

How to Complete the Clinical Research Scope of Duties Forms

Clinical Research Volunteer/Student Scope of Duties Form:

- **Purpose:**

This form is used by UCLA faculty and staff to invite the following to receive clearance to conduct research that may have involve access to patients/human research subjects, identifiable/clinical data, or clinical areas/buildings:

- Individuals who will volunteer (uncompensated) in clinical research at UCLA Health/DGSOM
- Individuals who will volunteer (uncompensated) in clinical or non-clinical activities for UCLA School of Dentistry
- UCLA Students who will be receiving UCLA Student Research Program (SRP) course credit to conduct clinical research at UCLA Health/DGSOM
- UCLA Students who will be receiving UCLA SRP course credit to conduct research at UCLA School of Dentistry

As the inviting faculty/staff, please complete and sign the form before submitting to the Volunteer Office via email, fax (310-267-3670), or in person. Once approved, the invited individual will be contacted to start the clearance process.

- **Non-IRB Studies:** If the assignment will only involve NON-IRB Studies (such as IRB exempted, Quality Improvement, etc.), please indicate type of project next to the IRB#. (If not applicable, please indicate: "N/A")
- **Hours and Locations:** Please ensure these two fields are completed. If you do not know the exact start date, you may indicate "ASAP" and duration of assignment (maximum 2 years, if the individual will continue, please submit an updated CRVSOD Form with a new end date/duration).
- **Contact with Study Participants:** Study Participants include potential/current/past research subjects, patients, or relatives of research subjects/patients.
- **Receiving Stipend or Credit:** This form is NOT used to process the following individuals:
 - NON-UCLA Students receiving credit/stipend or on a formal rotation at UCLA Health/DGSOM
 - UCLA Students receiving stipend (monetary payment or scholarship)
 - Practicum/Graduate/Medical/Allied Health Students invited for "clinical training"
 - Individuals required to complete certain hours to receive a certificate/license/degree/court ordered community service completion
 - Outside Licensed Physicians/Visiting Researchers invited to collaborate with projects/studies
- **Checklist of Duties and Sections 3, 4, 5, and 6:** Please ensure all sections are completed. If any sections do NOT apply, please check "does not apply".
 - **For Section 3 (Laboratory Duties):**
 - Any duties that requires explanations or listing must be included in detail for risk purposes.
 - Any duties involving sharps/needles, hazardous or biohazardous materials will be reviewed.
 - Please note that volunteers and students are not permitted to directly handle human bodily fluids or extracts (blood, urine, stool, saliva, etc.)
 - Information of the laboratory parameters will be sent for acknowledgment and confirmation.
 - **For Section 4 (IRB Approved Research Duties):**
 - To ensure that your volunteers/students are processed in a timely manner:
 - Please include ALL checked duties from this section to the webIRB application under section 1.1a under Other Personnel". You may COPY and PASTE these duties:
 - Please include ANY additional duties that may involve human research subject interaction (including assisting with MRI Scans) that may be listed in other sections of the CRVSOD Form.

- TO ADD VOLUNTEERS/STUDENTS: A group name (ex. UCLA Health Volunteers and UCLA Students) should be listed in section 1.1a under "Other Personnel". "Key Personnel" titles are for staff. Include all listed clinical research duties that you would like the individual to assist.

Example: Section 1.1a of webIRB (Other Personnel)

<u>Name(s)</u>	<u>Description</u>
UCLA Health Volunteers and UCLA Students	Recruit participants, provide study information, hand out consent forms with staff supervision, assist with data management and analysis, screen potential participants, conduct follow-up visits to collect data, and review/analyze clinical data using Care Connect and/or medical records. (Will assist staff with participants with MRI Scans), (transport bio specimen/research samples), etc.

- If your volunteer/student is assisting with MRI Scans at the Brain Mapping Center and/or Staglin Center in Semel, please list the duty under Section 6 of the CRVSOD Form and complete/sign the addendum of appropriate duties (located on the BMC website or request it from Lily Zhang).
- **For Section 5 (Access to Systems and Protected Health Information [PHI] Duties)**
 - If Care Connect will be requested for the volunteer/student, please ensure all fields and initials are completed in section 5. MedNet IS required to access CC, please check it even if the volunteer or student will not use it for emailing. Title for such accesses should be requested as: "Volunteer".
 - Please indicate access to Care Connect/Medical Record in the webIRB application of the volunteer/student/group's description if access will be used for research purposes.
 - If *any* duties listed under section 5 is checked, please have the **Personal Device Form** completed. This is used as a written attestation for compliance to specify use of personal device (if applicable) and what other devices will be used for Computer duties, Care Connect, and/or MedNet. (NOTE: clinical data is not permitted to be stored or accessed using personal devices)
- **For Section 6 (For Other Duties not Listed):**
 - Even if this section does NOT apply, please respond to the shadowing/observing question. Please see Section 1 in regards to the Shadowing Policy.
 - If the listed duties include contact/interaction with patients/research participants/research data, IRB Approval may be required.

For Personal Device Form:

- If no personal device will be used for the volunteer's/student's assignment, please indicate in Question 4 and specify what other device will be used instead (for example: UCLA Workstation, UCLA Owned Device, etc.).
 - Please continue to answer the rest of the compliance questions, those that do not apply, please place "N/A".
- If a personal device will be used, please ensure all information regarding the device is specified for Compliance review. Please note that personal devices may not be used to access Medical Records, Care Connect, or Protected Health Information (PHI).

For IRB Listing Template:

- This form is used as a template in case there are multiple IRB studies in which the volunteer/student will assist and duties are different for each study. You may create your own addendum with the same type of information.
- If there is none or only one, this may not be necessary.