

# **Visit Procedures & Form Completion**

**MTN 005**

**Study-Specific Training**

# Where are these procedures described?

- ✓ Protocol Table 4 (Screening)
- ✓ Protocol Table 5 (Enrollment)
- ✓ Protocol Table 6 (Follow-up Visits)
- ✓ Protocol Table 7 (16-Week/Study Termination Visits)
- ✓ SSP Section 7 (Checklists)
- ✓ Appendix I of the protocol

# Visit Checklists

- ✓ Each site should develop visit checklists for each study visit
- ✓ Examples are provided in SSP Section 7
- ✓ Checklists may vary by cohort (IVR vs. no-IVR)
- ✓ Checklists should be designed so that procedures are listed in logical order according to visit flow

# Order of Presentation

- Per visit, we will cover:
  - ✓ Visit procedures
  - ✓ Form completion
  - ✓ Relevant checklists and exam details

# Screening Procedures



# Complete Physical Exam



# What Must Be Included?

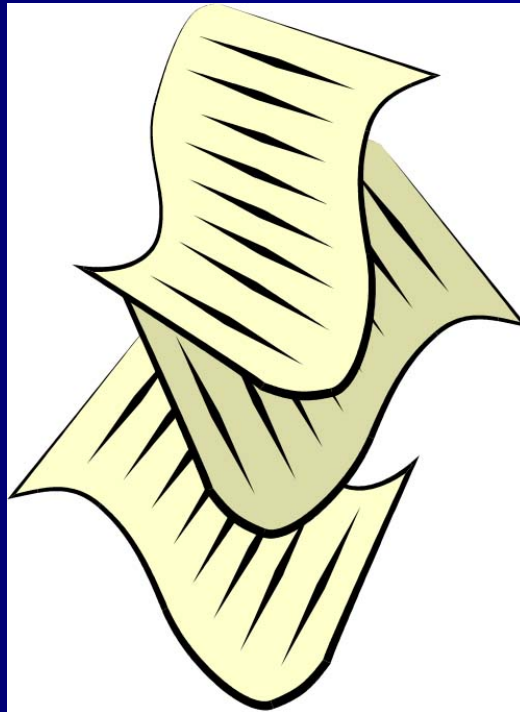
- See Appendix III of the protocol
  - Height (may be omitted after the Enrollment Visit)
  - Weight (may be omitted after the Enrollment Visit)
  - Vital signs
    - Temperature
    - Pulse
    - Blood pressure
  - General appearance
  - Abdomen
  - Other components as indicated by participant symptoms

# Eligibility Checklist





# Screening Forms



# Questions?



# Enrollment Procedures



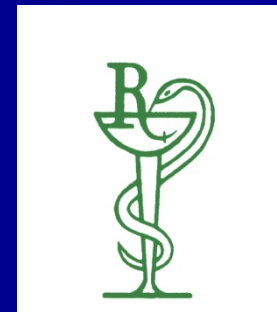
# Enrollment Forms



# Questions?



# Randomization



**Pharmacy**

# Follow-Up Visits

An appointment reminder card with a white background and blue accents. At the top left is a black stethoscope icon. To its right, the text "YOUR NEXT APPOINTMENT" is written in blue, bold, sans-serif font. Below the stethoscope, the text "Has An Appointment" is written in a black, bold, sans-serif font. Underneath this, there are checkboxes for the days of the week:  Mon,  Tues,  Wed,  Thurs,  Fri, and  Sat. At the bottom, there are two lines for "Date:" and "Time:". To the right of the card is a red, 3D-rendered first aid kit with a white cross on its lid.

# Follow-Up Visit Forms





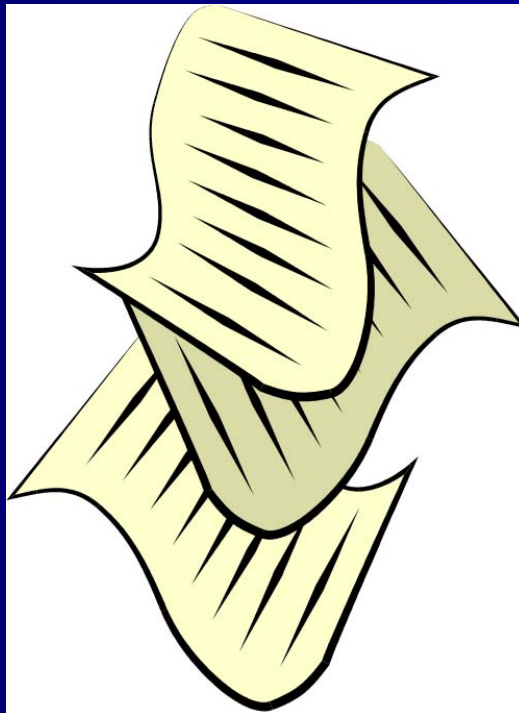
# Questions?



# Termination / 16-Week Visit



# Termination / 16-Week Visit Forms



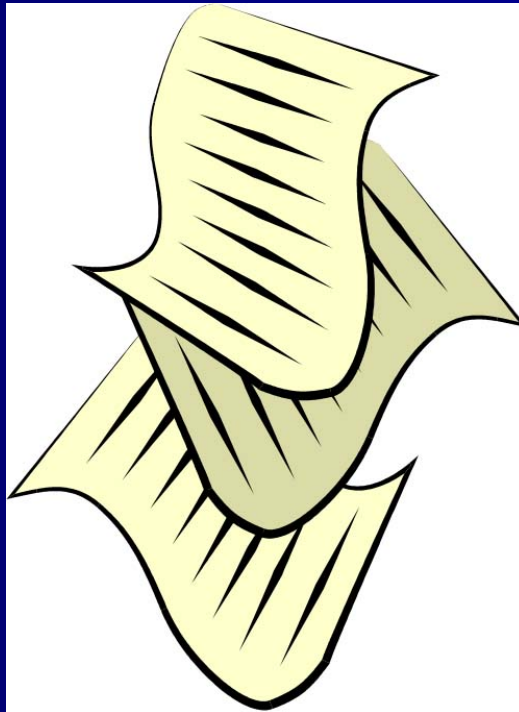
# Questions?



# Interim Visit



# Interim Visit Forms



# Questions?

