Software-Induced Burden: When All You Can Say is "My Software Made Me Do It!"

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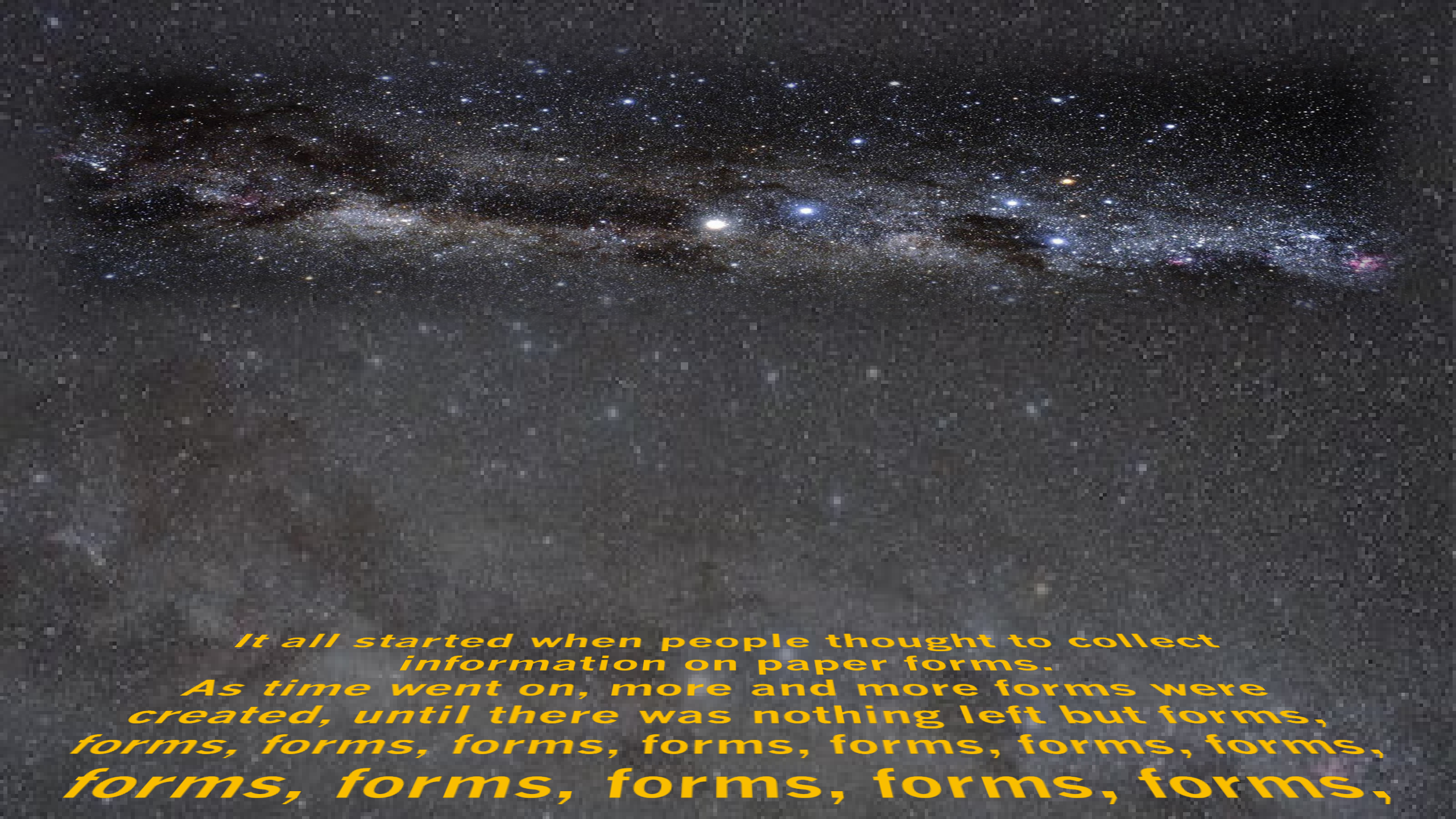
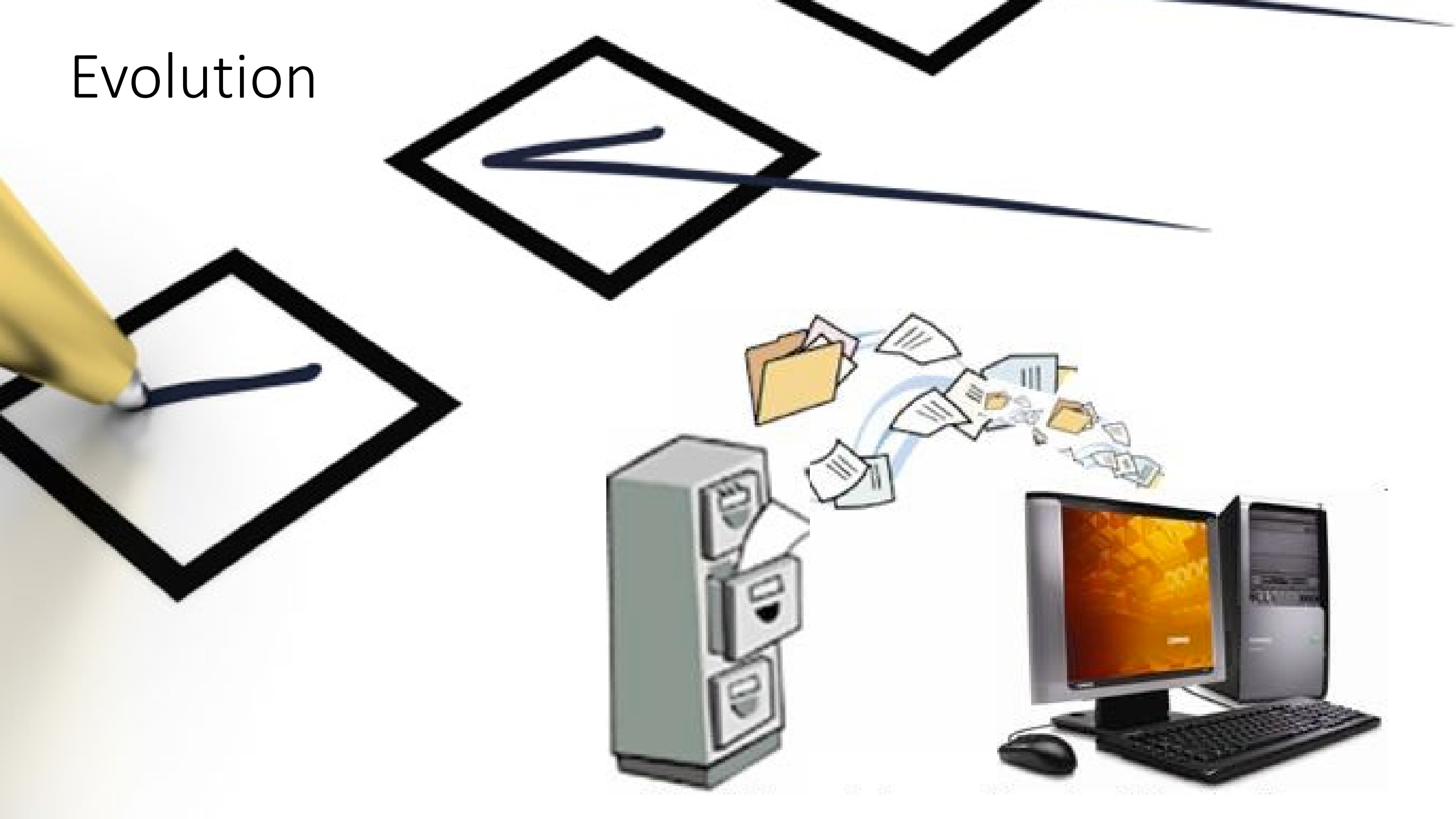
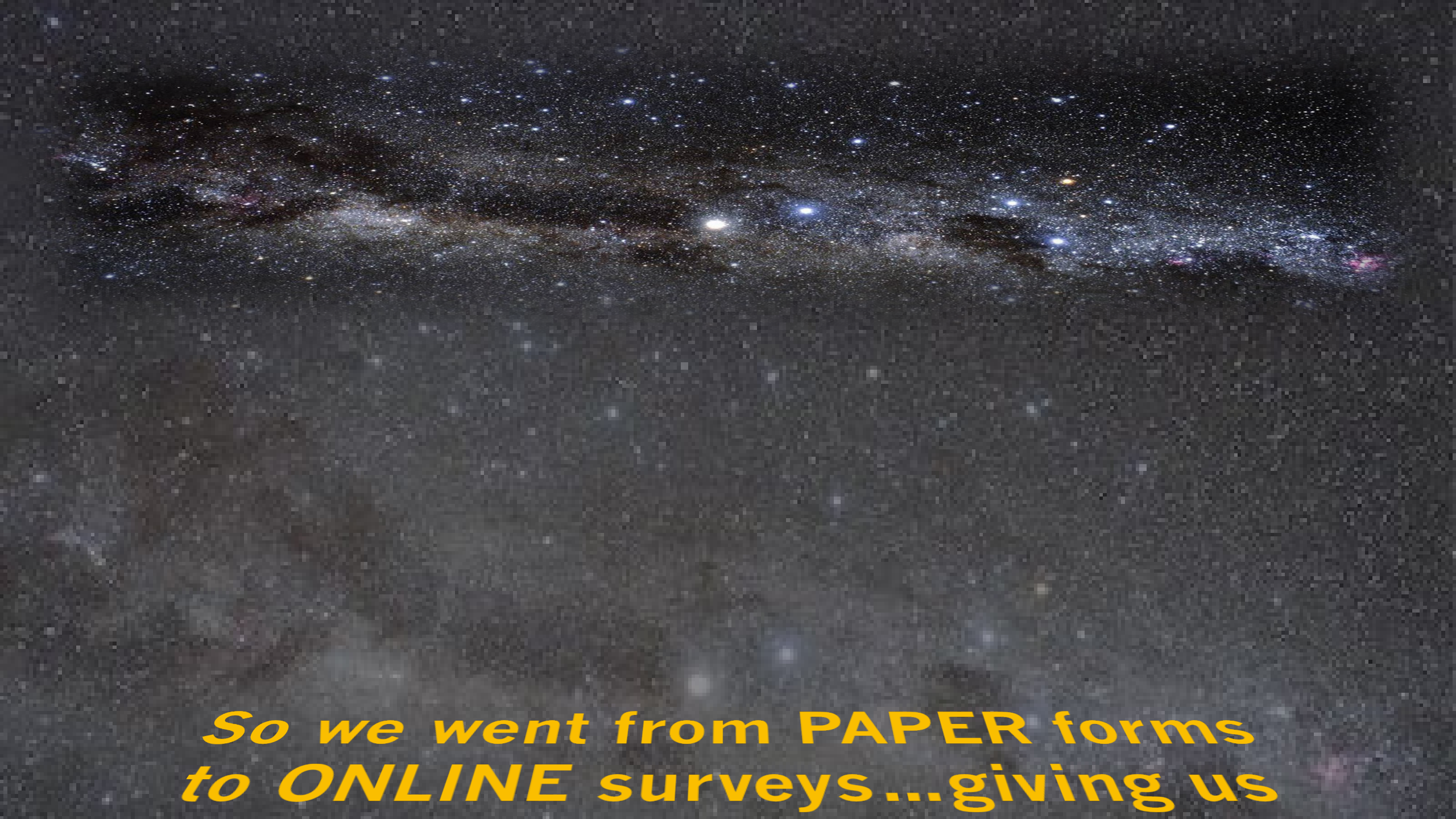

It all started when people thought to collect information on paper forms.
As time went on, more and more forms were created, until there was nothing left but forms,
forms, forms, forms, forms, forms, forms, forms,
forms, forms, forms, forms, forms, forms,

Paperwork burden!

Evolution




So we went from PAPER forms
to ONLINE surveys...giving us

CLICK HERE
Electronic burden!

Why?

Learning Objectives

How can we identify the source(s) of burden?

- Types of software systems
- Automation of business processes
- Supplemental off-line data captures.

How can we (gasp!) reduce the burden?

Burden Defined

- Adhere to regulation or [over] interpret regulation?
- “Required” but doesn't contribute to productivity?
- Confer delays, costs, and unpredictability?
- Examples:
  - Record keeping (sign/make an entry to say that something was done)
  - Reporting requirements (send a list/summary/data set as a status update)
  - Inspections (??)
  - Applications or information requests (i.e., forms)
  - Others?
- Administrative vs. Regulatory…

So then what is business process induced burden?

Scenario (part 1)

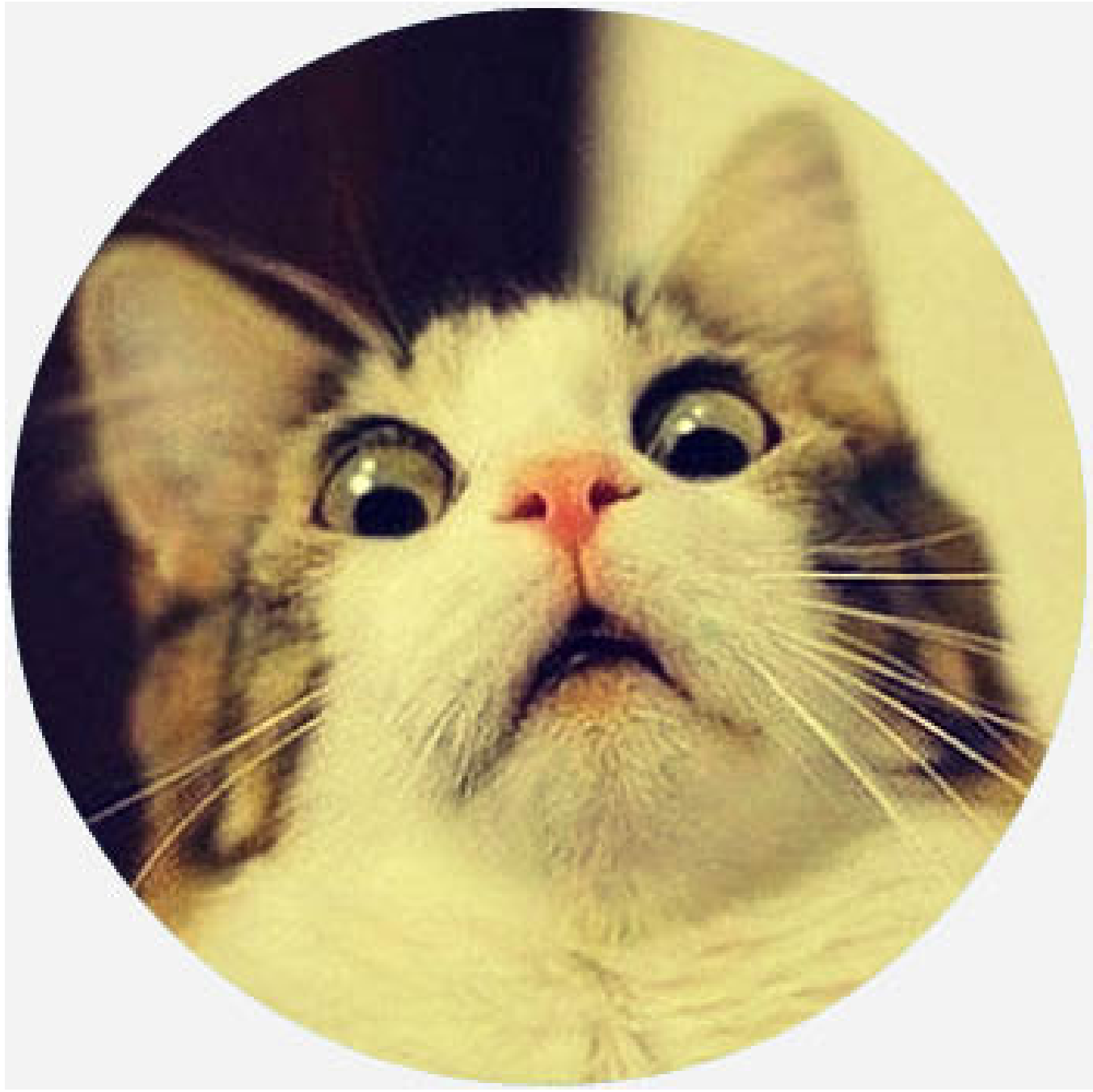
- I receive a letter from my child's school nurse that she is missing immunization information for my child, specifically on the chicken pox vaccine
- I call her to inform her that my child actually had the chicken pox, so there was no need for a vaccine.
- She says ok. She asks that, when convenient, my child's doctor update the state-wide immunization database (which both doctors and school nurses can access).
- I say ok. She has cleared my son. Nothing further is needed.
- All is well.

Scenario (part 2)

- AND THEN, my child's school's office administrator sends me a letter indicating the need for immunization information.
- I call.
- She informs me that she needs the chicken pox vaccine information to complete her file.
- I inform her that I spoke with the nurse.
- She informs me that she needs the information to complete her file.
- I ask what she will do with the information.
- She said she will send it to the school nurse.

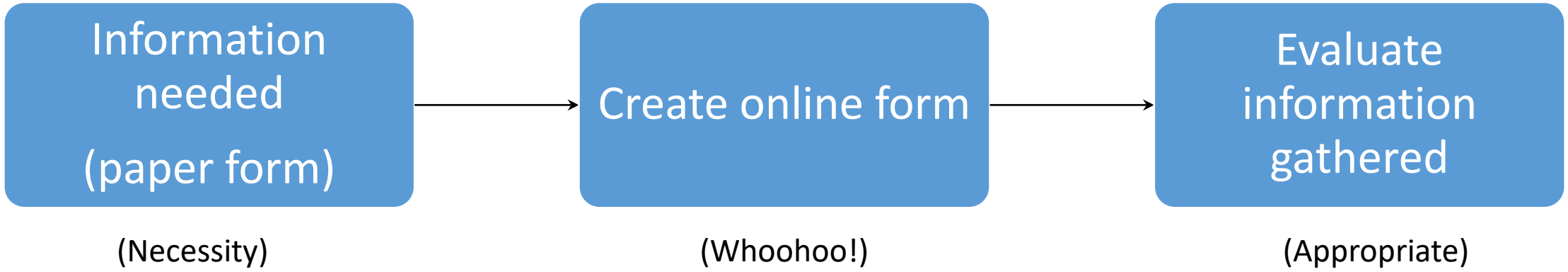
Scenario (part 2, continued)

- I inform her that I already talked with the school nurse and worked it out.
- She tells me she needs the paperwork to complete her file.
- I inquire about this database that can be accessed by the school nurse.
- She tells me about it. And that she needs the paper to complete her file so she can send it along to the school nurse.
- I thank her and politely tell her I can’t get it to her until the end of the week.
- I have forgotten to send it to her.

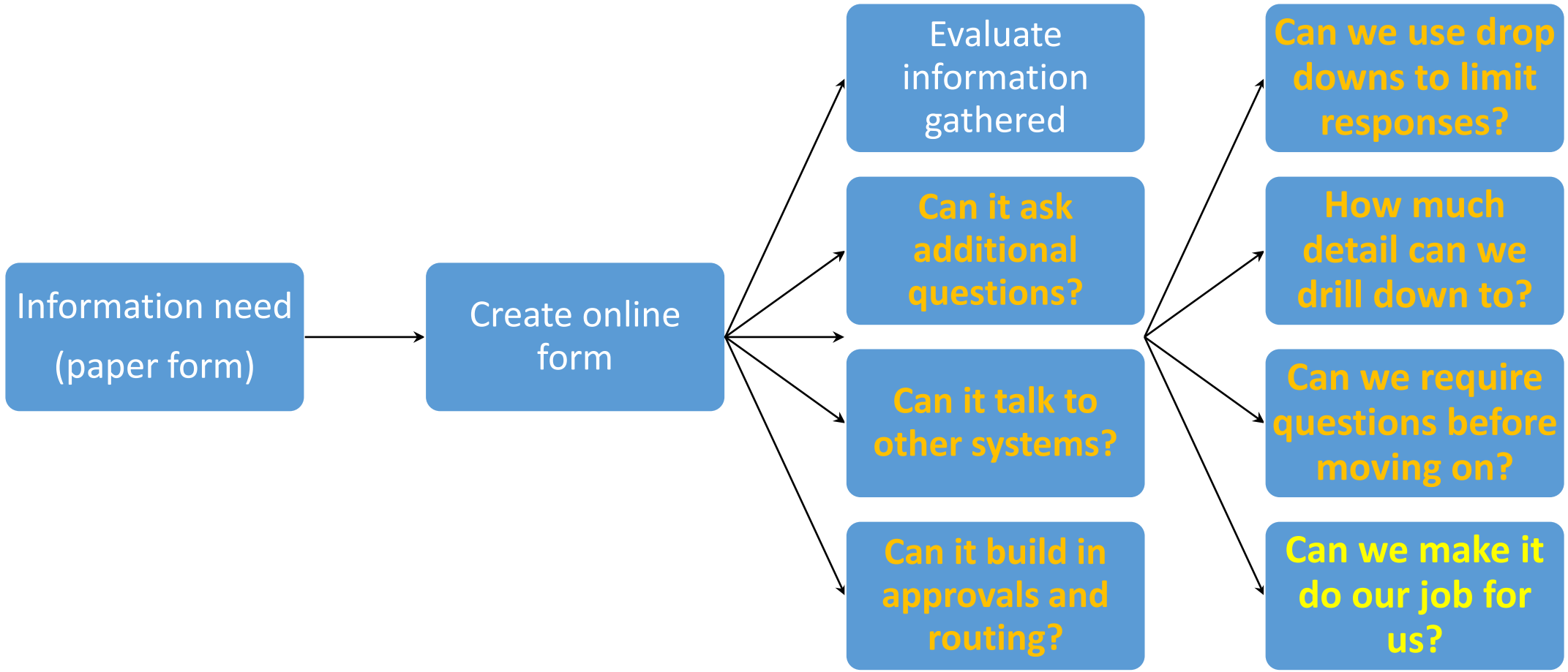


Why?

The natural progression from paper to online



The natural progression to self-imposed burden



Why self-imposed burden?

Why not just *progress*?

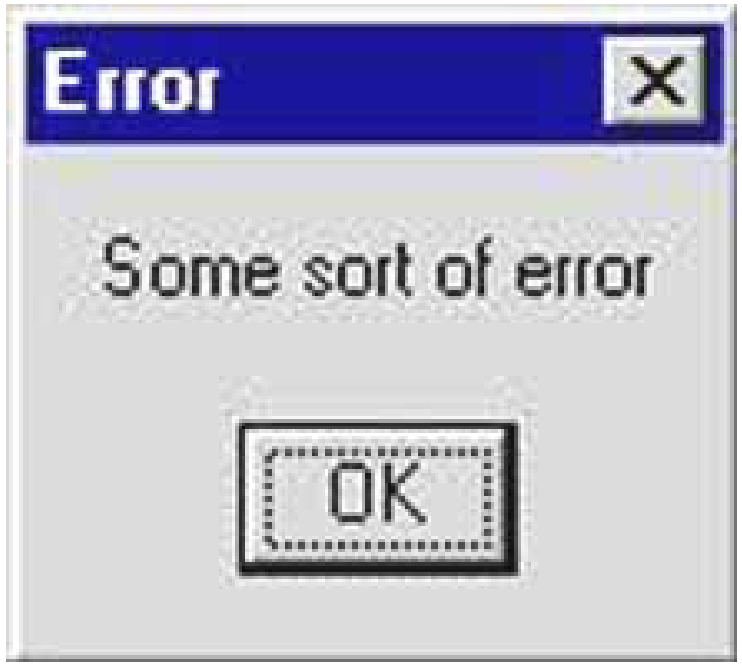
ANIMAL CARE & USE PROGRAM
UNIVERSITY OF MICHIGAN

- The Animal Care and Use Program (ACUP) at U-M includes:
  - Institutional Animal Care and Use Committee (IACUC)
  - Animal Care and Use Office (ACUO)
  - Unit for Laboratory Animal Medicine (ULAM)
  - Training Core (award winning): dedicated trainers, specialized workshops
  - ~600 Principal Investigators (animal users)
  - ~1192 active IACUC protocols (multiple species per protocol permitted)
  - 29 covered buildings and 200,000+ sq ft housing space (vivarium)
  - Annual animal use is in the tens of thousands
- Electronic eIACUC, significantly configured
- Bar coding, online transfer forms, online training records, detailed use and housing location information, etc.

Example 1

- IACUC Protocol (PRO)
  - Section on Anesthetics, tranquilizers, and sedatives
  - “Animal handling details” (response dictates required training)
  - System rule is to ensure congruency between
    - Any positive response to the section on anesthesia, tranquilizer, and sedatives
    - The selection of “anesthesia” in animal handling details
- Scenario: PI is administering a tranquilizer to the animal
  - Selects yes to the section
  - Leaves “anesthesia” blank in animal handling details
    - Evidently tranquilizers are not anesthetic agents

Result?


Error
Some sort of error
OK

Example 1 (rationale)

- If PI checks yes to section on Anesthetics, tranquilizers, and sedatives, then they must:
  - Also include a system validated anesthetic agent
  - Also select yes to anesthesia on animal handling details

- But:
  - Tranquilizers are not anesthetic agents

Example 1 (resolution)

- Workaround to permit the personnel amendment to move forward
- Occurred several times
- Time and energy of PI, ACUO staff, IT staff

Example 2

- Another institution (B) is using our facility for their animal work
- Institution B has an approved protocol already
- U-M and institution B have an MOU in place
- All animal work conducted at U-M

Problem?

How utilize our highly configured system to track the animals and PRO approvals if the PRO isn't "IN" our system?

(proposed) Solution?

Make them write a U-M protocol

Example 3

- ABSL-2 (biohazard) work is designated and approved in IACUC PRO
- Training is required based on selections in system
- Transfer of animals from ABLS-1 to ABSL-2 facilities requires submission of a ULAM-specific online form and approval of a transfer form (through our eIACUC).
- Scenario: PI wants to use a microscope that is in the ABSL-2 facility, but isn't using any BSL-2 substances.

- Guesses on how this plays out? ☺

Rutgers, the State University of New Jersey

- Newark
- New Brunswick
- Camden
    - Arts and Sciences IRB
    - Health Sciences IRB
        - Newark
        - New Brunswick
    - 4,001 active studies to date

Merger

- 2013
  - UMDNJ – Rutgers
  - Two different submission systems
    - Electronic vs. Paper
  - Two different FWAs
  - Business Processes
    - Today – all use the same electronic system

Grant Congruency

- Electronic system was purchased for human subject usage
  - Modules added
    - eCOI
    - RAPSS
  - Neither system talked to each other, didn’t have a common variable.
  - Once they did, they can all talk now
  - Workaround – had to constantly call the eCOI administrator as well as emails from grants specialists

Consultant

- Comes to your institution with a team. You speak to each member since they were brought in to ‘make the system better’.
- During meetings, you discover that they want to make the smart form questions not as many; cut them down.
- What resulted was a simpler process in the answers that investigators provide but more substance added to the attachments.
- Hence, more reading time on the part of the staff and the reviewers.

- Work-around – staff creates a cheat sheet that lists the common information that reviewers need.

Investigator Training

- One of your investigators wants to collaborate with another investigator from a different institution.
- Be the IRB of Record
- Human Subject Training (CITI)
  - Not the same modules are required

What do you do?

What **do** we do?

Don’t make the ham & cheese sandwich more complicated than it has to be.

Project “Ham sandwich”

Thummans

Black Bear

Applegate Farms

Healthy Choice

Hillshire Farm

House brand

Dry cured

Wet cured

Fresh ham

Butt end

Shank end

Center slice

Thin sliced

Thick sliced

Swiss

Provolone

White American

Yellow American

Cheddar (Mild, Sharp, Extra sharp?)

Muenster

Thin sliced

Thick sliced

Project “Ham sandwich”

Bread

- Roll
- Bun
- Sliced
- Wrap
- Pita

Thummans

Black Bear

A

He

Hills

House

- White
- Wheat
- Seeds
- Spinach
- Tomato

- Whole
- Half

:ed

ed

Butt end

Shank end

Center slice

Swiss

Provolone

White

Yellow

Cheddar

Muenster

Toppings

- Oil
- Vinegar
- Spices
- Mayo
- Mustard

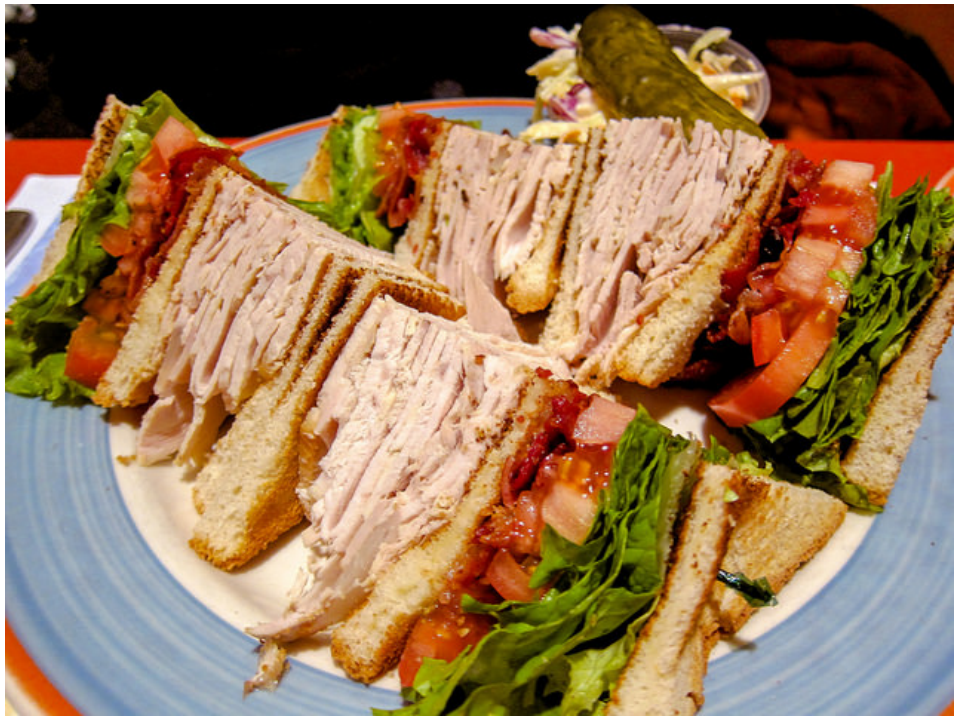
- Lettuce
- Onion
- Tomato
- Peppers
- Pickles

- Oregano
- Salt
- Pepper

Less is less or less is more?

How do we get our sandwich without imparting burden?

vs.



Burden – Source and Resolution (1)

- We paid a log of money for our software!!
- We shall therefore:
  - Build business processes around our software.
  - Design ways to make it do more for us, even if we have to collect a lot of additional information.
- Instead, how can we make the software work for us?
- Ask before you query:
  - Why do we need this data?
  - How will we use the data?
  - Can we get it any other way?

Burden – Source and Resolution (2)

- Something happened 1% of the time in 1% of the population,
- To make sure it never happens again, we're instituting a new policy / process for everyone!

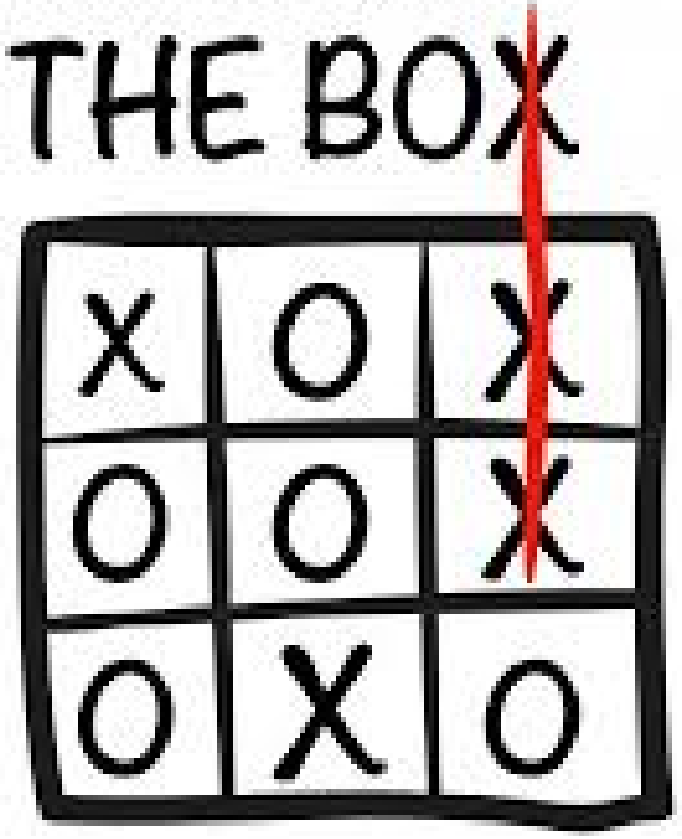
- Is 100% compliance attainable?
- Is the new policy / process more of a penalty to the majority vs. useful to the minority?
- Will the policy / process even address the root cause of the original issue?

Burden – Source and Resolution (3)

- Other?
- Resolution?

Electronic Submission

The Balance

Follow roadmap	Removes human factor
Automation	Removes interaction
Improve efficiency	Training
Enhances process management	Instruction guide
	Beta Testing

THINK
OUTSIDE
THE BOX