Study Subject Information (i.e. patient information) should cover the following:

1. Header (e.g. study subject information and informed consent) addressed to the prospective research subject
2. Brief title of the research project; concise and clear (may include a subtitle with more detailed name)
3. Invitation to participate (including short and concise description of the study)
4. Specification on voluntariness (information that participation is voluntary and can be discontinued)
5. Details of the trial organization and personnel (names of the sponsor, doctor / investigator, CRO etc.)
6. Background and purpose of the trial
7. Trial methodology and procedures (duration, visits, lab tests, examinations, medication etc.)
8. Benefits of participation (including a mention of not necessarily receiving any direct benefit etc.)
9. Risks of participation (known or presumed adverse effects or other effects)
10. Possibility for discussion and immediate contact with the doctor during the trial
11. Methods used to protect trial and health data and secure confidentiality
12. Information on costs and reimbursements (participation is free and how other costs are covered)
13. Insurance for trial subjects (including information on compensation for possible injuries)
14. Conclusion of the trial (treatment options after trial termination, information on results or not)
15. Further information (contact details of trial personnel)