

CRA TRAINING

BASIC II

# SITE SELECTION

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PRE-STUDY SITE VISIT (PSSV)

DAN SFERA

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## PROTOCOL

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- Discuss protocol
- Discuss study objectives, study design and procedures
- Investigators Brochure
- Study endpoints
- Inclusion and Exclusion criteria
- Subject visit schedules
- Laboratory requirements
- Serious Adverse events and non- serious adverse events definitions
- Discontinuation procedures

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## QUALIFICATIONS

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- Review Adequacy of the site
- Evaluate training and experience of PI and site staff
- Determine if they have the right access to the patient population
- Evaluate the sites interest in the study
- Determine how many other studies they are participating in

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## QUALIFICATIONS CONT.

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- How does the investigator delegate responsibilities and provide oversight
- Ensure each study team member has a back up
- Does the site have adequate time to conduct the study
- Has site been audited by the FDA
- Discuss ICH and GCP guidelines
- Determine if contract and budget has been negotiated (usually already complete by PSSV)

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## SUBJECT RECRUITMENT

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- How does the site plan to identify and assess potential study subjects
- Can they meet recruitment expectations for the study
- Discuss any barriers to enrollment
- Discuss recruitment methods and strategies
- How many subjects they expect to be screened

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## INFORMED CONSENT FORM

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- Discuss if they uses local IRB or central IRB
- Ask the site to describe their Informed Consent Process or provide a standard operating procedure
- Ask if site plans to recruit subjects from a vulnerable population (low Socioeconomic status, incarcerated population, homeless etc.)
- Discuss language of ICF (English, Spanish, etc.)

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## CRF (EDC) AND SOURCE

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- Discuss if the original source documents will be available during the monitoring visits
- Determine whether or not site uses paper or electronic source

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## SITE EQUIPMENT

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- Ask site to facilitate you on a tour of their site
- Review the following:
  - ✓ Type of site (public hospital, dedicated research center or combined)
  - ✓ Days/Hours of operation and emergency after hours procedures
  - ✓ Take notes on waiting room
  - ✓ Note the number of exam rooms and be sure to describe in report
  - ✓ Be able to describe laboratory area
  - ✓ Equipment: Centrifuge, EKG machine, Height and Weight Scale, Blood Pressure Cuffs, -20 or -70 freezer and access to dry ice (note calibration date and company)

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## SITE EQUIPMENT CONT.

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- Ask site to describe plan for receipt, storage, dispensing and return or destruction of study drug – must be double locked and limited access (in most cases)
- Review the space for non- IP study supplies (lab kits, regulatory binder)
- Ask site to show you monitoring area (might be a room, exam room or bathroom)

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## END OF PSV

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- Write up report with visit details
- Make a recommendation – discuss reasons why site is a good choice for the study or why the site should not be selected for the study

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**CRA Training:**

- ☐ **Basic I: GCP for Site Monitors**
- ☐ **Basic II: Site Selection**
- ☐ **Basic III: Site Initiation**
- ☐ **Basic IV: Site Monitoring**
- ☐ **Basic V: Site Close-out**
- ☐ **Advanced: I: Source Documents**
- ☐ **Advanced II: Site Regulatory**
- ☐ **Advanced III: Protocol Deviations, IP Accountability, Miscellaneous**

*THANK YOU*

