Preventive Disaster Research Ethics: Use of an Algorithm as Decision Support to Parse Disaster Activities as Research or Not

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Let’s “Flip” the Lecture

For an introduction and background

- Determining what’s research and what’s not
- https://youtu.be/ckb4Mq9lkWU

Podcast on YouTube

Context from Across the Pond in the USA

- Current effort to change US regulations for protecting human subjects through a notice of proposed rule-making (NPRM)
  - http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html
- Many reasons to update the regulations, but let's focus on how US regulations define research, which has proven vexing:
  - *"Research* means a systematic investigation…designed to develop or contribute to generalizable knowledge" (45 CFR 46.102(d))

NPRM

- Proposal:
  - “Exclude from coverage under the Common Rule certain categories of activities that should be deemed not to be research, are inherently low risk, or where protections similar to those usually provided by IRB review are separately mandated” (HHS website, 2016)
  - Use of online decision tool

My Concern

- Unless the definition of research is changed or defined better, public health projects will still pose problems.

- Public health practice:
  - Systematic collection of identifiable information
  - Usually not designed to be generalizable

- Existing guidance from stakeholders is good but voluminous
  - Council of State and Territorial Epidemiologists (CSTE, 2004) guidance is 60 pages

My Proposal

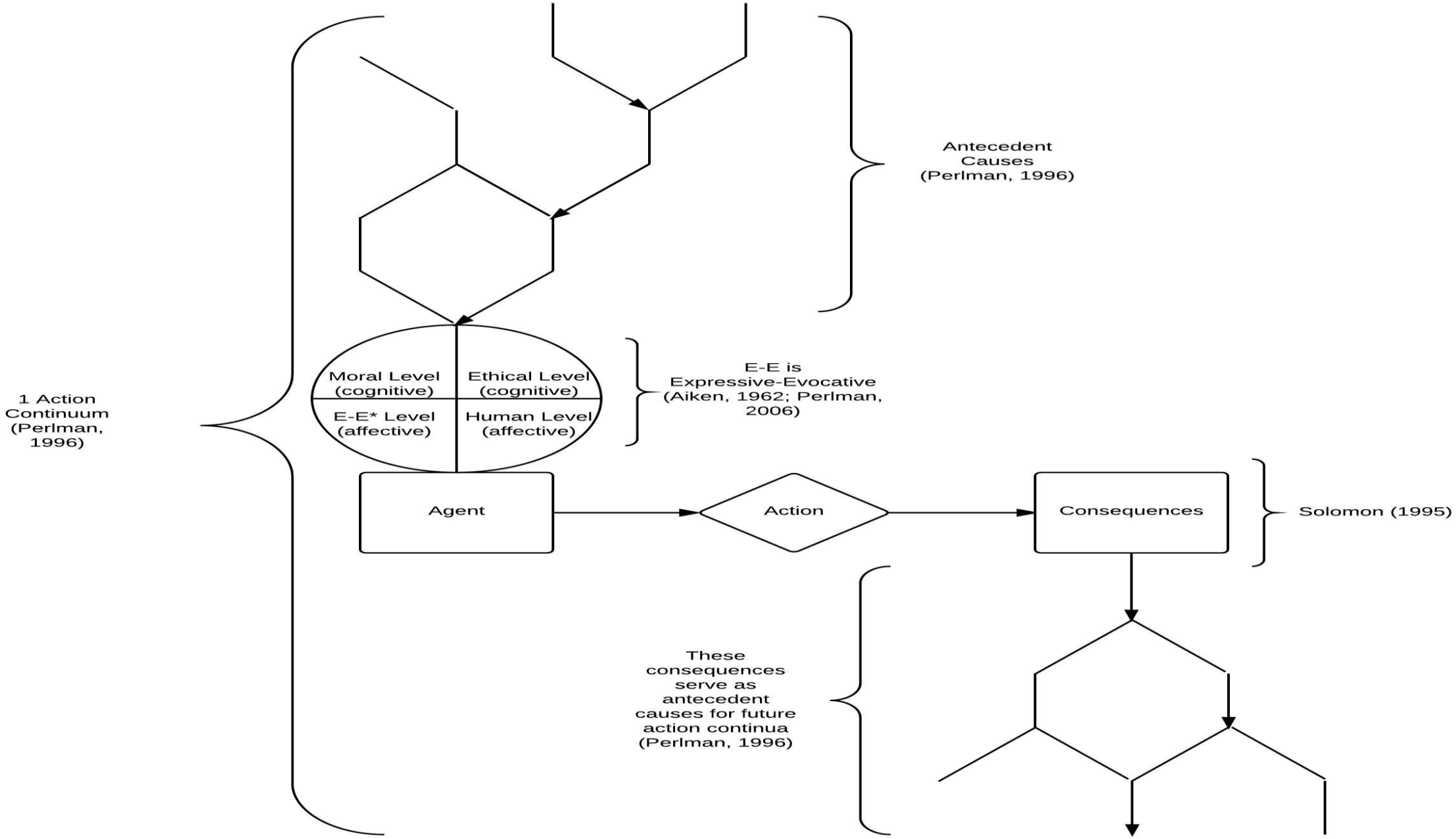
- Condense existing guidance into an algorithm
- Empirically test the algorithm with a number of known projects
  - Avoids the perception that research ethics review is not evidence based and is idiosyncratic and inconsistent
- Refine algorithm and produce interactive online version with inputs for information for documentation purposes but also to encourage reflection and thought

How Might This Work? – Let's Get Philosophical

- Research ethics review is too focused on regulatory compliance (Perlman, 2006)
  - Projects that might need ethical consideration lost in the effort for efficient throughput
  - Training is focused on regulations and compliance not ethical deliberation and considered moral judgements

Ethical Reflection Embedded in Decision Support Tools

- Builds ethical reflection into the process (and backgrounds it a la phenomenology)
  - Consideration of agents and their virtues
  - Consideration of moral duties
  - Consideration of positive and negative consequences of each stage of complex decisions



Perlman (2015) AJOB Neuroscience

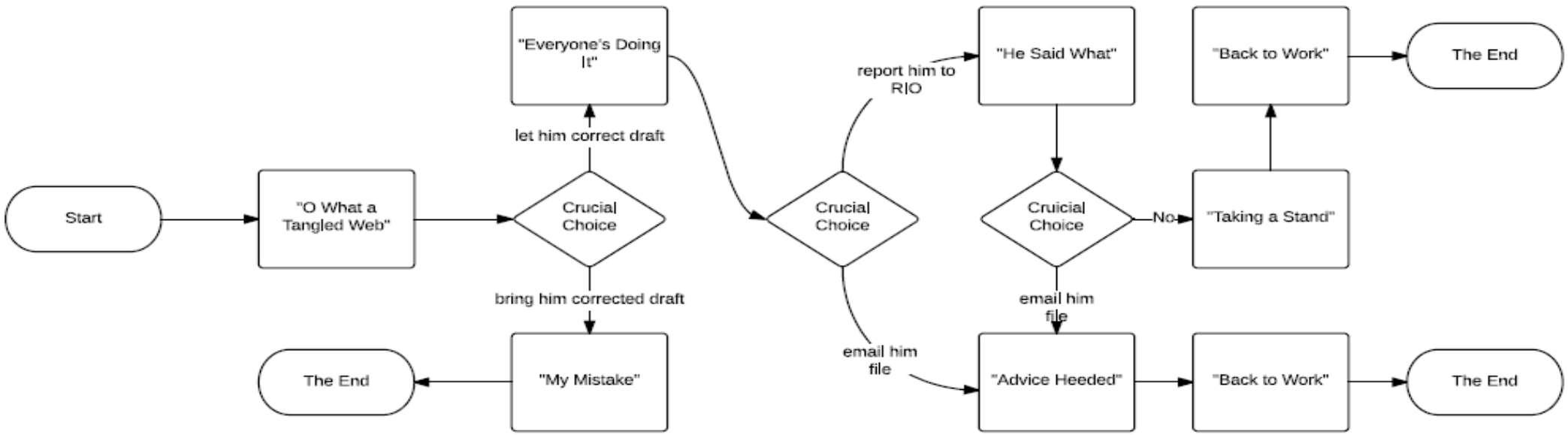
YouDecide™ - Empirical Testing and Refinement

- Tested with over 300 students and health professionals
- Use of standardized cases to reduce bias and enhance consistency

"Everyone's Doing It" +/-

"He Said What" +/-

"Taking a Stand" +/-



"My Mistake" +/-

"Advice Heeded" +/-

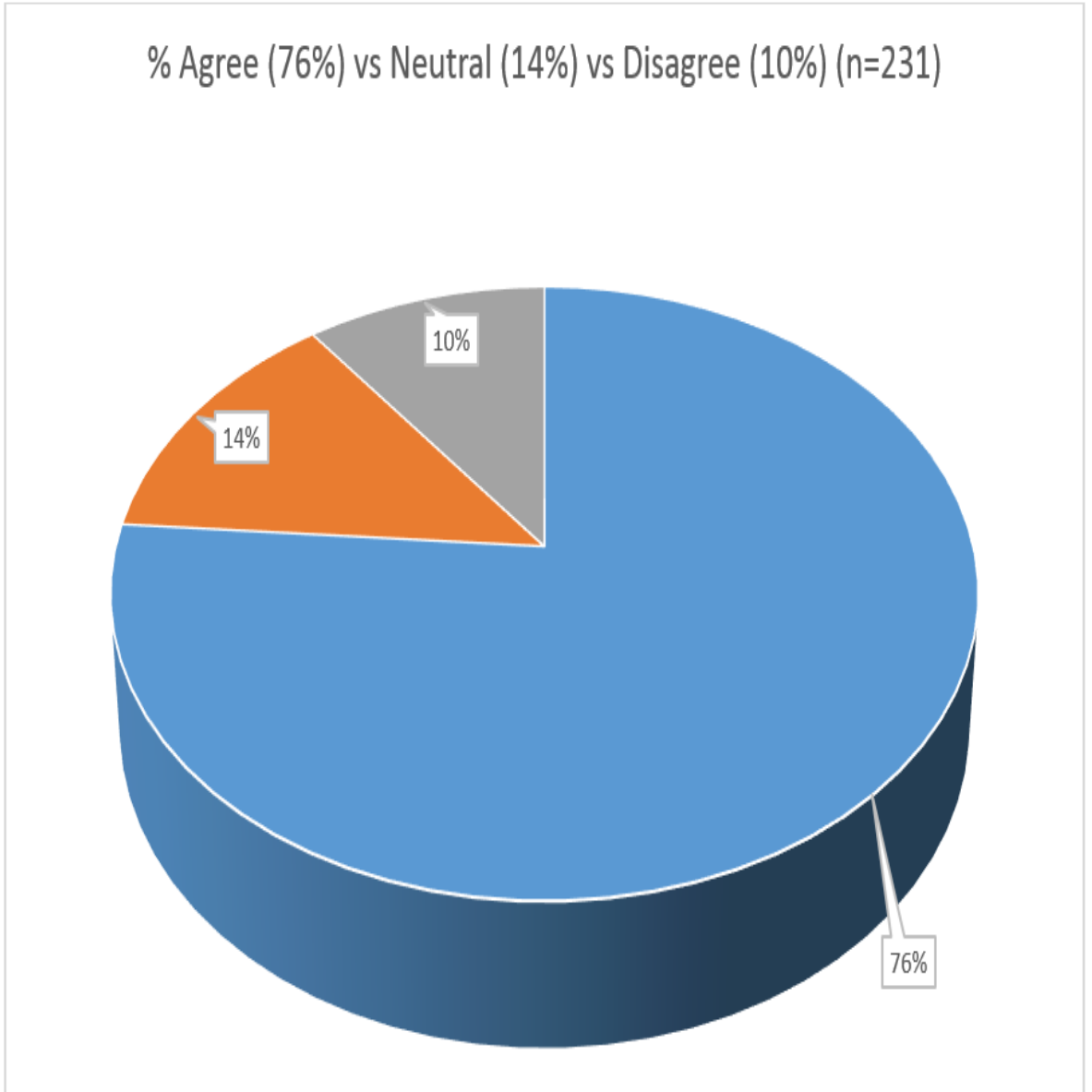
Overall Analysis

YouDecide™ - Results

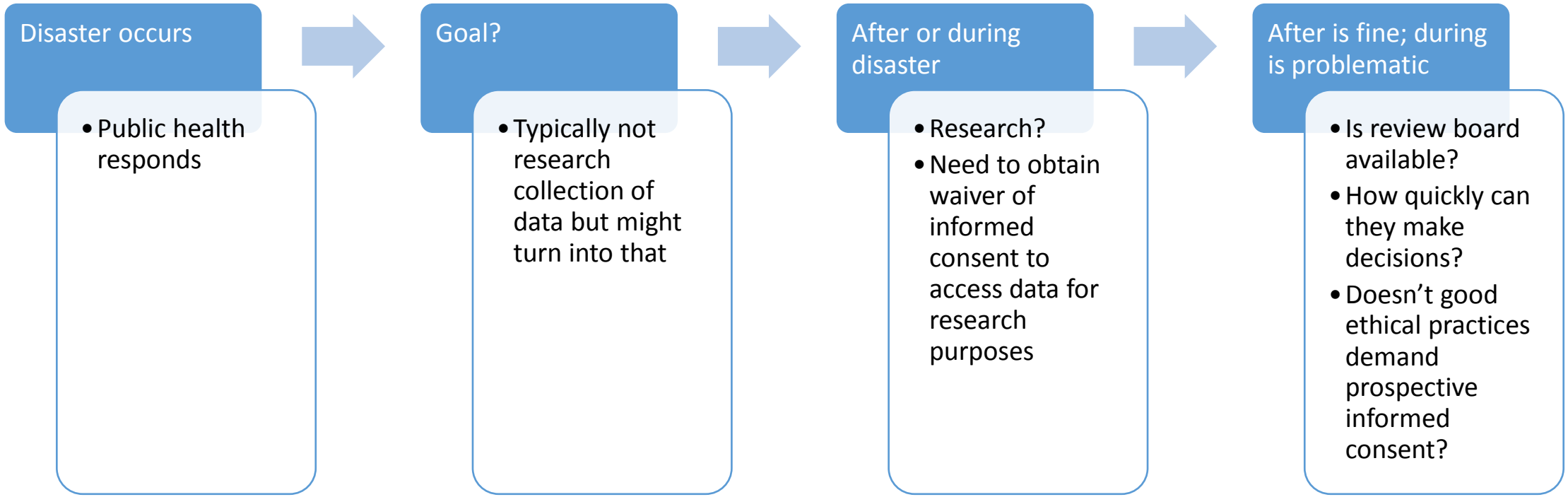
Test Venue	Date	N=	Participants	User Acceptance*
University of Pennsylvania	9/15/2014	55	UG nursing students	3.65±1.73
University of the Sciences	1/11/2015	17	UG business ethics students	2.35±0.93
University of Pennsylvania	2/2/2015	55	UG nursing students	2.81±1.36
Valley Health System	4/28/2015	28	Ethics Committee Members	1.96±0.93
Valley Health System	4/28/2015	24	Physician Residents	2.07±1.07
University of Arkansas	5/18/2015	40	Various health professionals	2.21±1.15
University of Pennsylvania	9/9/2015	59	UG nursing students	2.32±1.11
TOTAL or AVG		**278**		**2.48**

*Measured with the following question on a 7-point Likert scale, with 1=strongly agree and 7=strongly disagree: “YouDecide™ helped me to decide differently – to use my critical thinking skills to solve the problem.” Therefore, the lower the score, the better the user acceptance. SD=standard deviation.

Moreover, as the pie chart below indicates, an overwhelming 76% of the people tested agreed that YouDecide™ helps them decide differently (statistically significant at $p=0.005$, $X^2=28.145$).



Let’s Focus on Disasters – Current Process



Preventive ethics approach to disaster research

Disaster planning process

- Before disasters, use simulations to anticipate or plan research use of data
- Training module to reinforce prospective ethical considerations

Use of a YouDecide™ type algorithm

- Input of information = documentation for review boards
- Changing from an ex post facto regulatory check to a prospectively considered moral judgment

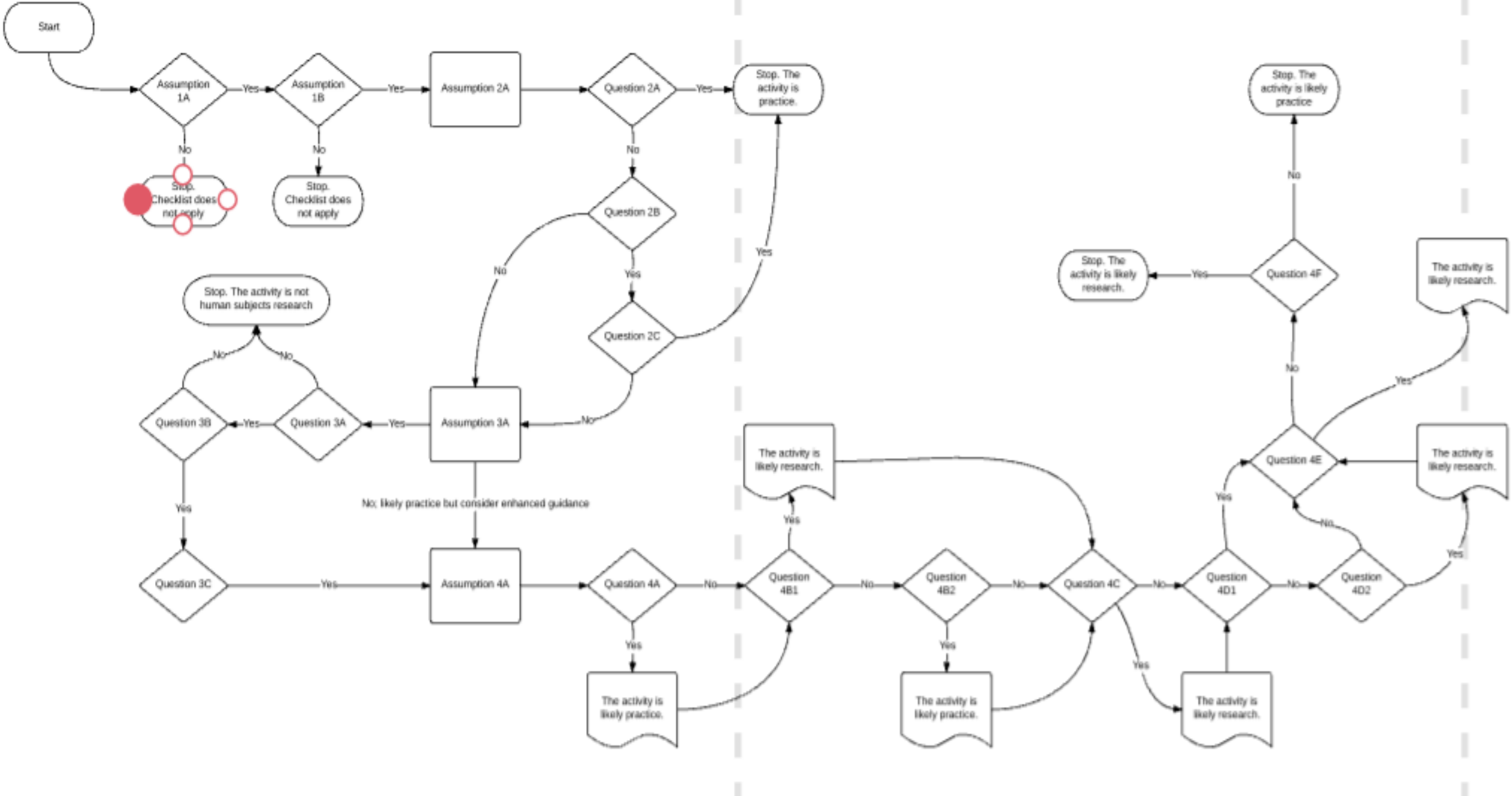
If needs change during disaster?

- At least project information or consideration of same has been done in a calmer, more reflective time than during the “pressure cooker” environment of a disaster response

Step One – Creation of a Preliminary Algorithm from Existing Guidance Documents

- It needs:
  - Testing
  - Refinement
  - Online development and deployment as a piece of software

- Sources:
  - CSTE (2004) Report
  - Hodge (2005)


Start
Assumption 1A
Yes
Assumption 1B
Yes
Assumption 2A
Question 2A
Yes
Stop. The activity is practice.
No
Stop. Checklist does not apply
No
Stop. Checklist does not apply
No
Question 2B
Yes
Question 2C
Yes
No
No
Stop. The activity is not human subjects research
No
No
Question 3B
Yes
Question 3A
Yes
Assumption 3A
No
Yes
Question 3C
Yes
No: likely practice but consider enhanced guidance
Assumption 4A
Question 4A
No
Yes
The activity is likely practice.
Yes
The activity is likely research.
Question 4B1
No
Question 4B2
No
Question 4C
No
Question 4D1
No
Question 4D2
Yes
The activity is likely practice.
Yes
The activity is likely research.
Yes
Question 4E
Yes
The activity is likely research.
No
Question 4F
Yes
Stop. The activity is likely research.
No
Stop. The activity is likely practice

Future Work

- Make available on website in interactive form
  - End product=customized process flow diagram, based on YouDecide™ inputs and architecture, to document argument for/against particular determinations
- Turn it into a downloadable app for field deployment
- Integration into enterprise software for research review committees
- Customization for international contexts and individual country regulations

How Can You Be Involved?

- Need feedback
- Question:
  - How does your country or region handle the determination of what's research and what's not?
- Suggest highlighting determination of research as a consideration in revisions for CIOMS document
- Possible grant collaboration to test algorithms in international contexts via Fogarty Center grants from NIH

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