

# A Comprehensive Clinical, Microbiological and Immunological Assessment of Patients With Suspected Post Treatment Lyme Disease Syndrome and Selected Control Populations

NCT00001539

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<b>Status</b>	RECRUITING
<b>Sponsor</b>	National Institute of Allergy and Infectious Diseases (NIAID)
<b>Enrollment</b>	700 participants

## Key Eligibility Criteria

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### Inclusion (17)

- SCREENING FOR SUSPECTED PTLDS
  - Age  $\geq$  13 years old, suspect of suffering from Lyme disease
  - POST-TREATMENT LYME DISEASE SYNDROME (PTLDS)
  - For the purposes of this study, PTLDS is defined as (1) occurring in male or female patients aged 13 and above (2) who have been diagnosed with confirmed or probable Lyme disease per CDC definition (<https://wwwn.cdc.gov/nndss/conditions/lyme-disease/case-definition/2017/>). Study physician will review history to confirm probable cases. (3) They have received recommended antibiotic therapy (4) and have persistent or relapsing symptoms and/or signs for at least six months after therapy [4, 5]. (5) They also should have no other documented explanation for their signs and symptoms.
  - LYME ARTHRITIS CONTROLS
- ... and 12 more (see full listing online)

### Exclusion (27)

- Age less than 18 (less than 13 for patients with PTLDS)
  - Weight less than 70 Lb. (35 kg)
  - Pregnancy or lactation
  - Women with childbearing potential who are sexually active with a male partner and unwilling to use effective contraception during the evaluation and treatment phases of the protocol.
  - Clinically significant laboratory abnormalities including positive test for syphilis (RPR), HBsAg, anti-HCV, anti-HIV.
- ... and 22 more (see full listing online)

## Locations (1 total)

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National Institutes of Health Clinical Center, Bethesda, Maryland, United States