1.1. Background

The International Conference of Harmonization (ICH) E6 standard, *Good Clinical Practice: Consolidated Guidance*, accepted as regulatory guidance by the U.S. Food and Drug Administration (FDA), states:

The contents of a clinical trial protocol should generally include (6.1.7) Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial. *This information is also required according to FDA 21 CFR 312.53(c)(iv)).*

Sites and sponsors are required to keep documentation of (8.2.11) Normal value(s)/range(s) for medical/laboratory/technical procedure(s) and/or test(s) included in the protocol. (To document normal values and/or ranges of the tests); (8.2.12) Medical/laboratory/technical procedures/tests: certification, or accreditation, or established quality control and/or external quality assessment, or other validation (where required), to document competence of facility to perform required test(s), and support reliability of results.

1.2. Name and Addresses of Laboratories

SHC Clinical Lab
300 Pasteur Drive, Room H1520
Pavilion E, Level 1, E12
Stanford, CA 94305

SHC Clinical Lab at Hillview
3375 Hillview Avenue
Palo Alto, CA 94304

Stanford Cancer Center South Bay
2589 Samaritan Drive
San Jose, CA 95124

Stanford Clinical Lab at Redwood City
450 Broadway Street, Room L010624
Redwood City, CA 94063

1.3. Normal Values

Complete and submit a "Request for Clinical Laboratory Documentation" form.

1.4. Director CV and Medical License

To meet regulatory requirements, and in cooperation with Stanford University School of Medicine, the Clinical Laboratory at Stanford Hospital and Clinics will provide the information described below. Because the clinical laboratory director is not directly engaged in individual research projects at Stanford, the director does not provide a curriculum vitae or medical license.

Note: If a request for the laboratory director's CV or license includes evidence of a regulatory requirement for these items, this best practice position will be evaluated.

1.5. Clinical Laboratory Licenses and Certifications

SHC licenses and CLIA certification are available from the hospital website or via request form available on websites in the School of Medicine.

1.6. Resources

- E6(R2) Good Clinical Practice: Integrated Addendum (FDA website)
- 21 CFR 312 Investigational New Drug Application (FDA website)
- Spectrum, Stanford Center for Clinical & Translational Research & Education
- Stanford Health Care, Pathology & Laboratory Medicine (www.stanfordlab.com)