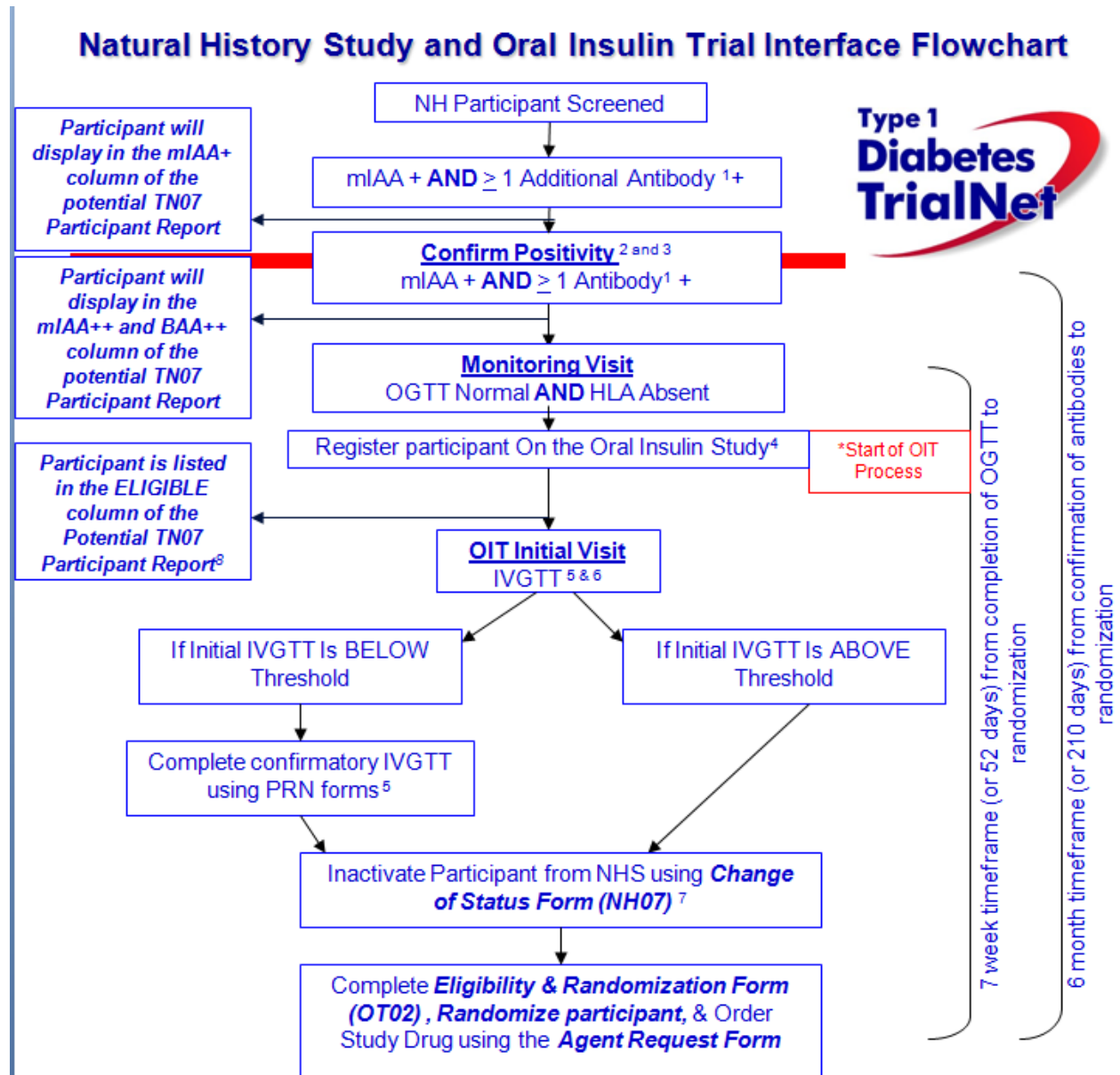


## Appendix A. Progression from TN01 to TN07



- 1 Additional Antibodies = ICA, ICA512 or GAD65
- 2 Confirmation can take place in the Natural History/Pathway to Prevention Study.
- 3 Participant doesn't have to confirm positive for the same autoantibody as long as the participant is still positive for at least one additional autoantibody, besides mIAA. If participant is negative on first confirmation, then a tiebreaker test can be performed at an Interim Visit using PRN Natural History/Pathway to Prevention Forms
- 4 When registering a participant on the Oral Insulin Study, the site should enter the same local ID the participant has from the Natural History/Pathway to Prevention Study or if the Oral Insulin site is a different site than the Natural History/Pathway to Prevention site, a new local ID should be created and entered by the site.
- 5 Repeat IVGTT if below threshold. If the IVGTT has to be repeated, the participant can be randomized the same day as the repeat IVGTT is performed.
- 6 Results of the initial IVGTT must be received BEFORE a participant can be randomized. If the results of the IVGTT don't come back from the lab within the 7 week timeframe for the OGTT then the issue will go to the Eligibility Committee for review. The OGTT may have to be repeated to start the 7 week clock again.
- 7 Date on Change of Status Form (NH07) should be the same as the randomization date
- 8 Participant is listed on the TN01 Potential TN07 Participant Report as ELIGIBLE