 20 hours or more salary
  - Use Assist Type RAFC if less than 20 hours salary
  - Use Assist Type RAF on each PTA if PTAs are <20 hours but total hours salary >=20. So 10 PTAs each paying 4 hours salary would all be Assist Type RAF

- **FLSHP Stipend Tab**
  - use if paying stipend from sources such as training grants or gift accounts
  - use as INFO ONLY to document pay from outside support given directly to fellow (i.e., through SHC, PAIRE or VA payroll) or direct-paid fellowships.

  - CANNOT Use FLSHP Stipend to generate wages earned for on-call duty or moonlighting.

Paying Clinical Fellows Tuition

- A Registration fee of $125 is charged per term

- Assist TAL Tab—use if paid salary. Calc TAL feature on Assist Salary tab will automatically generate tuition for you.

- FLSHP Tuition Tab—use if paid stipend or by outside support

Appointment Processing & Pay

- Questions?

Exceptions to Clinical Appointments

- A written justification request from faculty sponsor, submitted along with appointment packet, is required in the following cases:

  - MD was conferred more than 6 years ago
  - An initial appointment is requested at less than 100%
    - 90/10 or 80/20 – e.g. 90% Postdoc/10% Instructor position
    - Offer letter must indicate 90% postdoctoral compensation separately from 10% instructor compensation
  - Fellow has completed more than 5 years of research
  - Non standard curriculum – Advanced training

Special Appointments - Exceptions

- Non-U.S. MD Trainees:

  - Can be advanced clinical trainees with MD credentials and/or clinical duties who are non-US citizens or have non-US MD training and are sponsored by Stanford University

  - Requires CA Med Board License Section 2111 exemption. Must obtain GME Approval first.

Non-US MD Trainees (Assumes Incidental or Full Patient Contact for the purpose of treatment)

- Visas and CA Med Board License exemption approved by ECFMG and processed through GME

- ECFMG Certificate Requirement

- Consideration must be given if trainee desires to complete US residency

- Trainee may not bill for services

Non-US MD Trainees
(Research Only – including patient oriented research unrelated to treatment)

- Visas processed through OPA and approved by Bechtel

- Basic or Clinical Research

- Not eligible for change in program. Cannot switch to a clinical trainee visa status.

MDs on Visas – J-1 Visa Status Issue

- **ECFMG** will allow maximum of 7 years of clinical scholar program

- **MDs** cannot be appointed to a research appointment (without ECFMG approval) prior to a clinical appointment as this is considered a change in program

- **Completion** of studies and 2 year return home requirement:
  - J-1 Research Scholar status
  - J-1 Clinical Scholar status

Clinical Trainees at the VA or PAIRE

- ## Stanford Policy Applies:
  - ❑ Must be appointed by Stanford faculty member
  - ❑ Same Clinical Fellow appointment process
  - ❑ Use Stanford offer letter (modified for PAIRE per prior OPA approval)
  - ❑ Must include VA proof of support

- ## Usually waive Postdoc Benefits – waiver form is still needed

Appointment Preparation and Processing

- Questions?

Immunizations and HealthStream Training

- Occupational Health – Immunizations
- SPECTRUM – HealthStream Training

Occupational Health Services
1101 Welch Road

- Immunization Record should not be submitted to OPA with appointment packet

- Departments must see that fellows complete the required Health and Safety training prior to start of appointment (next slide)

- If you have any questions, please contact Occupational Health Services at (650) 723-5922

Occupational Health Services
1101 Welch Road
Required Training and Tests

■ All clinical fellows require the following documentation or tests:

1. Documentation of 2 step TB skin tests within the past 3 months OR

2. Documentation of Quantiferon test (QFT) within past 3 months.

3. Chest-X-ray within past 3 months if history of positive TB skin test or QFT

4. Documentation of Serology/Titer levels for:
   1. Measles/Rubeola
   2. Mumps
   3. Rubella
   4. Varicella
   5. Hep B Ab

5. Documentation on Tdap and/or Influenza (seasonal)

6. N95 Respirator Fit Test (highly recommended)

Occupational Health Services
1101 Welch Road
Required Training and Tests

- GME fellows require pre-hire physical exam

- All pre hire physicals are done at the Occupational Health Satellite Office at 300 Pasteur Dr. Stanford CA 94305 Room H0124

- Take the escalator located behind the main gift shop (near cafeteria) of Stanford Hospital, go to the ground floor and follow the signs, turn right and then immediate left.

HealthStream Training for Postdoctoral Fellows involved in Clinical Research

Jessica P. Meyer, MBA, Program Coordinator

Linda S. Walker, Program Administrator

Spectrum??

- Spectrum is the Stanford Center for Clinical and Translational Education and Research

- Spectrum Operations, Training and Compliance is one of 12 programs, and is the single point of contact for clinical research

- http://spectrum.stanford.edu/training-mentoring/educational-prog/med-residents.html

http://spectrum.stanford.edu

Spectrum OTC

Facilitating Translational Research at Stanford, Spectrum OTC (formerly SPCTRM) serves faculty and clinical research personnel at:

- School of Medicine

- Stanford University Medical Center

- Lucile Packard Children's Hospital (LPCH)

- Veterans Affairs Palo Alto Health Care System

OTC Mission

Enhance the quality of clinical and translational research performed at Stanford by:

- **Providing education**, required training and professional growth opportunities

- Functioning as a **single point of contact** for Industry and Faculty with queries regarding clinical research at Stanford

- **Working with University and Hospital** administrative offices on compliance and clinical trial processes

- **Maintaining the regulatory integrity** of a growing community of sponsor-investigators at Stanford

- Managing the **Health Screening, Safety and Compliance (HSSC) program** for School of Medicine clinical research staff involved in human subjects research

- Administer the **HealthStream Training for Postdoctoral Scholars Program** for SoM clinical trainees involved in human subjects research

Spectrum

The Stanford Center for Clinical and Translational Education and Research

STANFORD UNIVERSITY

Search Spectrum... | Go

RESEARCHER RESOURCES | **TRAINING AND MENTORING** | **PATIENTS AND COMMUNITY**

Researcher Resources

Clinical Research Resources

Overview
Biomedical Informatics
Biostatistics – Study Design
Spectrum Child Health
CTRU (Clinical Facilities)
Operations, Training & Compliance
(formerly SPCTRM)
    Contact Us
    Budgeting and Billing
    Study Facilitator Services
    Regulatory Services
    Education and Training
    Clinical Res Course - ICCR
    Calendar
    Staffing Your Research Study
    Study Tools & Forms
    Stanford Clinical Trials
    SPCTRM site map
Core Resources
Ethics
Need to Know
Resources and Contacts

Other Research Resources

Overview
Centers and Programs
Core Facilities
Institutes of Medicine
Shared Resources
Funding Opportunities
Calendars and Events
Community Engagement
Grants and Publication Info
Other Resources & Contacts
Need to Know

Login

Login with SUNetID
(to access all site features)

Education and Training

Education and Training Overview

CALENDAR

♦ **Calendar**
    Spectrum Clinical Training. **Calendar »**

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TRAINING

♦ **Getting Started**
    Whether new to Stanford or in need of a refresher course, this list of training programs provide you with the information necessary to successfully conduct clinical research at Stanford while maintaining compliance with University, OSHA, Joint Commission, Stanford Hospital and Clinics, and Lucile Packard Children's Hospital and clinics. **More »**

♦ **Health Screening, Safety and Compliance (HSSC) Program**
    Required for all non-faculty Stanford University School of Medicine (SoM) clinical research personnel involved with human subject research and data (clinical trials). **More »**

♦ **HealthStream for Postdoctoral Scholars**
    Required for all SoM postdoctoral scholars involved in clinical research at Stanford. A joint effort by Spectrum OTC and the Office of Postdoctoral Affairs. **More »**

♦ **Sponsor-Investigator Training**
    Required for those investigators who intend to obtain their own Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications from FDA. **More »**

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EDUCATION

♦ **Intensive Course in Clinical Research: Study Design and Performance**
    A one-week immersion course developed at Stanford for new clinical investigators, senior residents, fellows and junior faculty, interested in pursuing careers in clinical and translational research. **More »**

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♦ **Workshops**
    ♦ **Upcoming Workshops**
        Workshops offered by Spectrum OTC and affiliates **More »**
    ♦ **Past Workshop Presentations**
        Past presentations available to view and download **More »**
♦ **Request a Workshop**
    View list of possible workshop topics, or suggest a topic. **Workshop Request Form »**

RESEARCHER RESOURCES | **TRAINING AND MENTORING** | **PATIENTS AND COMMUNITY**

Researcher Resources

Clinical Research Resources

Overview
Biomedical Informatics
Biostatistics – Study Design
Spectrum Child Health
CTRU (Clinical Facilities)
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(formerly SPCTRM)
  Contact Us
  Budgeting and Billing
  Study Facilitator Services
  Regulatory Services
  Education and Training
  Clinical Res Course - ICCR
  Calendar
  Staffing Your Research Study
  Study Tools & Forms
  Stanford Clinical Trials
  SPCTRM site map
Core Resources
Ethics
Need to Know
Resources and Contacts

Other Research Resources

Overview
Centers and Programs
Core Facilities
Institutes of Medicine
Shared Resources
Funding Opportunities
Calendars and Events
Community Engagement
Grants and Publication Info
Other Resources & Contacts
Need to Know

Login

Login with SUNetID
(to access all site features)

TRAINING – HealthStream – Postdoctoral Scholars

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*REQUIRED TRAINING:

HealthStream for Postdoctoral Scholars Program

HealthStream™ Training is a joint effort of Spectrum Operations, Training and Compliance and the Postdoctoral Affairs Office, in collaboration with Lucile Packard Children's Hospital (LPCH), and Stanford Hospital and Clinics (SHC).

Mandatory!

HealthStream Training is mandatory for all School of Medicine (SoM) postdoctoral scholars working on research studies involving clinical (human subject) research and data (clinical trials).

Goals of HealthStream™ Training

- Protect the health and safety of Stanford University clinical research personnel working with patients, clinical trial volunteers and /or patient health information (PHI) and
- Provide information and training for the safety of and to equip staff to perform patient-care duties within School of Medicine departments, in LPCH, SHC, VA Palo Alto Health Care System (VAPAHCS) and satellite facilities.

Completing HealthStream™ Training

HealthStream™ Training is completed through the e-Learning Management Tool- the HealthStream Learning Center™ (HLC) within 30 days of assignment date, annual thereafter.

If you are a current or new postdoctoral scholar within the School of Medicine, please complete the online **Assessment Form** to determine whether you are eligible for **HealthStream™ Training**. *Be advised you will need a SUnet ID to open this page.

If you have already received your log-in instructions, please visit **SUSOM HealthStream™** to view your HealthStream assignments.

Additional Resources:

Office of Postdoctoral Affairs

Cancer Center

Research Compliance Office

Environmental Health & Safety

Spectrum, The Stanford Center for Clinical and Translational Education and Research

- Spectrum | Child Health
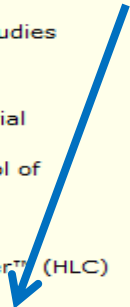- Spectrum | Operations, Training and Compliance (OTC)
    Email: clinicaltrials@med.stanford.edu

    OTC Services: *Infrastructure Support* | *Education and Training* | *Facilitator Services* | *Community Engagement* | *Research Coordinator Services* | *Regulatory and Compliance Consultation* | *CTR Management Tools and Services*

Questions?

If you have questions about this program, please contact:

Jessica P. Meyer

Geraldine Solon

What is HealthStream™ Training?

- HealthStream™ Training is a joint effort of the Spectrum Office of Compliance, Training and Operations and the Postdoctoral Affairs Office, in collaboration with Lucile Packard Children's Hospital (LPCH), and Stanford Hospital and Clinics (SHC).

- HealthStream Training is *mandatory* for all non-faculty School of Medicine (SoM) clinical research personnel, involved with clinical (human subject) research and data (clinical trials).

- The goal of HealthStream Training is:
  - ***to protect the health and safety of Stanford University clinical research personnel working with patients, clinical trial volunteers and /or patient health information (PHI)*** and
  - to provide information and training for the safety of and to equip staff to perform patient-care duties within School of Medicine departments, in LPCH, SHC, VA Palo Alto Health Care System (VAPAHCS) and satellite facilities.

- HealthStream Training is completed through the e-Learning Management Tool- the HealthStream Learning Center™ (HLC).

Are the Postdoctoral Scholars in your department involved in Clinical Research?

- **If the postdoctoral scholar has or will have in the next 12 mos.:**
  - ❑ In person, face-to-face contact with research participants?
  - ❑ Access to PHI (protected health information) through enrollment, billing, phone screening, data analysis, etc)? Access to medical records (EPIC/Cerner)?
  - ❑ An office or place where clinical research is conducted in a Stanford Hospital (SHC/LPCH/ and or clinics) Building?

HealthStream Training is **required** if any of the above questions are answered "YES".

PostDoc HealthStream Training Process
http://postdocs.stanford.edu

Step 1: Complete Online Form

https://stanfordmedicine.qualtrics.com/SE/?SID=SV_0Do8MAvpoDThLeI

Step 2: Spectrum Reviews Form
➢ Determine eligibility.
    ➢If non-eligible, sends notification to postdoc and department administrator
    ➢If eligible, creates profile in the HealthStream™ Learning Center (HLC)
        ➢ Sends course assignments to "Students". Students will have 30 days to
        complete this training.

Step 3: Spectrum audits Completion Status
➢ At the end of every month, Spectrum audits postdoc profiles on HealthStream.
➢ If incomplete, Spectrum will send "Out of Compliance" notices to postdoc,
Department Administrator and Alistair Murray

Step 4: Annual Compliance Audits
➢Each fiscal year, Spectrum sends non-compliance reports to Rania Sanford and
Alistair Murray.

Department Manager Access to HealthStream

Department Managers can obtain access to the HealthStream Learning Center to review and monitor postdoc HealthStream compliance.

Contact Jessica Meyer to obtain access and instructions. You will need to provide the following:

1. Name
2. Department/Division
3. Email
4. Phone
5. Stanford Employee ID # (8-digits)

PostDoc HealthStream Training Modules

HealthStream Initial Assignments include the following courses:

1. Code of Conduct (includes Deficit Reduction Act)
2. Standard Precautions: Bloodborne Pathogens and Other Potentially Infectious Materials
3. Prevention of Healthcare-Associated Influenza- Infection Control
4. Quality Improvement
5. Patient Rights
6. Safety Reporting- Patient Safety Net
7. Electrical Safety
8. Emergency Preparedness
9. Fire Safety Awareness and Response
10. Confidentiality Statement
11. Service Excellence (SHC or LPCH)
12. National Patient Safety Goals
13. Respiratory Therapy
14. Cultural Diversity – Sexual Harassment
15. Prevention of Hospital Acquired Infections

PostDoc HealthStream Training Modules

Some of these courses have Pre-Assessment Tests

HealthStream Annual Assignment:

1. ***Rapid Regulatory Compliance***: Clinical II:Gen/Fire/Elec/Back/Rad./MRI Safety, Ergo, Lift/Transp, Slips/Trips/Falls,LatexAllergy, HazComm, WorkplaceViol., EmergPrep, Infec.Control:HAI, HandHyg, Bloodborne, StdPrec, Airborne/Contact/Droplet Prec, PPE

Additional Clinical Research Training

Please see Clinical Research Personnel Training Checklist (PostDocs)

- Additional Training may be required:
  - CITI Training (Human Subject Research Protection) from the IRB
  - eProtocol Training from the IRB
  - See Training Assessment in STARS via AXESS (http://axess.stanford.edu)
  - Biohazardous Material Training from EH&S
  - Competency Training (i.e. Sedation),
       contact SHC: Vickey Weir, Ph: (650) 725-4611

- Also recommended are the Spectrum Orientations
  - General Orientation- How to Conduct Clinical Research at Stanford
  - Budgeting and Billing- How to Budget a Study and how the Billing System works at Stanford
  - Please see the Education Calendar for dates and to register. (http://spectrum.stanford.edu/researcher-resources/clinical/otc/calendar-training.html)

Clinical and Translational Research Resources
(see CTR Training Checklist for PostDocs)

- **Cancer Center http://cancer.stanford.edu**

- **Research Compliance Office** http://humansubjects.stanford.edu

- **Environmental Health & Safety**
  http://med.stanford.edu/somsafety/training.html

- **Spectrum, The Stanford Center for Clinical and Translational Education and Research** http://spectrum.stanford.edu

  - **Spectrum | Child Health** http://spectrumchildhealth.stanford.edu

  - **Spectrum | Operations, Training and Compliance**

  - http://spectrum.stanford.edu/researcher-resources/clinical/otc.html

    Email: clinicaltrials@med.stanford.edu

    - Services: CTR Planning; Biostatistics Consultation; Education and Training; Help Desk/Facilitator Services; Research Coordinator Services; Regulatory and Compliance Consultation; Study Navigator; CTR Management Tools and Services; Website

Questions??

■ Contact:

❑ Jessica P. Meyer, 650-498-6140, jpmeyer@stanford.edu

❑ Linda Walker, 650-498-6498, linda.walker@stanford.edu

❑ Luciane Carrillo, 650-721-1071, lucarril@stanford.edu