FAIR Ethics

Making Ethical Review Processes more Machine Actionable

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IG Ethics and Social Aspects of Data

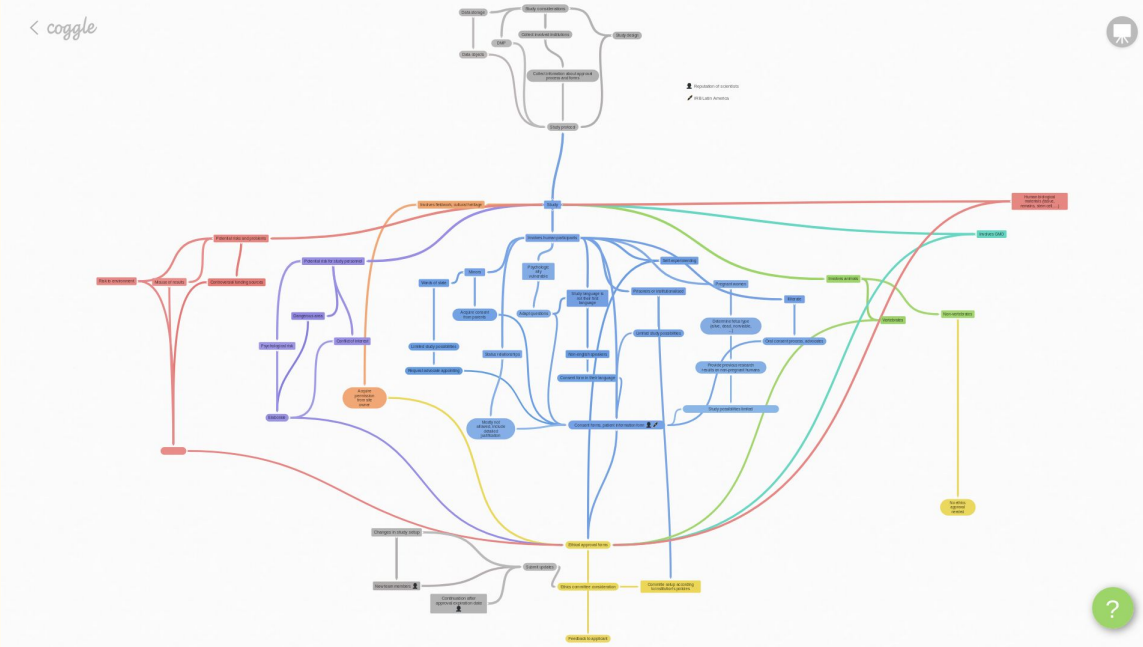
- Ethics of data
- Social aspects of data

but also

- data and metadata *about* ethics and social aspects of data

Multiple perspectives on the ethical review process

- **Research ethics**
- **Patient** / participant
- **Reader** / reuser
- Physician
- **FAIR**
- **Technical**
- Policy
- Legal
- …



Research ethics perspective

The purpose of ethical review is to consider the features of a proposed study in the light of ethical principles, so as to ensure that investigators have anticipated and satisfactorily resolved possible ethical objections, and to assess their responses to ethical issues raised by the study.

1991 International Guidelines for Ethical Review of Epidemiological Studies

Patient perspective

Make all documentation around ethical approval and consent freely available—Blank consent forms should be made publicly available alongside trial registration, accompanied by the participant information sheet. Similarly, correspondence with ethics committees and other bodies with a similar role should routinely be made publicly available. This will allow ethics processes to be independently reviewed, publically discussed, and learnt from.

Mendel, J., Goldacre, B., Ernst, E., & Whittle, S. (2016). Problems with ethical approval and how to fix them: lessons from three trials in rheumatoid arthritis. BMJ, i4626. doi: 10.1136/bmj.i4626

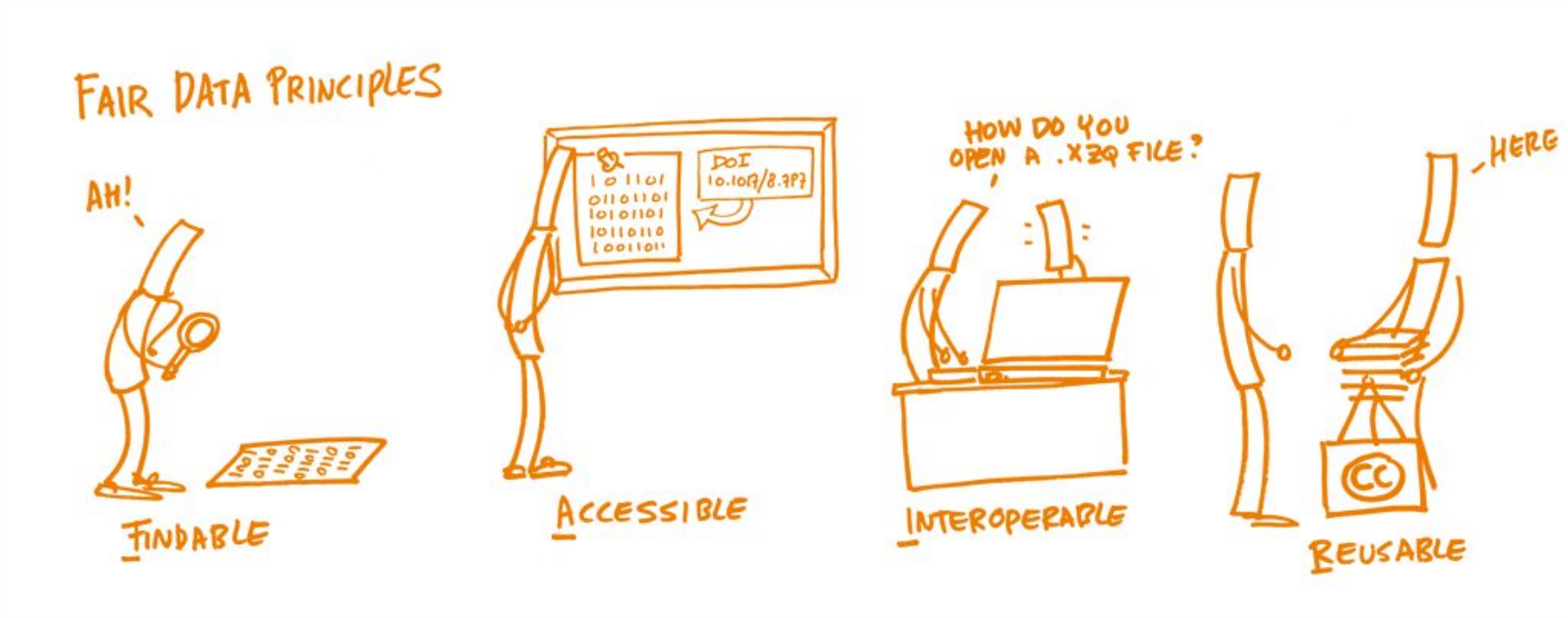
Reader perspective

Ethics statement

All studies were approved by their local ethics committees; all patients gave informed consent.

- Which aspect of the research triggered the need for ethics approval?
- Which were these local ethics committees, and who sat on them?
- How to find relevant documentation (e.g. the consent forms)?
- What options did the relevant Ethics Committee(s) have to choose from?
- Was there any discussion within the Committee(s)?
- Was there any discussion with the team who had requested the approval?
- Was there any modification to the request following such discussions?
- How to find past approvals or rejections for similar research?
- How long did the process take?

FAIR perspective

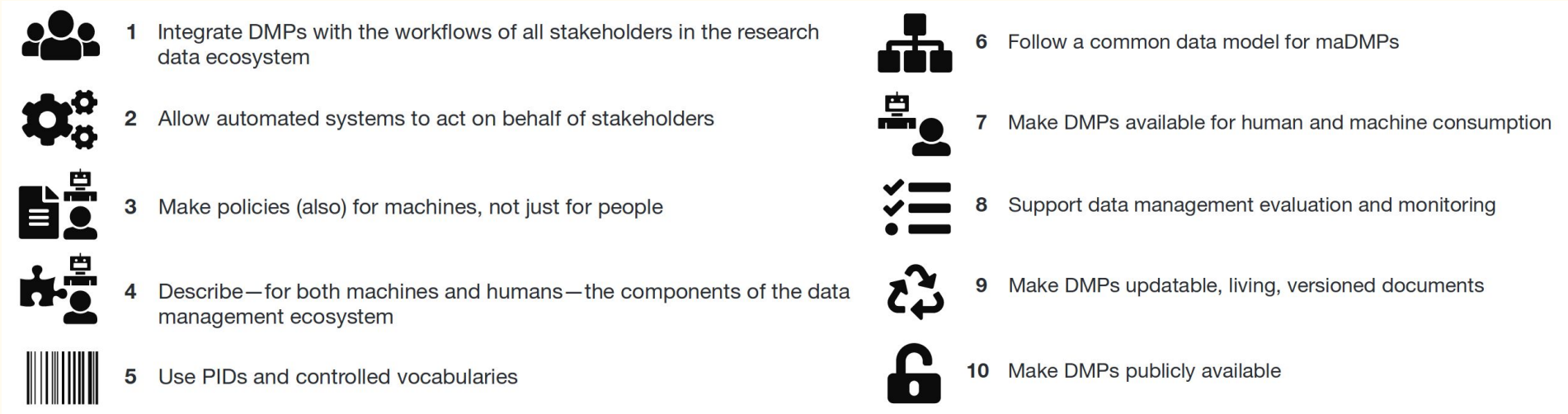


Wilkinson et al. (2016) doi.org/10.1038/sdata.2016.18

[image: fosteropenscience.eu CC0]

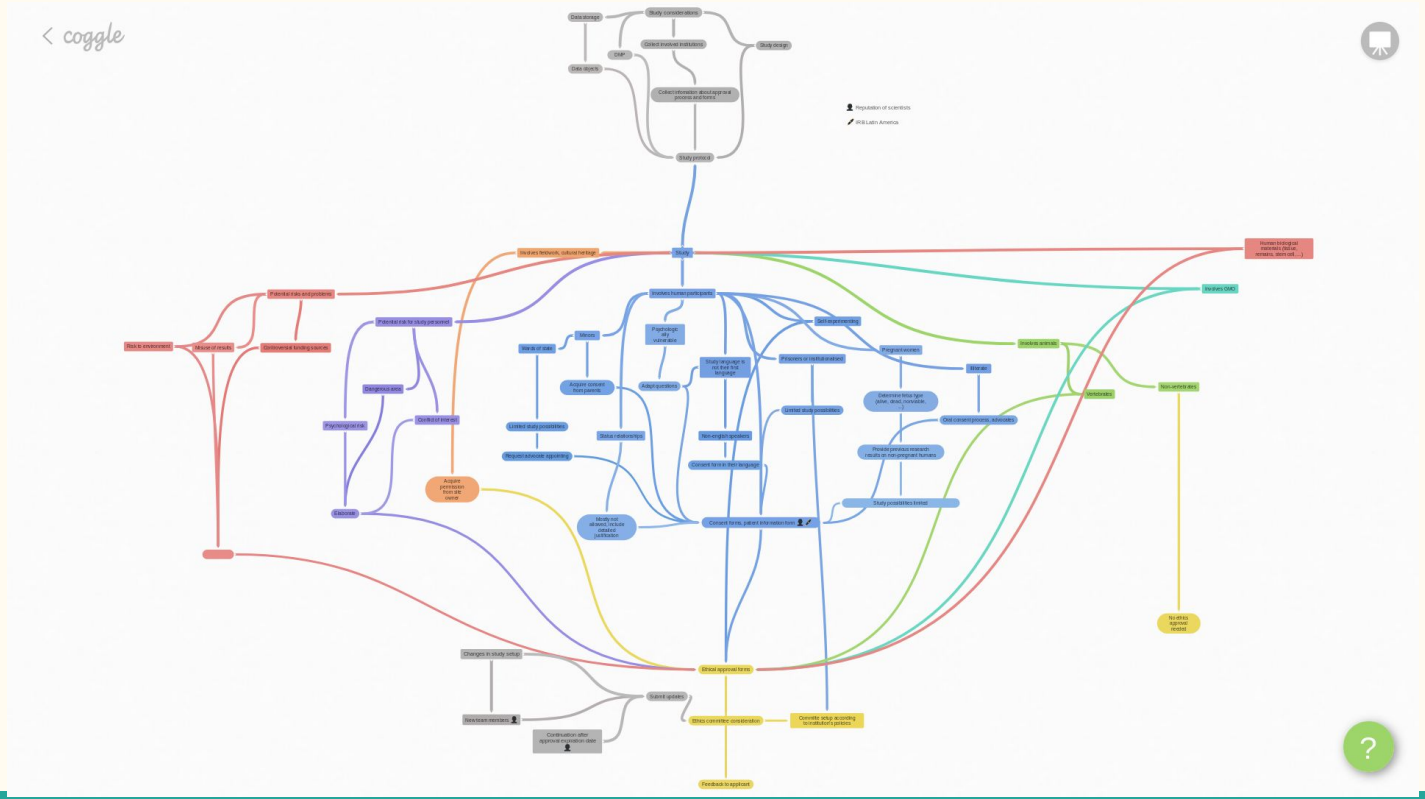
Technical perspective: making ethics data FAIR

- Inspiration from progress towards machine actionable Data Management Plans, e.g. through
  - DMP Common Standards WG
  - Exposing Data Management Plans WG
  - Ten principles for machine-actionable data management plans



PIDs = Persistent Identifiers; DMPs = Data Management Plans

Zooming out again: the ethics approval process



More examples

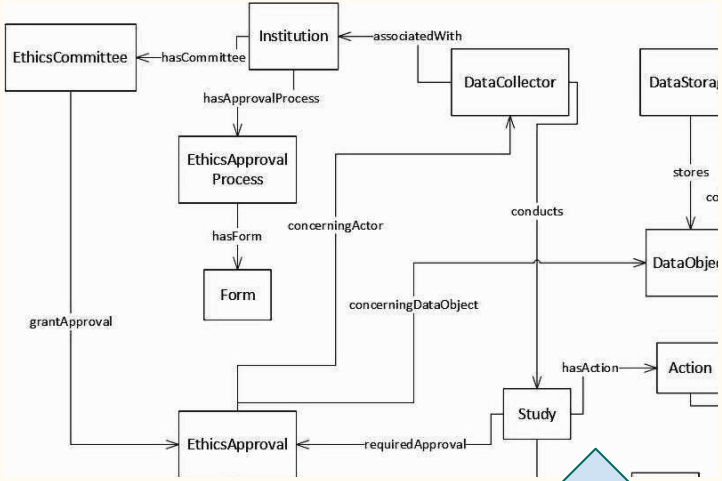
- "The **proposed investigation** received the **approval** of the **Ethics Committee of the United Oxford Hospitals**."
- "The **study** was approved by the **ethics committee** of **the hospital**, and **the patients** gave **informed consent**."
- "The **project** was **approved** by **two local Ethics Committees and one national committee"**
- "The data collected anonymously will be made available to any research group in the world following the data-sharing agreement initiative (http://www.wellcome.ac.uk/News/Media-office/Press-releases/2016/WTP060169.htm), provided that they have a clear, non-redundant research question and a **biomedical research Ethics committee approval"**
- "Does your work need IRB approval? Better check, says author of **retracted paper"**
- "you *may need* the **approval** of **your IRB or Ethics Committee** to *use the data*"
- "The **article** included the statement '**Ethics approval Regional Medical Ethics committee of medical and health research ethics, South East Norway**, and the **Norwegian data inspectorate**', when in fact the study did not itself have approval."
- "The **relevant ethics approval** for **this study** was granted by a **Department of Primary Industries NSW Animal Ethics Committee** of qualified scientific and lay members (**AEC Number 100802/04**). Field work was carried out under **NSW Fisheries Scientific Collection** Permit **P01/0059(A)-2.0**."

PID

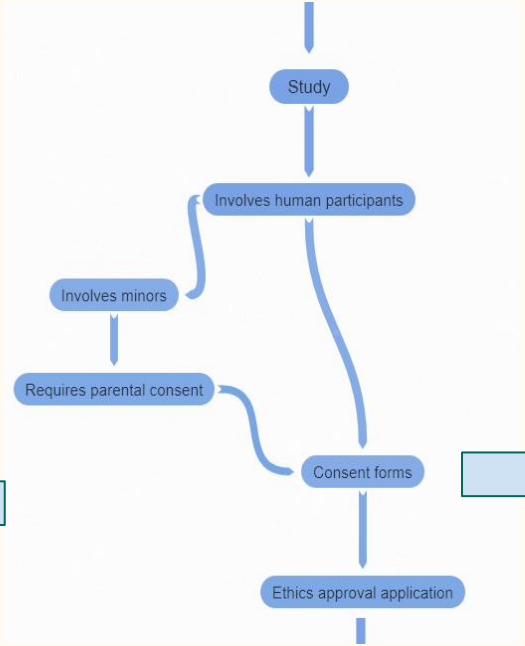
emphasis added to highlight opportunities for using persistent identifiers

5 Use PIDs and controlled vocabularies

Zooming back in



Process components represented in ontology



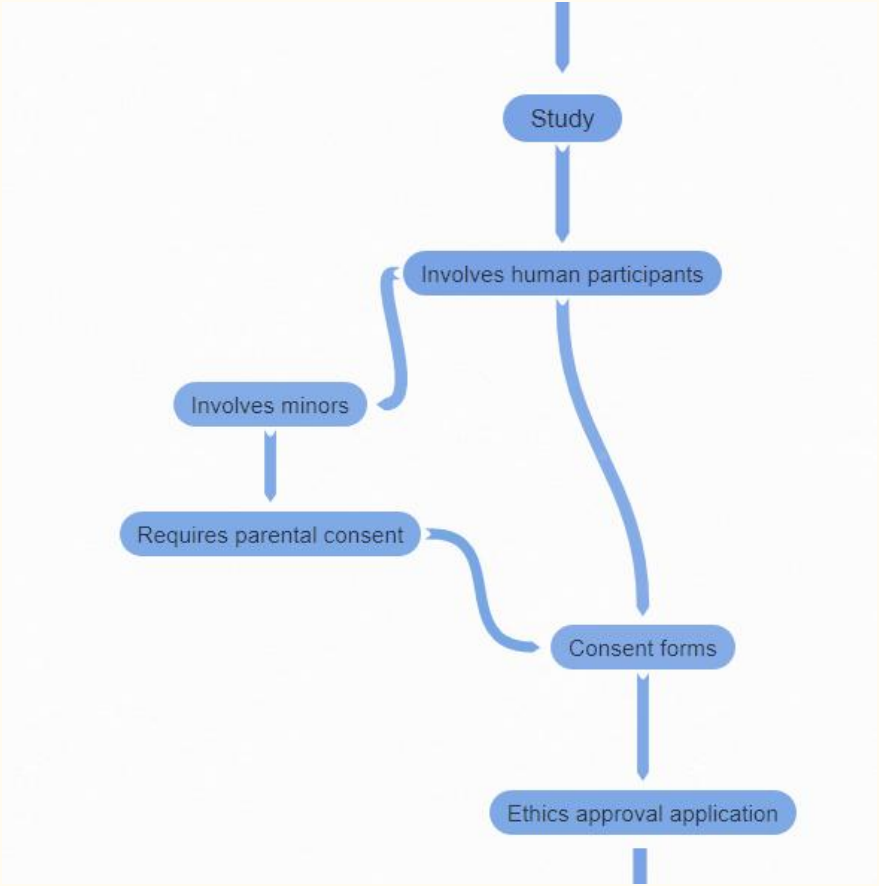
Process details determined by questionnaire

A. Does your study involve human participants? Yes No

A2. Does your study involve minors? Yes No

Process flow (excerpt)

- Application process is based on study subjects
- Different subjects have different requirements and restrictions
- Questionnaire to determine correct process (with requirements, restrictions)
- Ontology represents relevant concepts



Questionnaire

A. Does your study involve human participants? Yes No

A2. Does your study involve minors? Yes No

Requirement Studies involving minors require parental consent.
Please provide link to parental consent:

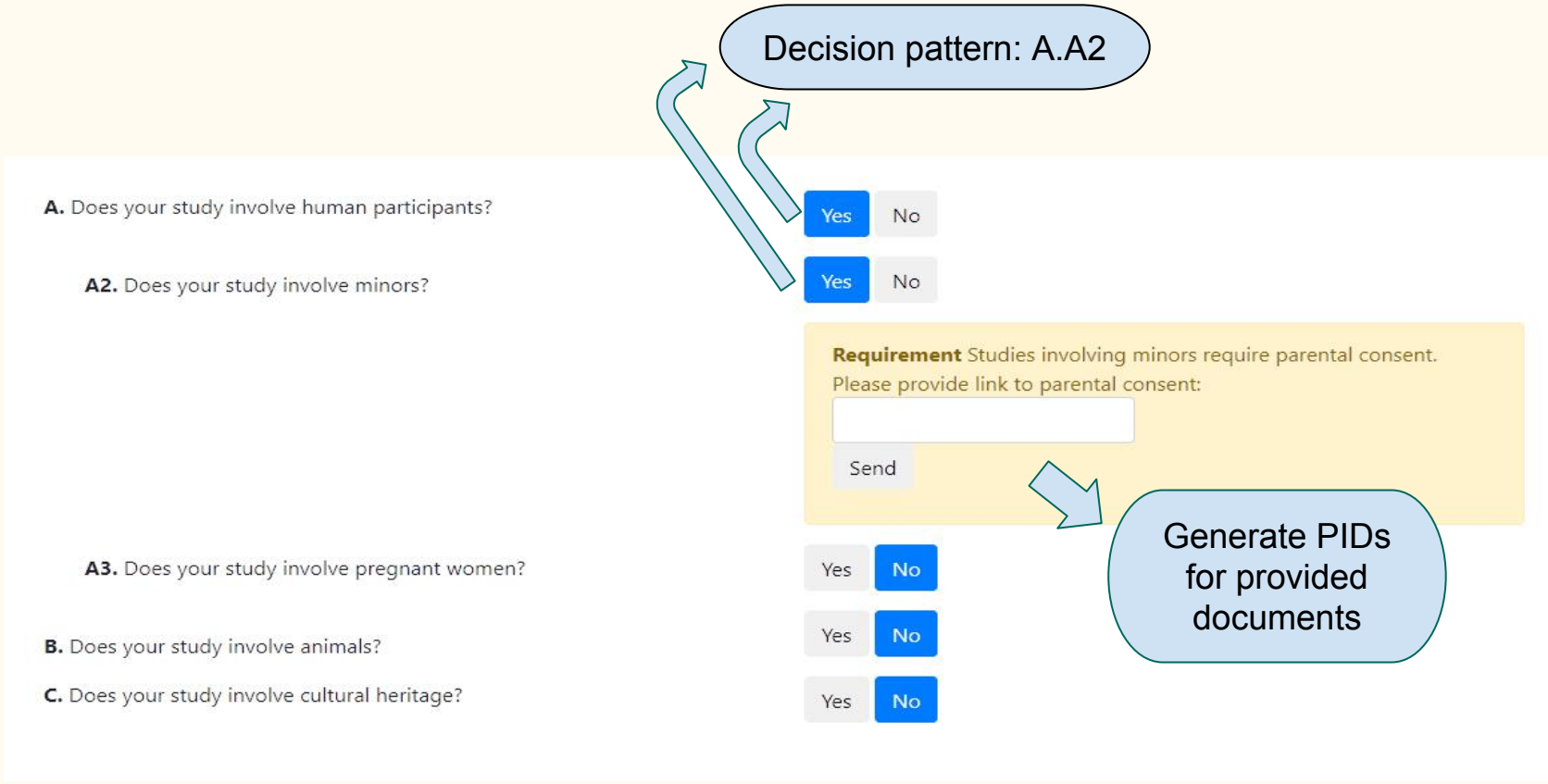
Send

A3. Does your study involve pregnant women? Yes No

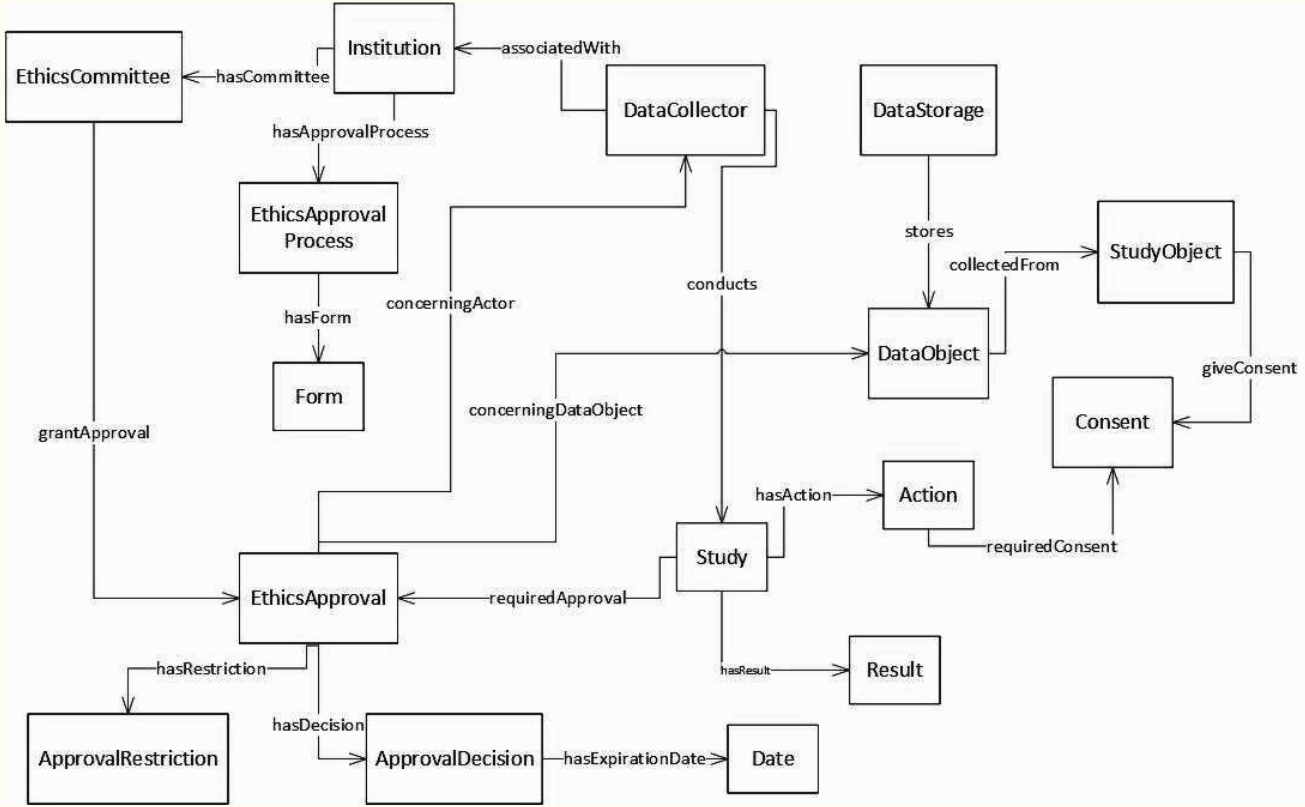
B. Does your study involve animals? Yes No

C. Does your study involve cultural heritage? Yes No

PIDs and Decision tree



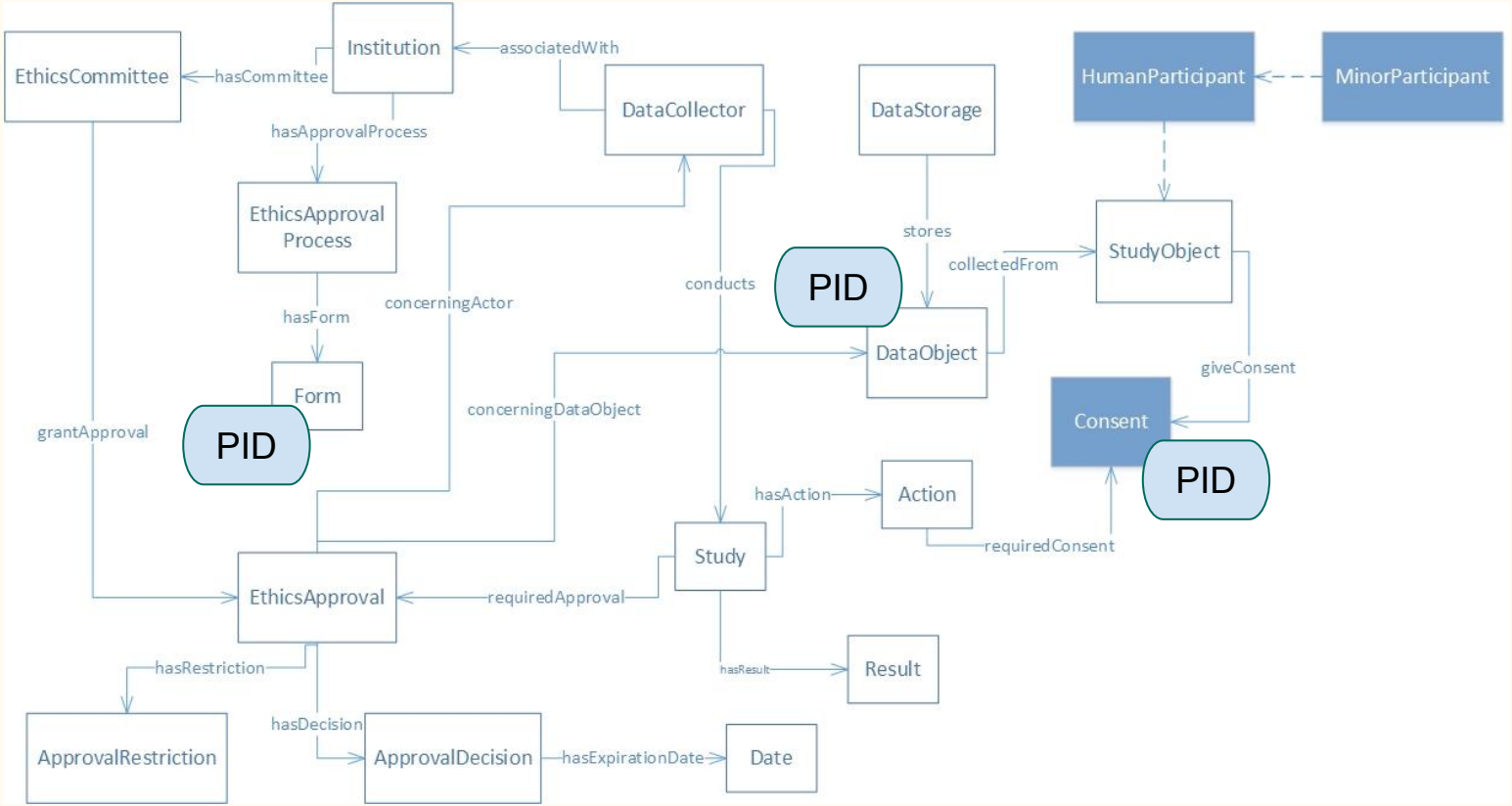
Ontology


Institution
EthicsCommittee
hasCommittee
associatedWith
DataCollector
DataStorage
hasApprovalProcess
EthicsApproval Process
stores
collectedFrom
StudyObject
conducts
concerningActor
hasForm
DataObject
Form
giveConsent
concerningDataObject
Consent
grantApproval
hasAction
Action
Study
requiredConsent
EthicsApproval
requiredApproval
hasRestriction
hasResult
Result
hasDecision
ApprovalRestriction
ApprovalDecision
hasExpirationDate
Date

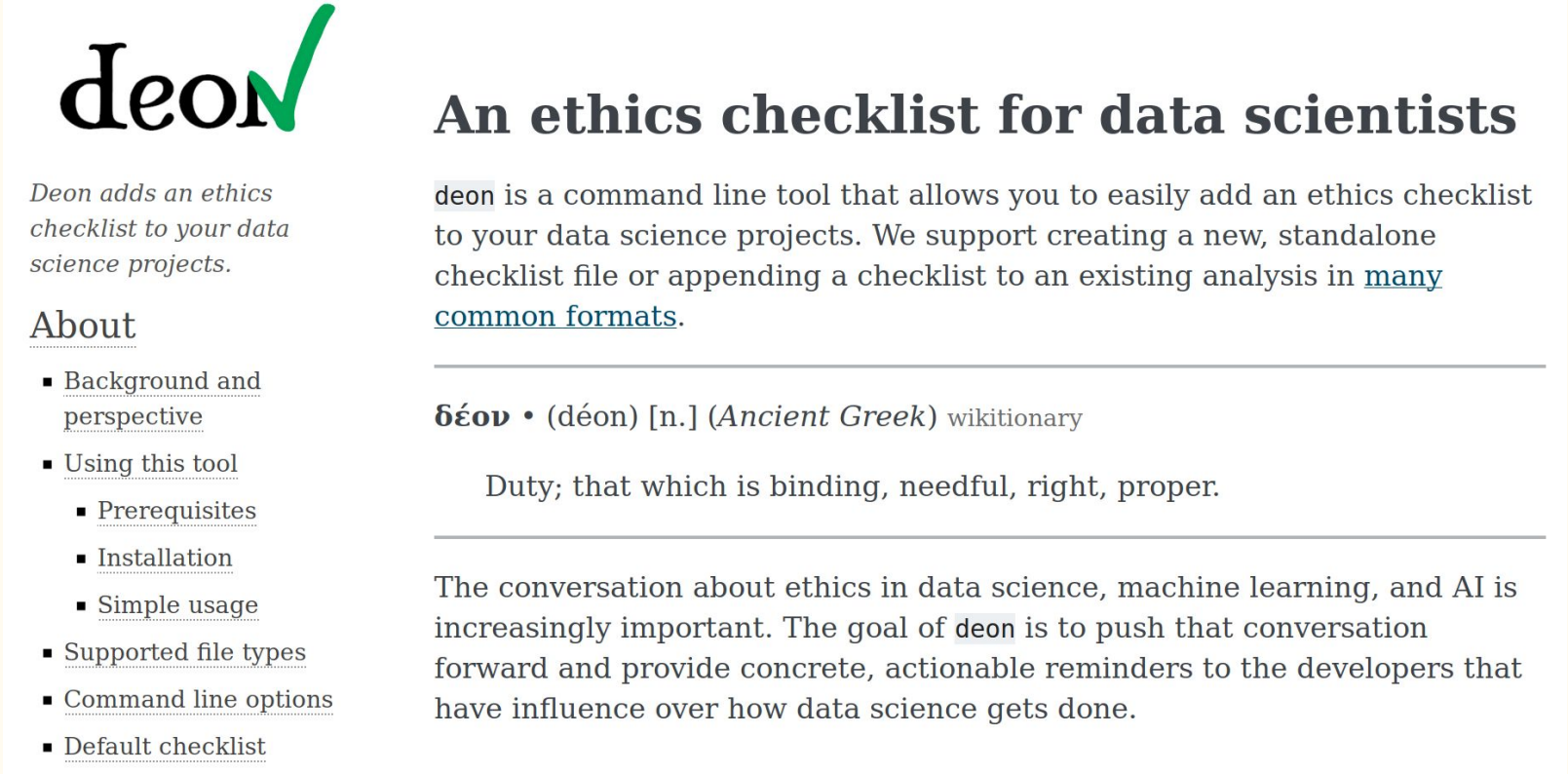
Use of PIDs in ethics statements

- "**This study** was **cleared** by the **Research Ethics Committee (CEP/CONEP)** (**CAE number**: **13813613.9.0000.0006**)"
- "**The research** was **approved** by the **Human Research Ethics Committee** at **Charles Sturt University, Australia**, **protocol number H17013**."
- "**approved** by the **Western Sydney University Human Research Ethics Committee** (**approval number H10384**)."
- "**Approval** for **the study** was given by **The University of Southampton Ethics Committee** (**ERGO Ethics Number**: **2411**)"
- "**Ethics of Animal Experiments Committee of Konkuk University**, South Korea (**Permit Number**: **KU16192**, **KU16193**)."
- "**Balearic Islands Human Research Ethics Committee** in January 2017 (CEI-IB, **#IB 3341/16 PI**)"
- "conducted under **CSIRO Social Science Human Research Ethics Committee Approval**: **project 055/16**"
- "The **study protocol** was **approved** by the **Ethics Committee of the Faculty of Tropical Medicine, Mahidol University** (**MUTM2013-021-01**) and the **Oxford Tropical Research Ethics Committee, University of Oxford** (**OXTREC 1013-13**)."
- "**The study** was *conducted* in *accordance* with the *guidelines contained* in the **Declaration of Helsinki II** and was **approved** by the **local ethics committee of the University of Granada, Spain** (**protocol**: **23/CEIH72015**)."
- "**The study** has been **approved** by the **local ethics committee (Medical University of Graz, Austria)** in *compliance* with the *current revision* of the **Declaration of Helsinki**, **ICH guideline for Good Clinical Practice** and *current regulations* (**EK-number**: **24-123 *ex* 11/12**)."
- "*Collars* weighed less than 2.5% of the body mass of the baboons and were **approved** for use by **Swansea University Ethics Committee** (Swansea University **IP-1314-5**)"
- "**Ethical approval** was **obtained** from the **London Westminster Research Ethics Committee** (**11/LO/1667**), and **informed consent** was **obtained**."

Ontology - Associated PIDs from process excerpt



Similar efforts



Outlook & input for the panel discussion

- The more machine actionable the system becomes,
  - the more likely it is that the bureaucratic burden on people can be reduced
  - the more possible it becomes to find similar cases to inform current deliberations
    - just imagine case law without the cases being accessible
  - the more we can measure relevant aspects of the process
    - and from there derive data to
      - measure compliance with current policy
      - inform future policy
- The more transparent the system becomes,
  - the more likely standards are to be applied consistently
  - the more possible it becomes to
    - teach ethics consistently across sites
    - address issues of equity
  - the more informed potential participants can be about specific lines of research they might engage in