

## **Appendix J. TN07 Oral Insulin Training Materials Reference Tool**

<u>Purpose</u>: This document outlines the available trainings and/or procedural documents for the TN07 Oral Insulin Study. All of the documents referenced are available on the TrialNet TN07 Oral Insulin Protocol Page.

Name	Location	
Review TN07 Protocol	TN07 – Working Documents Portlet → Current IRB	
	Documents → Protocol	
Review Protocol Certification Quiz (To	TN07 – Working Documents Portlet → Current Tools →	
obtain Key, please contact your Clinical	Training Documents Folder -> Certification Quizzes Folder	
Center Coordinator or the TNCC)		
Review Volunteer Understanding	TN07 – Working Documents Portlet → Current IRB	
Assessment (and Key)	Documents → Volunteer Quiz	
Review Manual of Operations	TN07 – Working Documents Portlet→Current Manuals →	
	Manual of Operations	
<b>Review Pharmacy Manual of Operations</b>	TN07 – Working Documents Portlet→Current Manuals →	
	Pharmacy Manual	
Review Pharmacy Procedures Quiz (To	TN07 – Working Documents Portlet → Current Tools →	
obtain Key, please contact your Clinical	Training Documents Folder → Certification Quizzes Folder	
Center Coordinator or the TNCC)		
Review Pharmacy Procedures	TN07 – Working Documents Portlet → Current Tools →	
Presentation	Training Documents Folder	
Review Eligibility Overview Presentation	TN07 – Working Documents Portlet → Current Tools →	
	Training Documents Folder	
Review Progression from TN01 to TN07	TN07 – Working Documents Portlet → Current Tools →	
Presentation	Training Documents Folder	
Review IVGTT Training	TN07 – Working Documents Portlet → Current Tools →	
Daview N/CTT Due and ware Ovi- /T-	Training Documents Folder	
Review IVGTT Procedures Quiz (To	TN07 – Working Documents Portlet → Current Tools →	
obtain Key, please contact your Clinical	Training Documents Folder → Certification Quizzes Folder	
Center Coordinator or the TNCC)	TNICZ Warking Decuments Deutlet & Comment Teels	
Review Navigating to and Interpreting the List of Potential Participants Report	TN07 – Working Documents Portlet → Current Tools → Training Documents Folder	
Review TN07 Study FAQs and Participant	TN07 – Frequently Asked Questions Portlet	
FAQs	11107 – Frequently Asked Questions Fortiet	
Review TrialNet Clinical Assessments	TN07 – Working Documents → Current Tools → Assessment	
Training	Tools	
Review - Pill Compliance Calendars and	TN07 – Working Documents Portlet → Current Tools →	
Participant Medication Instructions	Assessment Tools	
Access and Download Assessment Tools	TN07 – Working Documents → Current Tools → Assessment	
for Visit Procedures	Tools	
Access and Download Assessment Tools	TN07 – Working Documents → Current Tools → Assessment	
for Visit Procedures	Tools	
Access and Download Visit Checklists	TN07 – Working Documents → Current Tools → Visit	
	Checklists	



## TN07 Oral Insulin Study Manual of Operations

Review TrialNet Clinical Assessments	TN07 – Working Documents → Current Tools → Assessment	
Training	Tools	
Access and Download Pharmacy Forms	TN07 – Working Documents → Current Tools → Forms →	
	Pharmacy Forms	
Review Laboratory Manual of	TN07 – Working Documents Portlet→Current Manuals →	
Operations	Lab Manual	
<b>Review Ways to Increase Pill Compliance</b>	TN07 – Working Documents Portlet → Current Tools →	
	Training Documents Folder	
Review Ways to Increase Participant	TN07 – Working Documents Portlet → Current Tools →	
Retention	Training Documents Folder	
<b>Review Harmonized Assay Adoption</b>	TN07 – Working Documents Portlet → Current Tools →	
Overview	Training Documents Folder	
<b>Review Harmonized Assay Adoption and</b>	TN07 – (B) Documents for Training & Guidance → 05.	
Oral Insulin BAA Eligibility	Protocol Training	
<b>Review TrialNet Specimen Management</b>	TN07 – Working Documents Portlet→Current Manuals →	
System (SMS) User Manual	Lab Manual → SMS User Manual	

## **Media Center Trainings**

It is recommended that your site review the following trainings on the TrialNet Media Center.

Subject Title	Material Title	Suggested Audience
TrialNet Training- Protocol	TN07 TrialNet Eligibility	All Site Members involved in the
Training TN07 Oral Insulin Study	Overview	TN07 Oral Insulin Study
TrialNet Training- Protocol	TN07 IVGTT Training	Site Coordinator; All Site members
Training TN07 Oral Insulin Study		who may conduct or assist with
		IVGTT procedures
TrialNet Training- Protocol	TN07 Abdominal Circumference	Site Coordinator; All Site members
Training TN07 Oral Insulin Study	Training	who may conduct or assist with a
		physical exam or collecting the
		abdominal circumference
TrialNet Training- Protocol	TN07 Pharmacy Procedures	Site Coordinator; Pharmacist; All
Training TN07 Oral Insulin Study		site members working on the TN07
		Oral Insulin Study that may handle
		study drug (including receiving,
		dispensing, returning, etc).
TrialNet Training- General	General- Adverse Event	Site members who will need to
Members Website	Reporting	report or review protocol AEs
TrialNet Training- General	General- Members Directory	All Site Members
Members Website	Overview	
TrialNet Training- General	General- Members Website	All Site Members
Members Website	Overview	
TrialNet Training – Harmonized	Harmonized Assay Adoption	Site PI; Site Coordinator; Site staff
Assay Adoption	Overview/NHS/OI studies	that will be reviewing participant
		results/eligibility

Note: Please contact your protocol CRA if you have any additional questions about the recommended training for your site staff.