

TOOL 1.5.2.1

Site Activation Checklist

INSTITUTIONAL LOGO	Site Activation Checklist
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Survey Number and Title: *enter text*

Protocol Version: *enter text*

Sponsor: *enter text*

No.	Item	Description of item to be checked	Confirmed as available / completed
1.	Institutional Review Board (IRB)/Independent Ethics Committee (IEC) approval (specify country)	IRB/IEC approval of the following: • protocol • Informed Consent Form(s) • any other written information to be provided to patient subjects • advertisement for participant recruitment (if used) • participant compensation (if any) • any other documents given approval • Case Report Form (if applicable)	☐
		IRB/IEC composition/membership list	☐
2.	Signed contracts	Signed Agreement, between involved parties	☐
3.	Confidentiality agreements (comment if part of contract)	Signed confidentiality agreements on site	☐
4.	Investigator Curriculum Vitae	CV and/or other relevant documents evidencing qualifications	☐
5.	Protocol	Current approved version of protocol on site and available to survey team	☐
6.	Participant Information Sheet & Consent Form	Approved IRB/IEC version of Participant Information Sheet & Consent Form on site	☐
7.	Medical/laboratory/technical procedures/tests	Medical/laboratory/technical procedures/tests to be performed locally (if applicable): • certification or • accreditation or • established quality control and/or external quality assessment or • other validation (where required)	☐
		Maintenance and calibration contracts available or quality checks defined (if not available)	☐
8.	Monitoring Plan	Monitoring plan available	☐

9.	Quality Plan	Quality Plan available	☐
10.	Risk Management Plan	Risk Assessment Complete/ Risk Management Plan available	☐
11.	Medical care for TB and ancillary issues identified through the survey. Other alternatives for medical care and follow-up.	Site initiation visit performed	☐
		Action items from site initiation visit required for site activation completed	☐
		Adequate number of staff and trained on survey procedures	☐
		Facilities deemed acceptable for survey conduct	☐
12.		All required supplies (e.g. sputum collection containers, X-ray films and lab supplies, etc.) are available	
13.	Data capture systems readiness	Database including edit checks complete including testing, eCRF and validation	☐
		Data Management Plan available	☐
		eCRF approved	☐
		eCRF accounts ready to activate	☐
14.	Document Storage	Secured place for document storage identified	☐
15.	Survey Forms and Logs	Including: <i>[provide specific list for survey]</i> Delegation Log, Participant Screening and Enrolment log, Sample inventory form, etc	☐

Comments:

No.	Comment as needed on any sections above

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Action Items:

I confirm that all items listed above for Site Activation are available/in place and allows site to begin survey enrolment.

Survey Manager (or Designee)

Check performed by: _____

Name (Printed)	Survey Role
_____	_____
Signature	Date (DD/MMM/YYYY)