KAISER PERMANENTE

Institute for Health Research - Clinical Trials Program
2550 S. Parker Road, Suite 200
Aurora, CO. 80014

Regulatory Required Document Checklist

- ✓ Form FDA 1572 (electronic template)
- ✓ Protocol
- ✓ Protocol Acceptance Form
- ✓ Financial Disclosure Forms (electronic template)
- ✓ Informed Consent Form (for use with our Local IRB)
- ✓ Investigator's Brochure
- ✓ Investigator's Brochure Signature Page
- ✓ All participant materials that need IRB Approval

Our Regulatory office can provide the following information **upon request:

1. CVs and Evidence of Qualifications (Medical Licenses) of Principal Investigator and all Sub-Investigators listed on the 1572 Form
    a. All CVs will be signed and dated within the preceding 24 months
    b. All CVs will reflect current title/role and document affiliation to institution where the research is being conducted
    c. Evidence of CITI GCP training for PI/Sub-I's
2. CVs and Evidence of Qualifications of Clinical Trials Staff listed on Site Delegation Logs
    a. All CVs will be signed and dated within the preceding 24 months
    b. Evidence of CITI GCP training as well as IATA Hazardous Shipping training documents
3. Site Contact Information
4. Laboratory Certification(s) and Reference Ranges for all labs listed on the Form FDA 1572
    a. CAPs and CLIAs
5. Informed Consent, HIPAA Authorizations, and Patient Bill of Rights that will include required Kaiser legal language
    a. Sponsor review required prior to Local IRB submission
    b. Once Local IRB Approved, an ICF and HIPAAs that will include IRB Approval Date
6. Local IRB Approval Letter
    a. Will be on institutional letterhead/IRB approval form
    b. Will clearly state all documents and their version reviewed/approved by IRB
    c. Will clearly state period of approval

    d. Will be signed by IRB chair or designee
7. Note to File with regard to Current IRB Membership Listing
8. Federal Wide Assurance Documentation for KPCO Local IRB
9. Delegation of Authority Logs
10. Documentation of Amendment or Site Initiation Visit Trainings
11. SOPs specific to Kaiser Permanente Colorado

Thank you for working with Kaiser Permanente Colorado Clinical Trials Regulatory Program. If the Sponsor has any questions or needs clarification about any of the aforementioned documents, please feel free to reach out to the Senior Manager of Clinical Trials, Kristi Bronkan.

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