

Thinking about the (ethical) challenges of early cancer research: developing real partnerships



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This talk: practicalities and possibilities

1. PRACTICALITIES: Extracts from Dixon Woods M et al 2008. “What do research ethics committees say about applications to do cancer trials?” *Lancet Oncology*:9:701

2. POSSIBILITIES: Some ideas on “working together” and “speaking the same language”



PART 1: practicalities

What do Research Ethics Committees say about applications to do cancer trials? An analysis of their letters to researchers.



96% - informed consent.

- Language and layout of Participant Information Sheet problematic

Ideas

- Don't leave it to the end
- WORD readability
- “Road testing” – (“PPI”)
- HRA / MRC guidance
<http://www.hra-decisiontools.org.uk/consent/>



95% - possible risks

- physical safety / side-effects or effectiveness of drugs / additional trial procedures / aspects of the drug schedule.

Ideas

- Clear explanation
- Expert review
- Patient involvement
- Presentation of balance
- “Key facts” template



71% - scientific design

- bad science is bad ethics

Idea

- Agree?! (and ensure this is addressed in submission)



48% - confidentiality of trial participants' information

- explicit arrangements for data protection
- explanations on transfer abroad

Ideas

- use and store de-identified data and provide an explanation of what will happen to data



36% - consent issues relating to the collection and use of human tissue

Idea

- Future proof your work (and that of others)



35% voluntariness

18% raising (false) expectations

- RECs were anxious that patients with cancer could be very ill and desperate, and thus highly vulnerable when faced with the offer of a trial.

Ideas

- Patient involvement
- “Honest choice” rather than “consent”



Part 2: possibilities

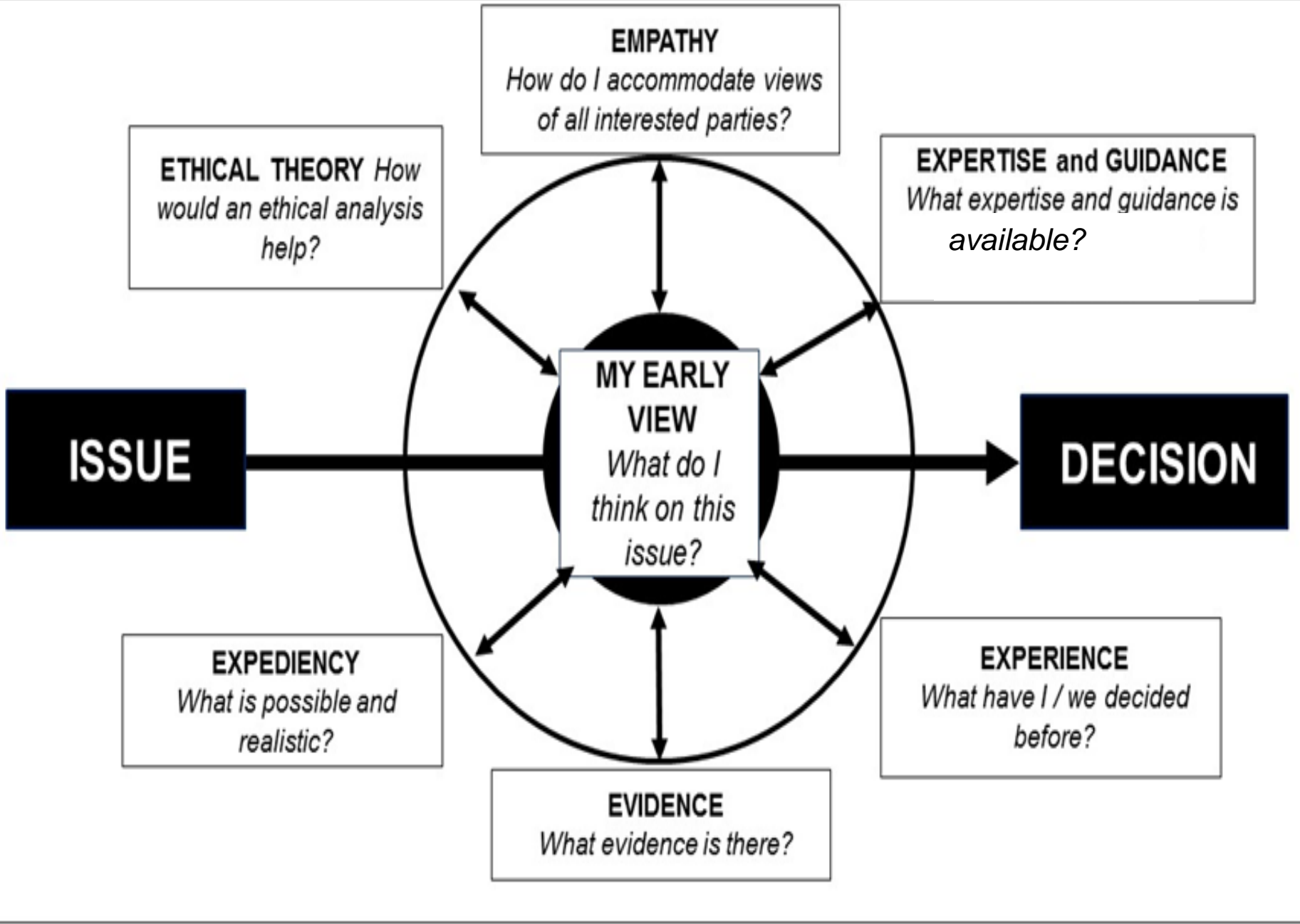
Working together and building bridges



Questions to ask yourself when designing research that will ease review (and make your study better) –

because they're the questions reviewers will (or should) ask you.





EMPATHY

How do I accommodate views of all interested parties?

ETHICAL THEORY *How would an ethical analysis help?*

EXPERTISE and GUIDANCE *What expertise and guidance is available?*

MY EARLY VIEW
What do I think on this issue?

DECISION

EXPEDIENCY *What is possible and realistic?*

EXPERIENCE *What have I / we decided before?*

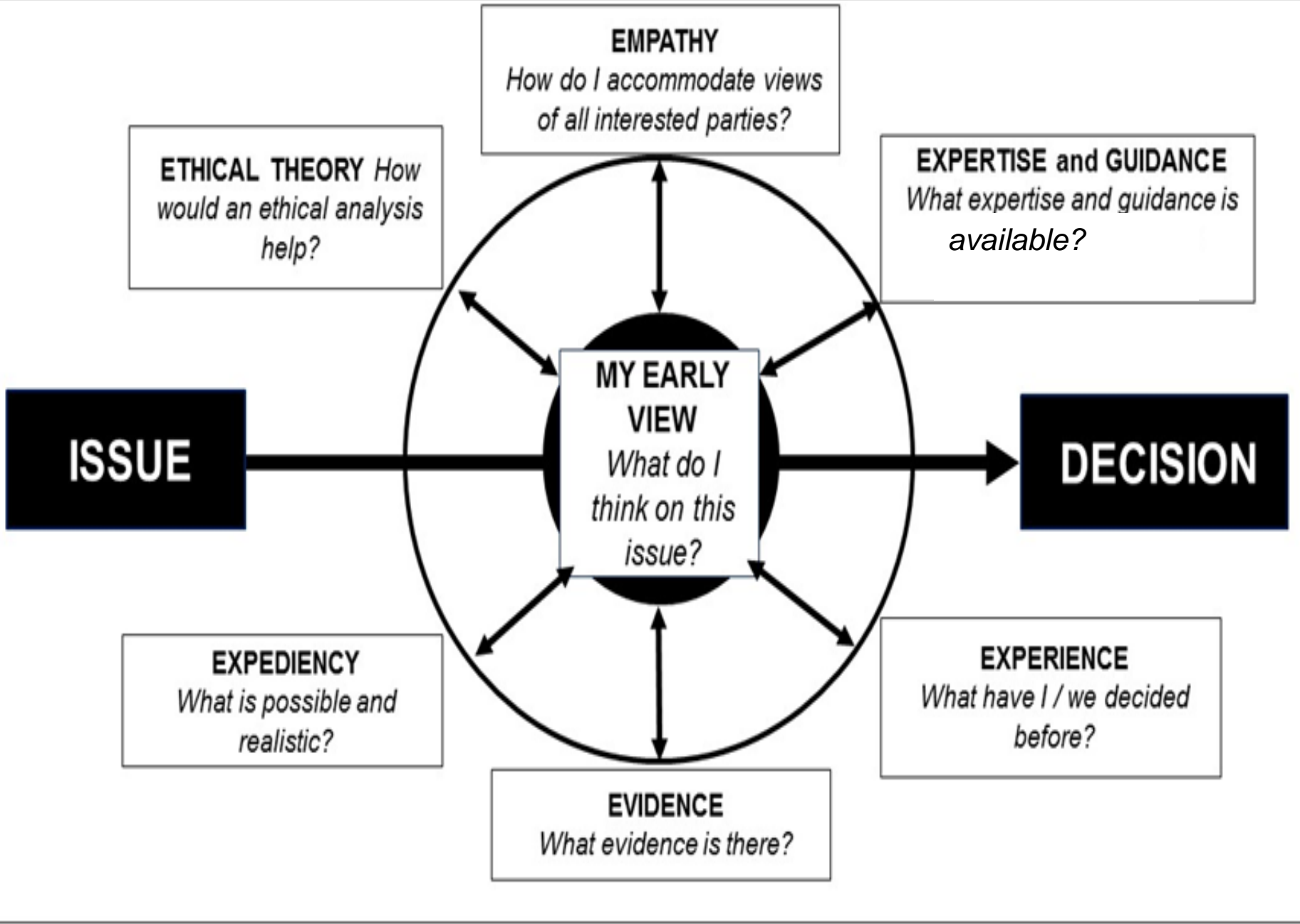
EVIDENCE *What evidence is there?*

ISSUE

What might this mean to researchers?

“Great or False Expectations?”





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DECISION

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**I hope this
might
help.**



- **Think**
- **Reason**
- **Conclude**

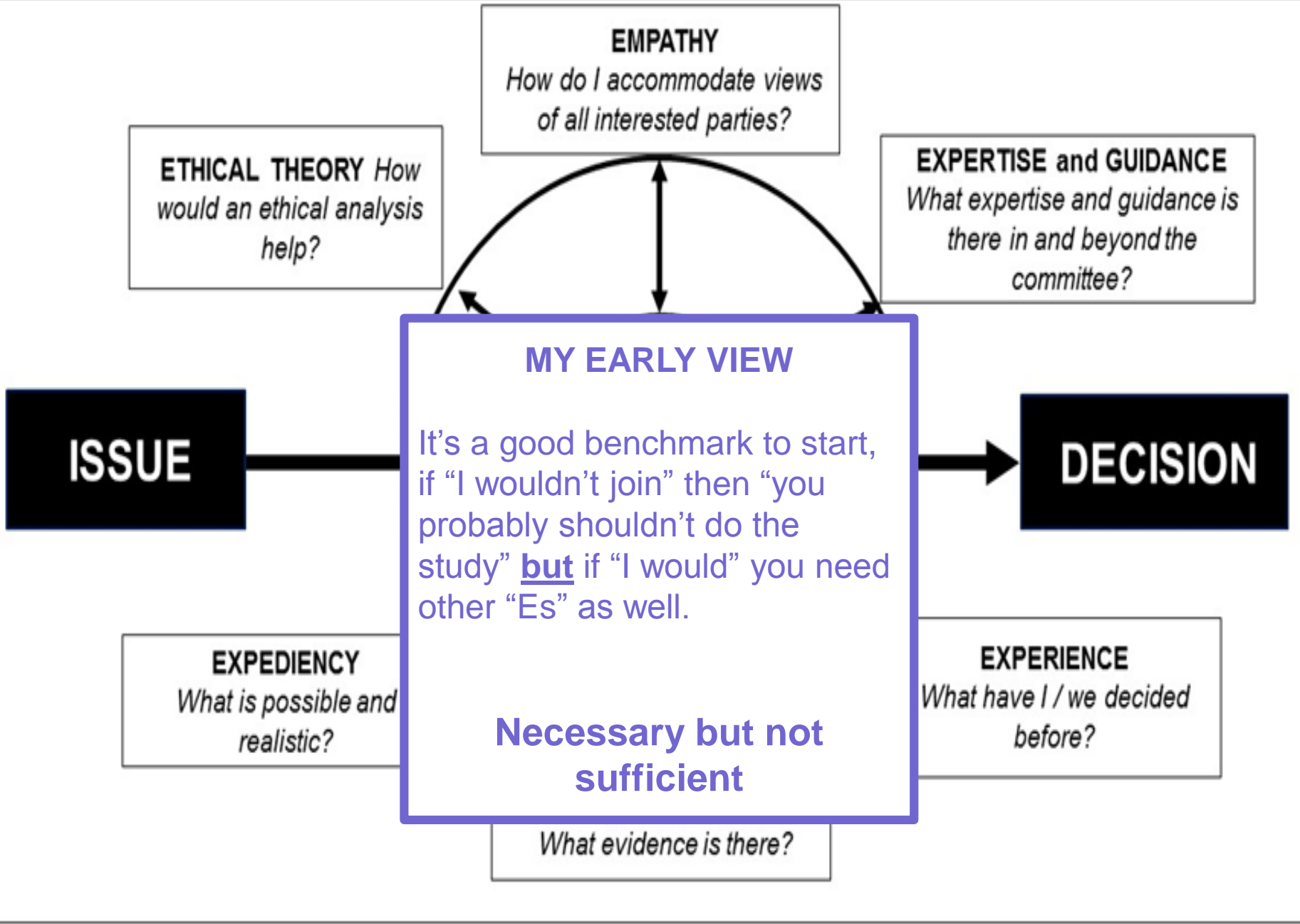


**Don't be
frightened: be
courageous**



Thank you for listening (if you have been)





ETHICAL THEORY

will help you frame any issue, bring reasons to the surface and help you talk to others.

BUT the required ethics of research design is limited.

You don't have to be Kant.



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What expertise and guidance is there in and beyond the



EVIDENCE

What evidence is there?

DECISION

CE
e decided
?

EMPATHY

Understanding all other viewpoints should be our guiding principle but recognise limitations to empathy.

Involve others (PPI) and double your research output!

ETHICAL THEORY How would an ethical analysis help?

EXPERTISE and GUIDANCE What expertise and guidance is there in and beyond the committee?

ISSUE

VIEW
What do you think on issue

DECISION

EXPEDIENCY
What is possible and realistic?

EVIDENCE
What evidence



How would you like it if the mouse did that to you?

EMPATHY

How do I accommodate views of all interested parties?

ETHICAL THEORY *How would an ethical analysis help?*

If only people were as smart as me.



EXPERTISE

Provide peer / expert review.

GUIDANCE

Have a small up to date library of authoritative guidance and refer to it.

Guidelines on the practice of ethics committees in medical research with human participants
Fourth edition

EXPERIENCE
What have I done before?

What experience is there?

ISS

ETHICAL THEORY *How would an ethical analysis help?*

EMPATHY
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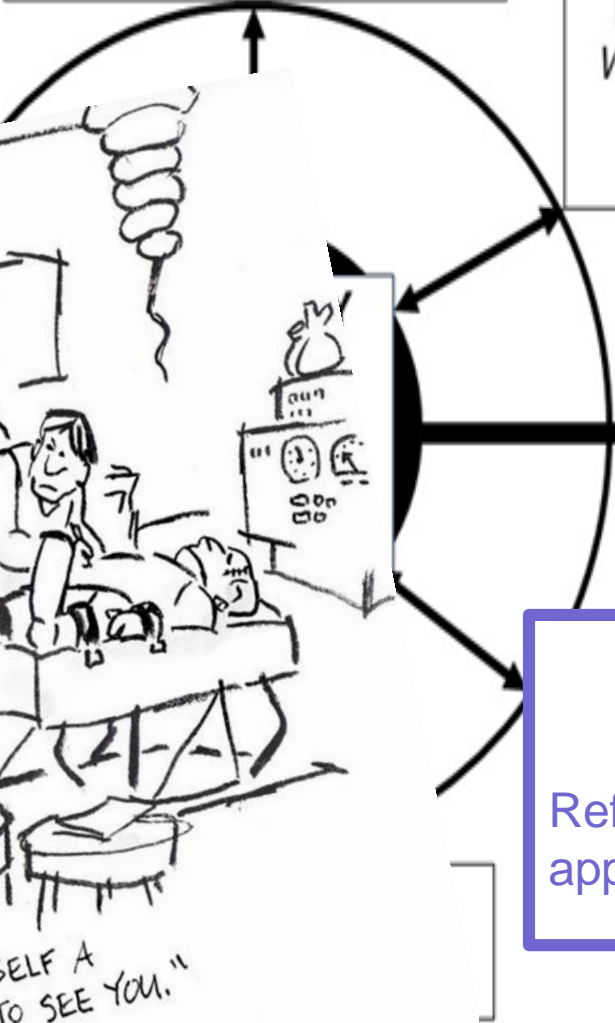
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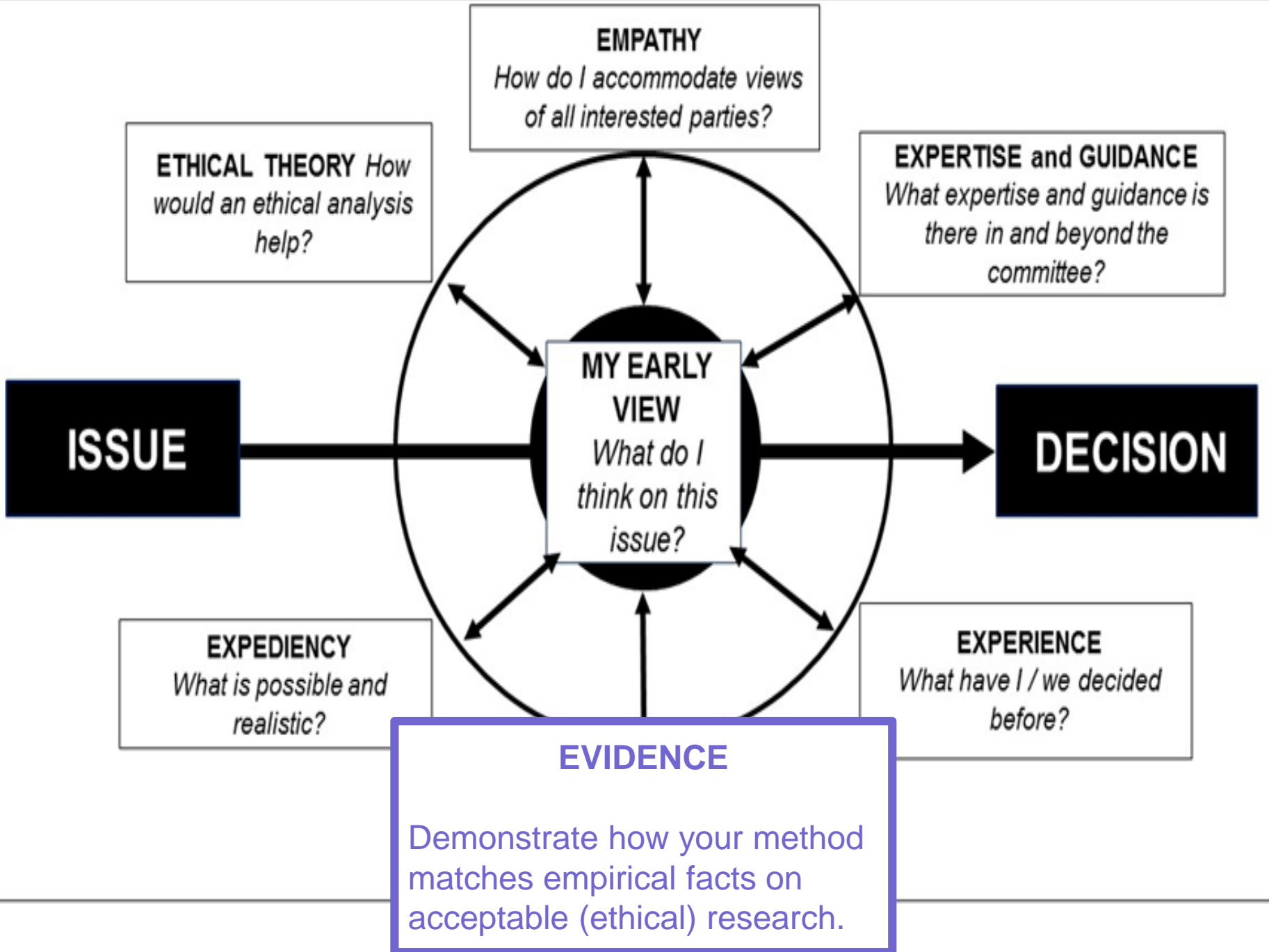


"SOMEONE CALLING HIMSELF A BIO-ETHICIST IS HERE TO SEE YOU."

DECISION

EXPERIENCE
Refer (tactfully) to past approved studies.





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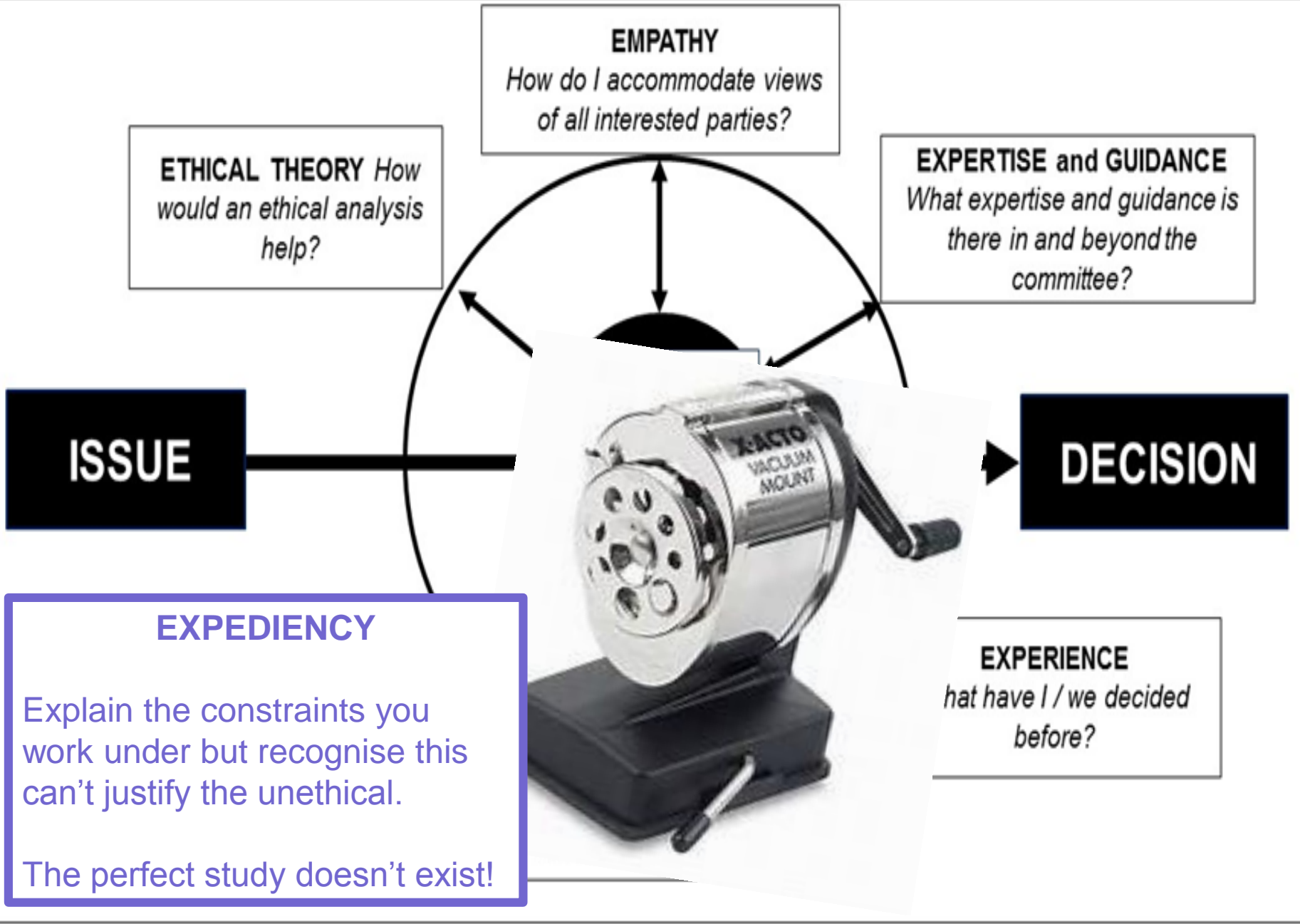
DECISION

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EXPERIENCE *What have I / we decided before?*

EVIDENCE

Demonstrate how your method matches empirical facts on acceptable (ethical) research.



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ISSUE

DECISION



EXPEDIENCY

Explain the constraints you work under but recognise this can't justify the unethical.

The perfect study doesn't exist!

EXPERIENCE *What have I / we decided before?*