Experiences from ethics review

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My profile

- Background in law and bioethics with focus on health, genetics, data protection, research ethics
- Ethics reviewer since 2017
- Participation in ethics screening, assessment and ethics check in various calls

- Also acting as ethics advisor and ethics mentor for various EU projects

Facilitating elements in ethics review

- Clear instructions and organisational support
- Use of functioning platforms allowing interaction between the experts before consensus meetings
- Use of pre-defined requirements with a possibility of modifications
- Certain options for further monitoring (e.g. ethics check, with various required expertise)
- Successful use of virtual meetings in the last two years

Main principles

CONSISTENCY

PROPORTIONALITY

General consideraties

- Different layers of responsibilities in monitoring ethics requirements
  - Ethics reviewer
  - Ethics advisors, ethics advisory boards, ethics mentors
  - Institutional oversight bodies (DPOs, ethics committees, etc)

- Different interpretations on some key concepts such as vulnerable populations, vulnerability and benefit sharing

General considerations

- Raising awareness among the researchers: should ethics review/requirements also play an educational role?
  - E.g. Setting requirements to follow trainings etc specially for ECR
  - Recommendations instead of requirements?

- Assisting researchers in fulfilling ethics requirements with providing some tips in ethics review report
  - Challenges for SMEs to fulfil the ethics requirements

Specific emerging considerations

- Data-driven research and increasing use of smart devices for data collection in research: dealing with uncertainties arising from implementation of the GDPR! (e.g status of data, adequate safeguards, …)
- AI-based research: reviewing technical aspects vs. ethical concerns? Not easy to draw a line!
- Emerging regulatory frameworks, interplay between them and the ethics requirements, and the relevant requirements
  - AI Act and other relevant ethics principles related to AI (e.g. Trustworthy AI)
  - Requirements specific to medical devices, such as Medical Devices Regulation, IVD, …
  - Data Governance Act, Data Act, DMA, DSA, …

The new approach

- Trust-based approach leading to fewer requirements: a welcome approach!
- Importance of taking a proactive approach in demonstrating awareness of the relevant ethics issues rather than waiting for the requirements

- More responsibilities for the ethics advisors and ethics advisory boards
  - Are they ready?
  - Are all the researchers supported by their institutions in fulfilling ethics requirements?

Thanks for your attention!