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for the Study of Medicinal Cannabis and Hemp
INSTITUTE OF EMERGING HEALTH PROFESSIONS

Cannabis Research Information for Jefferson's Institutional Review Boards

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Plants in the Cannabis Family

- Marijuana
  - Contains cannabidiol (CBD) and tetrahydrocannabinol (THC), among other cannabinoids
  - THC is responsible for the well-known intoxicating effects of marijuana and is the focus of the majority of medical cannabis research
  - CBD:
    - Non-intoxicating
    - Potential treatment for a number of medical conditions
    - May increase the effectiveness of medications containing THC
    - May mediate some of the negative side effects associated with THC
- Hemp
  - Contains CBD with trace amounts of THC
  - Legal gray area

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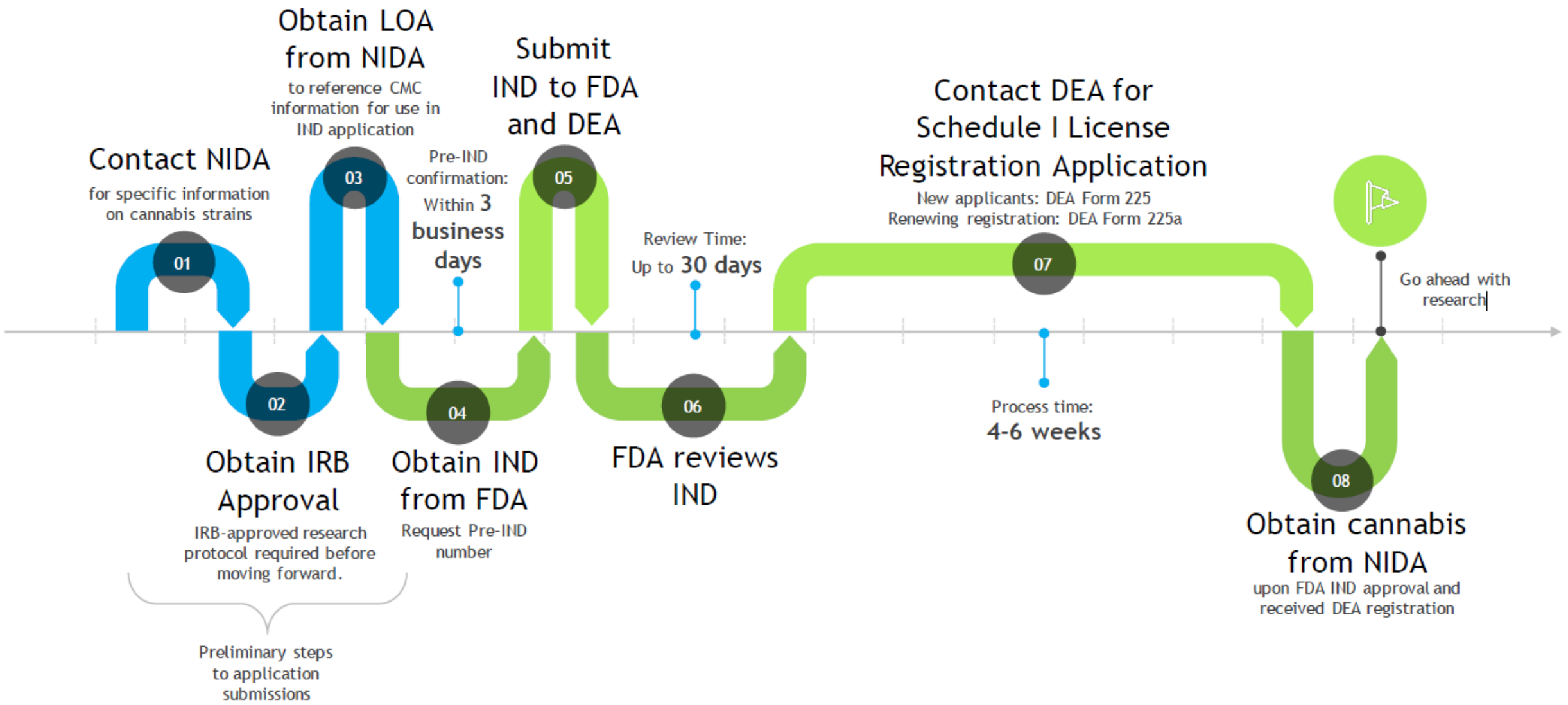
Cannabis: Schedule I Drug

- Schedule I drugs: No currently accepted medical use, high potential for abuse
- DEA currently lists “marijuana (cannabis)” as Schedule I
  - Certain medications (Epidiolex) containing CBD in schedule V
- DEA allows a single contract for the cultivation of research-grade cannabis
  - Potential for additional suppliers
- Process for initiating cannabis clinical trials is long and requires approvals from institutional IRB, DEA, FDA, and National Institute on Drug Abuse

Process for Conducting Interventional Research with Cannabis



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Preclinical Studies

- In vitro/in vivo studies requiring access to cannabis: same procedure as clinical trials, steps pertaining to human subjects skipped
  - Exception: research on a on a medication that may later be approved through the FDA
- Observational research: no need for FDA/DEA/NIDA approval unless cannabis is being provided by researchers
- Current regulations on CBD: hemp-derived products can be shipped interstate by the manufacturer for research

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Cannabis Research in Pennsylvania

- Medical marijuana legal with recommendation
- PA to be a “research hub” according to governor & legislators
- Chapter 20: provides for 8 ACRCs (universities) with CRs, affiliated research partners (growers/ processors/dispensaries)
  - May allow for tighter control of observational research
  - Will clinical trials be affected?

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Institutional Considerations

- Language used in physicians' recommendations
- Uncertainty in anticipated and actual participant response to medication relative to other medication used in observational research
- Media coverage of medications, especially with regards to CBD
- Equitability of access for diverse populations

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Areas to Watch

- Congressional legislation
  - 2018 Farm Bill
  - Rescheduling of cannabis from Schedule I
  - Legislation preventing federal agencies from interfering in state activities
- Departmental regulation language, especially DOJ
- FDA approach to cannabis medication & last-chance drugs
- PA – status of Chapter 20

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Questions for the IRB

- Can randomized or pseudo-randomized studies be approved?
- What language should researchers use to describe benefits and risks, given a number of unknowns that exist with cannabis?
- Can training be offered institutionally for researchers who wish to conduct research using cannabis?
- What about ACRC+CR developed studies, using PA-grown product?
- What about studies with hemp-derived CBD?

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Further Reading

FDA and Marijuana: FDA's role in the drug approval process, how the FDA supports sound scientific research

Botanical Drug Development: Guidance for Industry (FDA CDER)

"DEA speeds up application process for research on Schedule I Drugs"

"Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States"

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