DO I NEED TO SUBMIT THIS?

- If your study even just potentially involves humans as "participants" and there's a chance you'll generate publishable data, then YES.

- Research is defined as "any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." (45 CRF 46.102d)

- Researchers are also not allowed to self-determine if they need IRB review…

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WHICH TYPE OF REVIEW?

- There are essentially 3 types of review:

1. Administrative (Exempt)
   - Protocol will be reviewed by the IRB committee chair or Director of Research and Sponsored Programs to determine whether it is Exempt or requires IRB review
2. Expedited
   - Protocols involving no more than minimal risk, no discomforts above what's encountered in daily living or routine procedures, do not involve deception, and do not include protected populations
3. Full-board
   - Everything else (more than minimal risk, additional discomforts, protected populations, etc.)

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INFORMED CONSENT

- Documentation of informed consent is required by default, but waivers may be requested.

- Waiver of documentation of informed consent:
  - You don't have to retain a signed informed consent, but you still have to provide all the elements of informed consent to the participants

- Waiver of elements of informed consent:
  - Some or all of the elements of informed consent are not provided to the participants.

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INFORMED CONSENT

Waiver of documentation of informed consent

One of the following must be true:

1. The signature on the informed consent document would be the only record linking the participant to the research, and the principle risk of harm to the participant would be a breach of confidentiality (e.g. research on illegal activities).
2. The research presents no more than minimal risk of harm to participants, and involves no procedures for which written consent is normally required outside the research context (e.g. anonymous online surveys).

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INFORMED CONSENT

For a waiver of some/all elements of informed consent, each of the following must be true:

1. The research involves no more than minimal risk to the participants
2. The research could not be practically carried out without the waiver
3. The waiver or alteration will not adversely affect the rights or welfare of the participants
4. When appropriate, participants will be provided with additional information about their participation (e.g. studies involving deception)

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WHAT DO I NEED TO SEND IN?

- An electronically signed protocol submission form
- CITI completion certificates link to training page for all research personnel
- Documentation of research site permissions (for studies conducted at locations other than Berry College)
- Copies of all materials used to recruit participants
- Copies of all materials that participants will interact with during their participation
- Documentation of emergency/contingency procedures or materials distributed to participants as a result of an adverse event
- Informed consent (and assent, if necessary) document(s) or scripts

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