CONSENT FORM (version 3 24/09/04)

Title of project: Randomised controlled trial of a nurse-led self help treatment, versus supportive listening, versus treatment as usual for patients in primary care with Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME) – the FINE trial.

Please initial box

1. I confirm that I have read and understand the information sheet dated……………………(version………) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, without my medical care or legal rights being affected.

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from the Universities of Manchester, Liverpool or York, or from regulatory authorities, where it is relevant to my taking part in research. I give permission for these individuals to have access to my notes.

4. I understand that information obtained from me during treatment will not be discussed with my GP, but agree to the exchange of information between the researchers and my GP, should this become necessary.

5. I understand that data collected on me, including data on audiotape, will be handled, stored and destroyed in accordance with the Data Protection Act, 1998.
6. I understand that data collected may be stored in coded form for up to 20 years after my completion of or withdrawal from the study, after which time the data will be destroyed.

7. I agree to take part in the above study.

_______________________    ___________________    ___________________
Name of patient                  Date                      Signature

_______________________    ___________________    ___________________
Name of person taking consent   Date                      Signature

_______________________    ___________________    ___________________
Name of researcher              Date                      Signature

Permission to audio-tape therapy sessions Please initial one of these boxes

I give my permission for therapy sessions to be recorded and transcribed

I DO NOT give my permission for therapy sessions to be recorded and transcribed

_______________________    ___________________    ___________________
Name of patient                  Date                      Signature

_______________________    ___________________    ___________________
Name of person taking consent   Date                      Signature

_______________________    ___________________    ___________________
Name of researcher              Date                      Signature

NB Patients who do NOT give permission to for therapy sessions to be taped may still enter the trial.