

NINDS CDE Project
Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)
Immune Subgroup

In drafting the ME/CFS Immune recommendations, the group consisted of clinicians and researchers with deep experience in treating and/or studying this disease as well as group members who had relatives with ME/CFS. The subgroup supplemented published literature with patient reports of the immune manifestations they experienced to factor in the experiences of people with ME/CFS in making recommendations.

The biggest concern the Subgroup faced was with the demand that responding to lengthy questionnaires places on patients. Fortunately, these questionnaires are largely administered at baseline and will not have to be re-administered repeatedly. However, given the total volume of baseline questionnaires across all illness domains, it will be important to rationalize the questionnaires across domains. It will also be important for studies to find ways to spread out the demand on patients, for instance, by allowing patients to fill these in at home.

Below is an overview table of the recommended case report forms (CRFs) by the Immune Subgroup:

CRF Name	Classification (e.g., Core, Supplemental - Highly Recommended, Supplemental, Exploratory)
Medical History – Immune Module	Core: Immune system onset type Supplemental – Highly Recommended: Rome IBS criteria Exploratory
Physical Examination	Supplemental – Highly Recommended
Laboratory Tests – Immune Module	Supplemental – Highly Recommended: NK cell assay Supplemental
Exposure History	Exploratory