# Metabolic Pathology of Pediatric NAFLD

NCT05430178

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| **Status** | RECRUITING |
| **Phase** | Not Applicable |
| **Sponsor** | University of Oklahoma |
| **Enrollment** | 100 participants |

## Key Eligibility Criteria

### Inclusion (5)

- Age: All participants must be 10.0 to 20.9 years old at the time of enrollment.
- Sex: Male and Female participants are eligible.
- Race/Ethnicity: Participants of all racial/ethnic identities will be recruited.
- Body mass index (BMI): Participants must be either in the normal weight (NW control group) or obese \[Ob control, nonalcoholic fatty liver disease (NALFD) groups\] range for BMI percentile. BMI percentile will be calculated from age- and sex-specific growth charts for children.
- NAFLD status: The NAFLD group participants will be eligible if they are scheduled for liver biopsy for clinical reasons and their histopathology report confirms a diagnosis of NAFLD. NW control, and Ob control, and Liver control participants must not have diagnosed NAFLD.

### Exclusion (5)

- Chronic illness: Participants will not be able to participate if they have conditions that are likely to affect metabolic variables (either directly or due to required medications) or result in them being unable to complete the required tests. Such conditions could include, but are not limited to, untreated hypothyroidism or other endocrine disorders, rheumatoid arthritis requiring steroids or limiting mobility, cardiovascular disease, stroke, or cardiac failure, neurological disorders such as multiple sclerosis, cancer, liver diseases other than NAFLD (e.g., Wilson's disease), other organ disorders, or orthopedic conditions that limit physical activity.
- Acute illness: Participants will not be able to participate if they develop acute conditions that are likely to affect metabolic outcomes (either directly or due to required medications) or result in them being unable to participate; e.g., respiratory illness, infectious disease, fever, accident resulting in bone fractures, myocardial infarction, major depression. If such conditions resolve and there are no longer risks or likelihood of adverse effect on the study outcomes, participants may be rescheduled for testing.
- Medications and nutritional supplements: Medications, vitamins, or supplements that have known effects on the primary outcomes will be cause for exclusion. Examples include weight loss medications, glucocorticoids, or experimental medications used to correct a metabolic or hepatic condition. Medications used to control asthma, allergies, anxiety, depression, attention deficit disorder, menstrual cycle, hypothyroidism, gastric reflux, hypertension, and sleep will be allowed. Participants who are taking medications for treatment of acute illness or conditions such as cold, flu, injury, or infection will be rescheduled after they complete their treatment course.
- Pregnancy: Evidence of pregnancy or intent to become pregnant during the study is cause for exclusion.
- Smoking, alcohol abuse, or illicit drug abuse: Participants who smoke or have signs or symptoms of alcohol or substance abuse will be excluded.

## Locations (1 total)

University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, United States