

Consent Form Checklist

The following elements should be described in the consent form (check each item if present, or mark N/A if not applicable):

- _____ aims of the study
- _____ the fact that it is a research project
- _____ special research techniques to be employed, e.g. randomization
- _____ the procedure/therapy involved
- _____ alternative therapies (if a therapeutic trial)
- _____ potential benefit
- _____ potential risks (beyond minimal risk)
- _____ anticipated time duration
- _____ rules for the participant to stop their participation in the study at any time
- _____ voluntary nature of the study
- _____ statement that the participant may withdraw without prejudice
- _____ statement regarding confidentiality of records
- _____ statement of who will have access to the data
- _____ details of any financial compensation
- _____ statement that the participant may retain a copy of the consent form
- _____ the participant may consult with the investigator or Department Head at any time
- _____ use of lay language