ASPIRE Off-Site Visits

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Rationale

- *Why make an allowance for off-site visits in the protocol?*

Extended Clinic Hours

Improving Clinic Flow

Counseling

Off-site visits

Tracking Tools

Outreach

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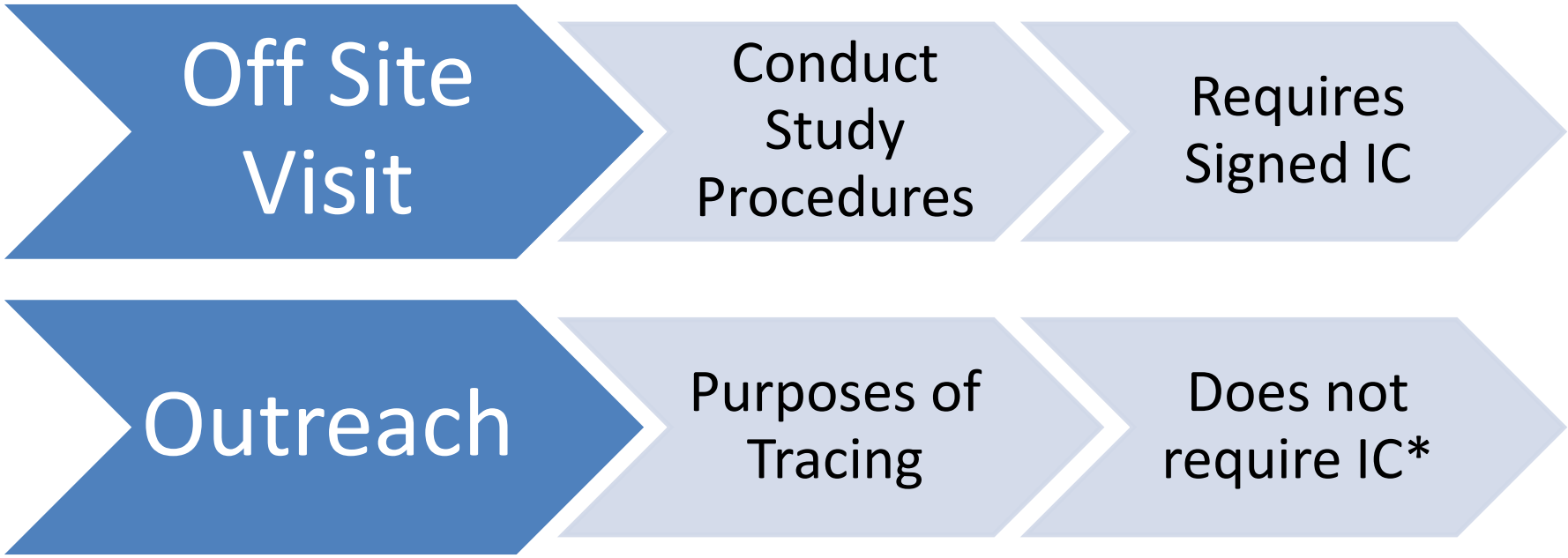
Off-Site Visit vs. Outreach



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When to Utilize?

- Generally expected that scheduled study visits will be conducted at the study clinic
- Off-site visits are a tool to be used when needed, should not be the standard
- IoR/designee discretion

What situations do you think would warrant?

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Permitted Locations & Visit Types

- Participant Home or other venues
  - Participant and staff both comfortable
  - Safety and confidentiality can be maintained

- All follow-up Visit Types
  - Monthly, Quarterly, Semi-Annual, PUEV/Term
  - Interim Visits

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Study Procedures

- Visit procedures should remain largely the same as they would for an in-clinic visit
- Some procedures may need to be modified or omitted due to limited capacity to conduct them off-site
  - ACASI
  - Physical/Pelvic Exams
- Missed procedures made up same as in-clinic

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Minimum Procedures for VR dispensation:

- **AE assessment and reporting** (verbal report of symptoms is acceptable; if symptoms indicate that further evaluation is necessary, this must be conducted prior to dispensing study product)
- **HIV testing and counseling** (including RR counseling) and **pregnancy testing** are required for product dispensation if this has not been done at the research clinic within the past 60 days (i.e. within last 2 scheduled visits)
- Collection of Used Ring (and unused, if applicable), if available
- Adherence Counseling/Product Use Instructions, as needed

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General Considerations

- Verifying Consent
- Safety/Confidentiality
- Staffing
- Managing symptoms/conditions requiring medical attention
- Materials/Supplies Required

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Lab Considerations

- Chain of custody for specimen transport
- Specimen handling/transport
- Safety (biological specimens, bio-waste)
- Testing timeframes
- Equipment and supplies
- Staffing
- Source Documentation

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Study Product Considerations

- Requests for VR in advance
- Chain of custody
- Transport conditions/temperature
- Procedures in the event study product is not delivered
- Collection and transport of used/unused VR
- Documentation

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Source Documentation Considerations

- No *completed* CRFs or other source documents should leave clinic
- Blank CRFs and staff notes summarizing source documents may be taken

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Preparing for an Off-Site Visit

Scenario

One week after her M4 visit, a participant's VR came out accidentally and fell into the toilet. It is still 3 weeks until her next scheduled visit. The IoR/designee decides to deliver a new VR as part of an interim visit in order to ensure ring coverage until her next scheduled study visit.

- What do you need to check/review before going?
- What materials do you need?
- Who is going?
- Where will the visit be?
- What are the minimum procedures required to dispense study product? How will these procedures be accomplished off-site?