DEPARTMENT OF PATHOLOGY & LABORATORY MEDICINE

CLINICAL STUDY PREPARATION CHECK LIST

SPONSORED PROGRAMS / HEALTH SYSTEM CONTRACTS
(http://research.ucdavis.edu/resources/forms/)

- Clinical trials typically go to Health Systems Contracts while all other studies go through main campus Sponsored Programs.
- Forms needed as part of the submission packet: (a) School of Medicine Transmittal Form, (b) Sponsored Programs Datasheet, (c) Itemized Budget, (d) Study Protocol (e.g., sponsor provided and/or IRB protocol), (e) Form 700U (all studies), and (f) Form 800 (NIH funded studies, studies involving human subjects).
- Submission packet first requires review by the submitting Department for Chair signature, followed by School of Medicine Dean's Office signature.

INSTITUTIONAL REVIEW BOARD
(http://research.ucdavis.edu/resources/forms/)

- Complete HRP-226 Administrative Approvals Form (Chair Signature Required)
- Complete HRP-503 Protocol Form.
- Complete HRP-502 Consent Form if applicable.
- Complete HIPAA form if applicable.
- Ensure all researchers have completed current CITI human subjects training.
- Submit packet to IRBNet.

PATHOLOGY AND LABORATORY MEDICINE
(http://www.ucdmc.ucdavis.edu/pathology/research/)

- Contact Pathology Clinical / Quality Research Team
- Complete CQR-001 form along with other documentation (e.g., study protocol, IRB, etc) if applicable and submit to Pathology for review.
- Following Pathology Clinical Research Oversight Committee approval, contact Client Services to ensure proper billing services are established.
- Studies involving research specimen testing will be required to submit a list of subject identification numbers to produce barcode labels. A bulk account and IRB approved protocol is required prior to obtaining the study stickers.

Version 1.0