Moving to eConsent

Exploration basic requirements and guidelines

LEGAL CONSIDERATIONS NON-WMO RESEARCH

- No legal prerequisite for identification of participant. Only proof of consent must be recorded.
- Researcher responsible for recording process and proof of consent pursuant to GDPR
- Not possible to develop a national procedure or method. Differences between research disciplines and institutes require customization.

FORM GENERATION

- Based on building blocks, which are maintained by back-office (data management/ethical department) .
- Researcher fills out details of experiment by making predefined choices, based on building blocks of consent and adding free text. As a result aligned consent form is generated

Higher efficiency

- Changes are implemented in the building blocks and not in complete forms with various versions. Easier to update and comply with changing demands society or law/guidelines.
- Less prone to errors and more uniformity within in your institute

BUILDING BLOCKS INFORMED CONSENT

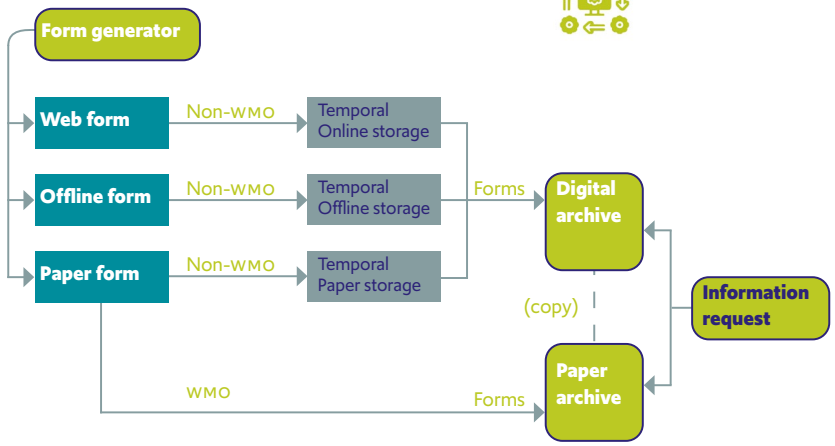
Introduction and general information (department, ethical review, insurance)
Purpose and background of the study
What participation involves
Advantages and disadvantages, including possible side-effects
Participation rights
Use and storage of your data
(NO) Compensation for participation
Contact details for questions / feedback
Signing of informed consent form

See also (CCMO)

HOW TO OFFER INFORMATION

- In bits and pieces. Participant has to scroll through each page
- Using animations
- Participant provides consent through conscious act. For example, checkmark and time stamp for general consent; actual typing for providing consent sensitive data.
- Get advice from Communication department
- Learn from other domains, e.g. develop-mental research, government, health care
- A good service would be to offer a portal (cf patient portals) presenting overviews of the information of the research to which the participant consented.

WORKFLOW



ARCHIVE

- 'Archiving by design' at the start of moving to eConsent with archive service
- Applicable storage term. Retention period is determined on a case-by-case basis (domain specific terms, importance of re-use, personal data) for more guidance see here.
- Project metadata assures cross referencing between the archived research data and the archived consent
- Ensure reliable archiving (forms cannot be changed, only authorized access)
- Destroy after end storage term by archive service
- Regular check (at least annually) on data sets

EXAMPLES ON PAPER

- UMC Utrecht
- Radboud University Nijmegen, Donders Centre for Cognition

EXAMPLES ECONSENT

- IQVIA
- Janssen
- Dariah Eldah consent form wizard
- eConsent ouders/voogden RUG