Clinical Trials Protocol

To ensure your safety and get meaningful results, the clinical trial must follow strict rules described in the research plan. This is called the clinical trials protocol.

The protocol is the research plan of action, like a recipe or instruction manual. It describes the "who, what, when, where, why and how" of taking part in a clinical trial. All of the information contained in the protocol is summarized in the informed consent form, so patients are not given a copy of the protocol.

It contains all the information required to do the trial, such as:

- Why the research is being done
- The purpose and goal of the clinical trial
- The scientific background information, including information on pre-clinical and early phase clinical trials
- The Principal Investigator
- The Sponsor
- The eligibility criteria, which determines if you are able to take part.
    - Each clinical trial protocol has a strict list of eligibility criteria to ensure patient safety
- The total number of patients needed to take part
- Treatment information, such as the name of the trial drug or treatment, the dose, how it is given and how often, and storage information
- Possible side effects, risks, and benefits of the new treatment
- What to do if there are side effects
- The frequency of your visits and all of the procedures that will be done at each visit
- How long the clinical trial is expected to last
- What information will be collected about you and how it will be used
- How to determine if the treatment is working or not working
- Your rights, including the right to stop participating in the trial at any time for any reason
- How long records need to be stored