

VAMHCS Office of Research Compliance

INFORMED CONSENT PROCESS WORKSHEET

Study: _____

Subject ID: _____

Date: _____

| Staff initials | Element explained /discussed | Subject / rep is able to restate | |
|---------------------------------------------------|---------------------------------------------------|----------------------------------|---|
| | | Y | N |
| | Background & Purpose of study | Y | N |
| | Procedures | Y | N |
| | Risks /Discomforts | Y | N |
| | Benefits | Y | N |
| | Alternatives | Y | N |
| | Costs / Compensation | Y | N |
| | Confidentiality | Y | N |
| | Right to Withdraw | Y | N |
| | Whom subject my contact for questions/emergencies | Y | N |
| | Storage of samples/genetic materials | Y | N |
| | | | |
| Person explaining the informed consent form: | | | |
| Length of time spent with subject/representative: | | | |
| Time CF signed: | | | |
| Representative's relationship to the subject: | | | |
| Copy of signed CF given to subject/rep? | | Y | N |
| Comments: | | | |
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