



## Site Selection Checklist

While the specific requirements will vary by protocol, the following categories list criteria that sponsors may use in considering a site or investigator for placement of a clinical trial. Be prepared to provide documentation on site questionnaires or

discuss the following areas at site-selection visits (RED  denotes answers or suggested responses):

### **PI should be qualified by education, training, and experience- *Demonstrate ability, credentials, reputation & research experience***

- License, board certifications, specialization, signed CVs, Human Subject Training Certification
- Clinical trial experience – # studies each phase and therapeutic area?
- History statistics to illustrate site track record – % of contracted subjects recruited; # subjects screened, #enrolled, # evaluable subjects?
- Study Sponsor or FDA audit outcomes?  provide comment on any corrective improvements
- Related publications?
- Percent effort dedicated to clinical research?
- Interest and familiarity with protocol/condition/test product? *If you read the protocol, you will likely have at least one question or comment.*

### **Potential subject population – *utilize KMSF to assess potential subject population*** ***Don't inflate numbers or over-promise***

- # subjects with indication under study?
- Estimated # subjects potentially meeting inclusion/exclusion criteria?
- Internal data base of potential subjects
- Typical recruitment methods and anticipated strategies
- Any competing studies?

### **Adequate staff & resources – *provide CVs, business cards, organizational chart***

- Number of dedicated vs. part time research staff
- Number of certified clinical research coordinators
- Back-up coverage for coordinators
- Experience with therapeutic area or required professional licensure

**Availability of appropriate facilities & equipment – ↩ (UKCRO has research facilities if needed – see PROFILE of UKCMC)**

- Hours of business operation
- Exam rooms for subject evaluation and treatment
- Clinical facilities and patient care and waiting areas
- Administrative facilities & office equipment (secure fax, computer ports for data entry, internet access, etc)
- Ancillary services
- 12-lead EKG
- Calibrated equipment with documentation logs (freezers, scales)
- Emergency equipment
- Local lab services and certifications
- Blood processing availability – dry ice, centrifuge, individual with Department of Transportation (DOT) Certification for shipping
- Area for monitor visits
- Secure supply storage area
- [Investigational Drug Service](#) available for dispensing and storage of investigational products (see below)
- Adequate document storage and Long term archiving facilities

**IRB services & turn around – ↩ provide [list IRB membership, meeting dates](#), copy of assurance with DHHS, IRB template of consent form**

- Local or central IRB? - ↩ UK must use local IRB
- How often does the IRB meet? ↩ UK IRB meets 6 times per month
- Is there a deadline for proposal submission? ↩ No deadline, protocols are assigned a meeting time upon submission.
- What is the average turn around time on approval? ↩ Varies, avg. 3 weeks to a month.
- Reading level requirement? ↩ 6<sup>th</sup> grade for UK IRB
- Does PI serve on the IRB? ↩ May serve but can not vote on their own protocols.
- IRB compliance with ICH GCP requirements? (Statement of Compliance available from ORI)
- Other review committees? ↩ scientific committees may apply for some research conducted in specific facilities-i.e. Markey Cancer Center [CCART](#), [VA Research](#), [GCRC](#)
- Additional IRB requirements? ↩ ([Human Subject Protection Training](#))
- Does the IRB charge a review fee? ↩ An administrative fee may be charged to the sponsor for time spent on IRB, fiscal and regulatory submissions, however the UK IRB does not currently charge for their services.

**Budget development and contract negotiations**

- Provide contact information for budget preparer and standard administrative charges and overhead percentage.
- Does institution have a master agreement with sponsor? ↩ check with clinical trial administrator to see if master language has been established.
- Provide contact for [clinical trial administrator](#) who will negotiate terms of the contract (↩ provide template contract upon request).

**Good Clinical Practice knowledge & compliance – ⇨ document any formal GCP training**

- Disclosure of any conflict of interest?
- Awareness of investigator responsibilities?
- Internal quality assurance checklists or reports? (⇨ ORI can provide a QA assessment form upon request)
- Site standard operating procedures? (⇨ UKCRO can provide sample SOPs upon request)
- Sample standardized documents (⇨ set up dummy source book)
- Training logs and certifications for ALL staff members

**Responsiveness of site and rapidness of study initiation**

- Availability – how soon are calls returned, questionnaires returned?
- Benchmark turn around on submission of regulatory document package
- Benchmark study initiation time
- Availability for monitoring visits
- Attendance at investigator meeting or conference calls

**Investigational pharmacy**

- Where will an investigational product be stored, dispensed, etc.?
- Does the drug require pharmacist involvement? ⇨ (If inpatient study must use the Investigational Drug Service per UK Hospital Policy 01-32)
- Who will maintain accountability records?
- Experience with voice response phone randomization and assignment
- Security of product
- Proper storage
- Any dispensing SOPs to ensure accuracy or prevent errors

**Geographically suited with best demographics**

- Demographic profile of region? ⇨ Much of the regional area is rural and consists of stable, non-transient people, with a high incidence of major chronic diseases. Use the following resources to answer questions regarding population demographics:
  - [Lexington Community Profile](#)
  - [Kentucky QuickFacts](#)
  - [Kentucky Information Page](#)
  - [Profile of General Demographic Characteristics - 2000](#)
  - [About UK](#)
  - [Kentucky Regional Demographics](#)
- Monitoring visit convenience – (⇨ UK is minutes from [Bluegrass airport](#); provide sponsor representatives with [Directions](#), [Hotel](#) and [Travel](#) Information & [Campus Guide](#))