Research Compliance Fundamentals

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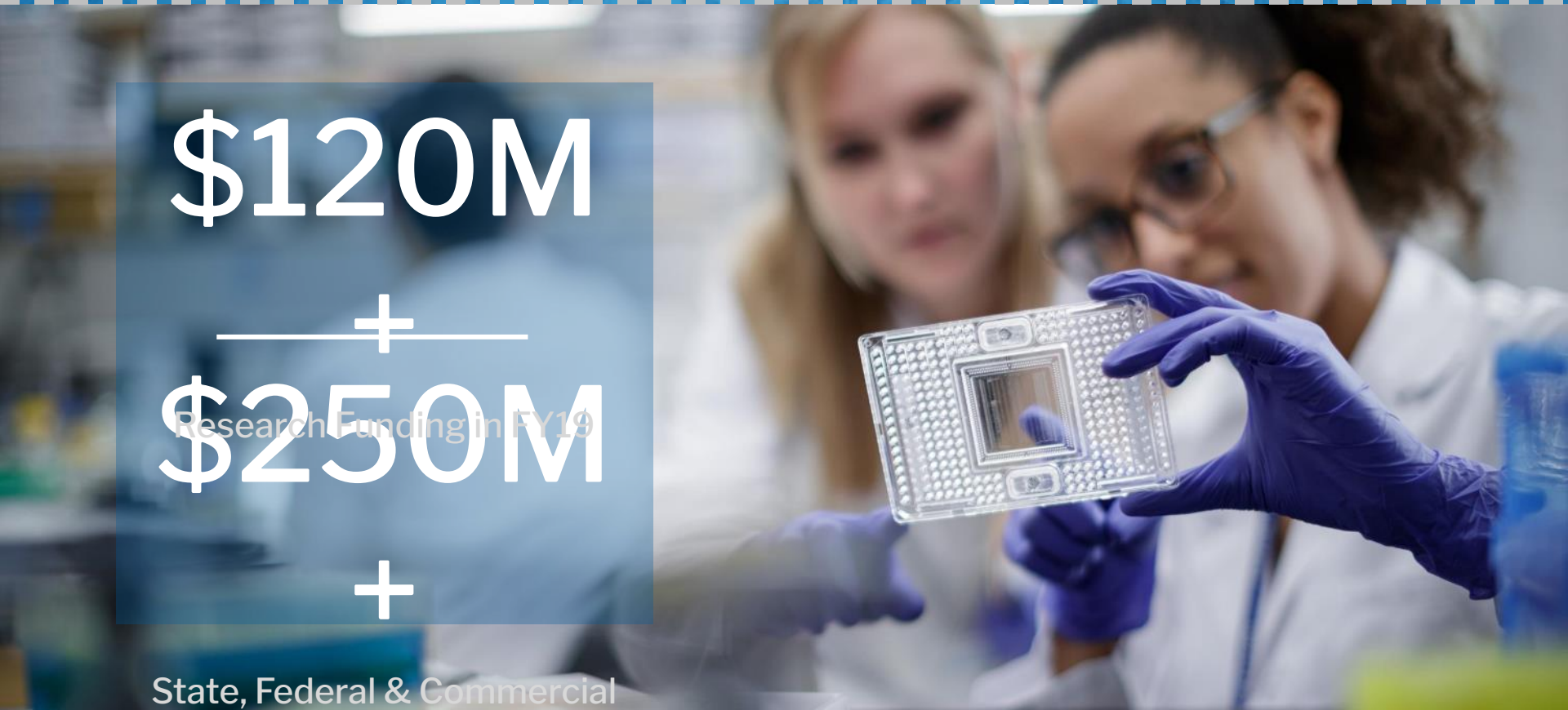
Your Courage Inspires Ours

Research

Moffitt's research focuses on cutting-edge discoveries that can be rapidly translated into improved diagnostic, preventive and therapeutic advances.

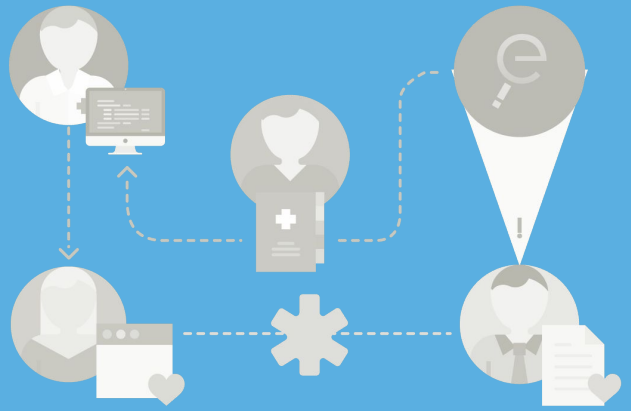


Clinical Trials

More than

1,900

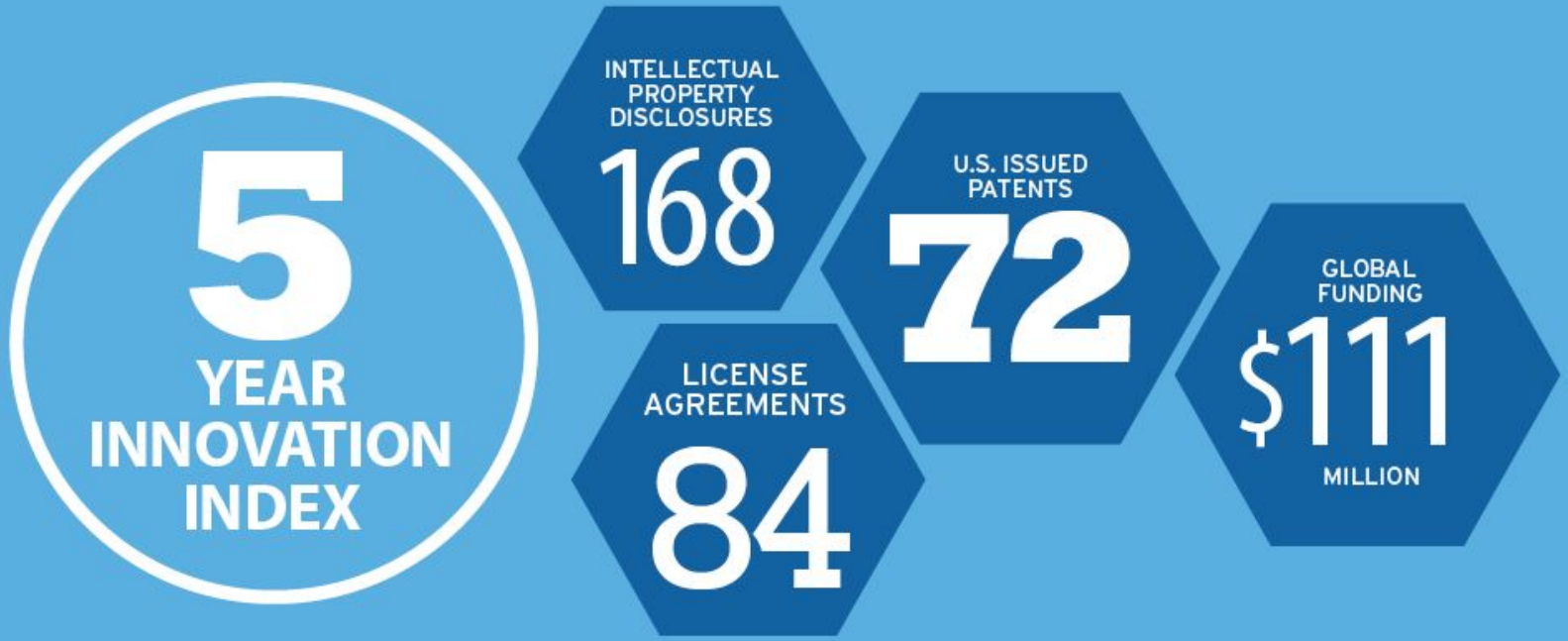
Clinical Trial Accruals Annually



630 Active Interventional Trials

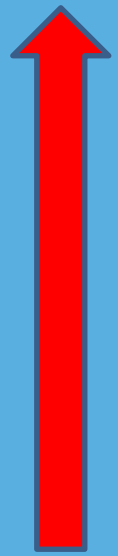
212 Trials initiated by Moffitt researchers

Expanding Industry Relationships



Advancing Moffitt discoveries by forging partnerships with startups and industry to bring cutting edge ideas and discoveries to the marketplace.

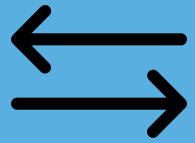
Landscape



- Volume of Activity
- Complexity
- Competition
- Scrutiny
- Demand for Accountability
- Large $ Investments in Facilities
- Pressure to maintain or decrease costs

Funding

Resources



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Research Compliance 101

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Research Compliance Areas

- Federal Awards
- Grant Expenditures
- Foreign Influence
- Animal Use & Care
- Human Subjects
- Stem Cells
- Research Safety
- Research Integrity
- Conflicts of Interest
- Controlled Substances
- Export Controls
- Research Information Privacy and Security

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Federal Awards & Grant Expenditures

- Time and Effort Reporting
- Allowable vs Unallowable Costs
- Foreign/Other funding or support

UW-Madison to pay $1.5 million to settle claim with U.S. government, DOJ reports

OIG Outlines Multiple Probes Into NIH, PIs Who May Have Failed to Disclose All Support

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Foreign Influence

Concerns include:

- "Shadow laboratories"
- Time commitment – sometimes full-time or substantial part time
- Substantial funding for research abroad (including start-up funds)
- Laboratory, equipment, personnel
- Signing bonus, salary, housing, other benefits
- Deliverables: training personnel, papers, patents/IP
- Creates conflicts of commitment (>100% effort), interest

NIH inquiries include 100s of investigators, resulting in investigator removals, terminations, repayments, and False Claims Act payments

> In order for NIH to make informed assessments of possible overcommitment and/or scientific or budgetary overlap, we will need to see complete copies (in original and in English translation) of foreign grants and employment contracts.

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Foreign Influence (con't)

Moffitt Cancer Center CEO, Center Director Resign after Compliance Review

December 18, 2019

Sacked Moffitt Officials Didn't Report Chinese Financial Ties

— Not clear what was done in exchange for payments

by Crystal Phend, Senior Editor, MedPage Today January 23, 2020

Hospitals

Top exec, researchers resign from Moffitt Cancer Center over concern of IP theft by China

House Select Committee begins query into Chinese interference in public research

The group will investigate Chinese involvement with UF and Moffitt.

By **Janelle Irwin Taylor** on January 22, 2020

The House Select Committee on the Integrity of Research Institutions kicked off Tuesday with its first meeting as the day was wrapping up in Tallahassee.

House Speaker **Jose Oliva** **convened** the committee to investigate foreign interference in United States publicly funded research, particularly by China.

Oliva launched the **committee** in response to situations at two Florida research institutions, Moffitt Cancer Center in Tampa and the University of Florida in Gainesville.

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Foreign Influence (con't)

本人以上信息均真实有效。
本人郑重承诺：被批准纳入“千人计划”半年内到岗，在华连续工作至少3年，每年不少于2个月。

The above information is true and correct.I promise to start working full time in China within six months after my application is approved. The minimum employment term is three consecutive years, with at least nine months working in China for each year.

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Human Subjects Research

- Common Rule
- Clinical Trial Billing
- OHRP
- IRB
- Informed Consent
- ICH-GCP

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FDA Regulations

- Investigational New Drug (IND)
- Investigational Device Exemption (IDE)
- Research Staff Qualifications
- In House Manufacturing
- Drug Accountability

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Export Controls

- What is Affected by Export Controls?
  - Foreign students and researchers' participation in research associated with a controlled technology
  - Ability to provide services to foreign nationals
  - Ability to send controlled equipment internationally
  - Disclosure of proprietary information
- Oversight of Export Controls
  - Dept. of State: Military technology
  - Dept. of Commerce: "Dual use" technology
  - Dept. of Treasury: Prohibits transactions with adverse

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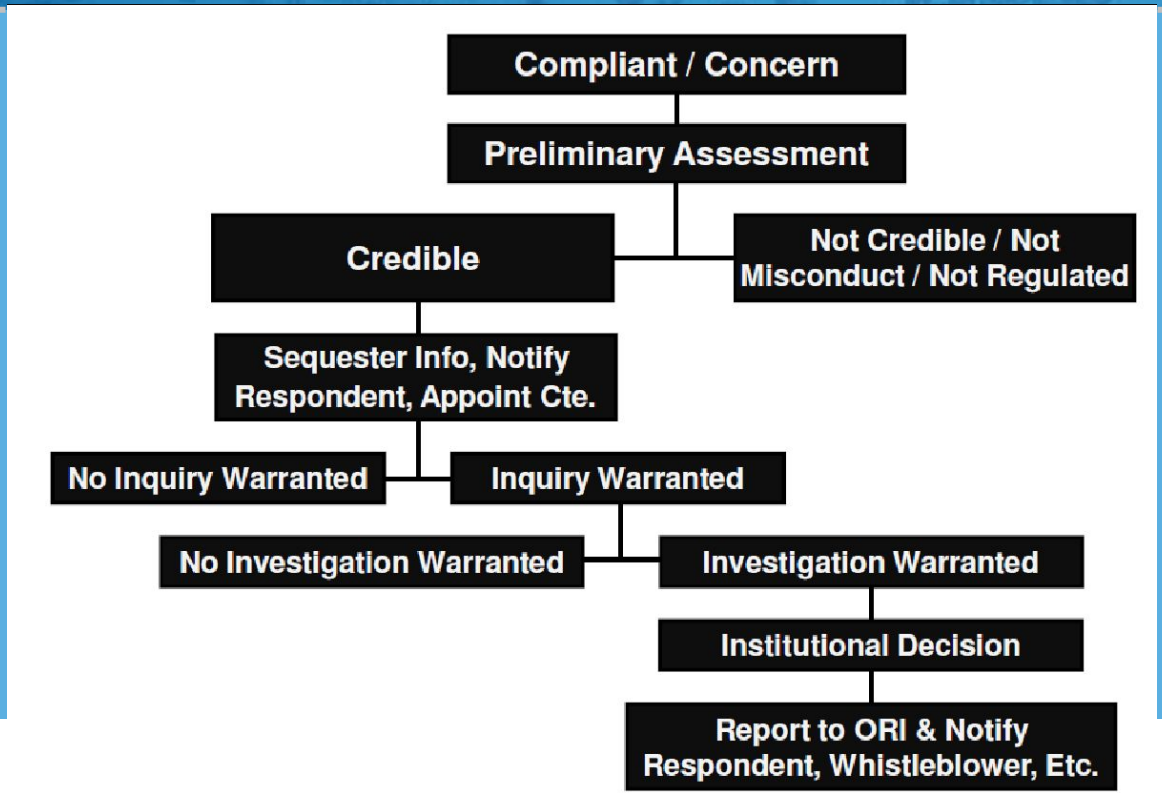
Research Integrity & Misconduct

Duke University settles research misconduct lawsuit for $112.5 million

www.pubpeer.com
www.retractionwatch.com

Harvard and the Brigham call for more than 30 retractions of cardiac stem cell research

Research Integrity & Misconduct



http://ori.dhhs.gov/

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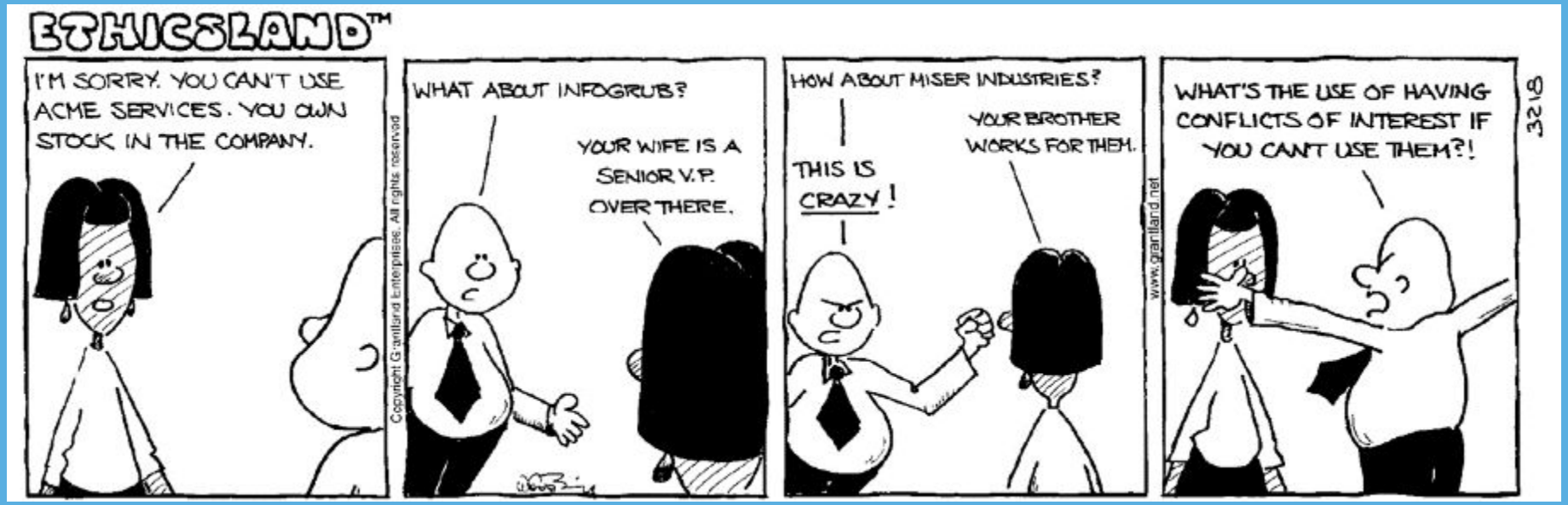
Conflicts of Interest



Conflicts of Interest

Financial Conflict of Interest (FCOI): Investigators engaged in PHS-supported research must disclose to their institutions *all significant financial interests as well as reimbursed and sponsored travel*.

- **Promotes objectivity in Research, ensuring there is "no reasonable expectation that the design, conduct, or reporting of Research will be biased or compromised by any conflicting financial interest of an Investigator."**
- **Investigator is defined as the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding.**

  Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work.

  For purposes of financial disclosure, the regulation also covers the Investigator's

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Conflicts of Interest Disclosure

Individuals' Conflict of Interest Disclosure Statement must be made prior to the submission of an application to PHS for research funding

- **COI Disclosure Statements must be made annually and to the Institution's designated official(s) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.**

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Conflicts of Interest Management

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institution Review Board, etc.);
- For research projects involving human subjects, disclosure of financial conflicts of interests directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); &
- Severance of relationships that create financial conflicts.

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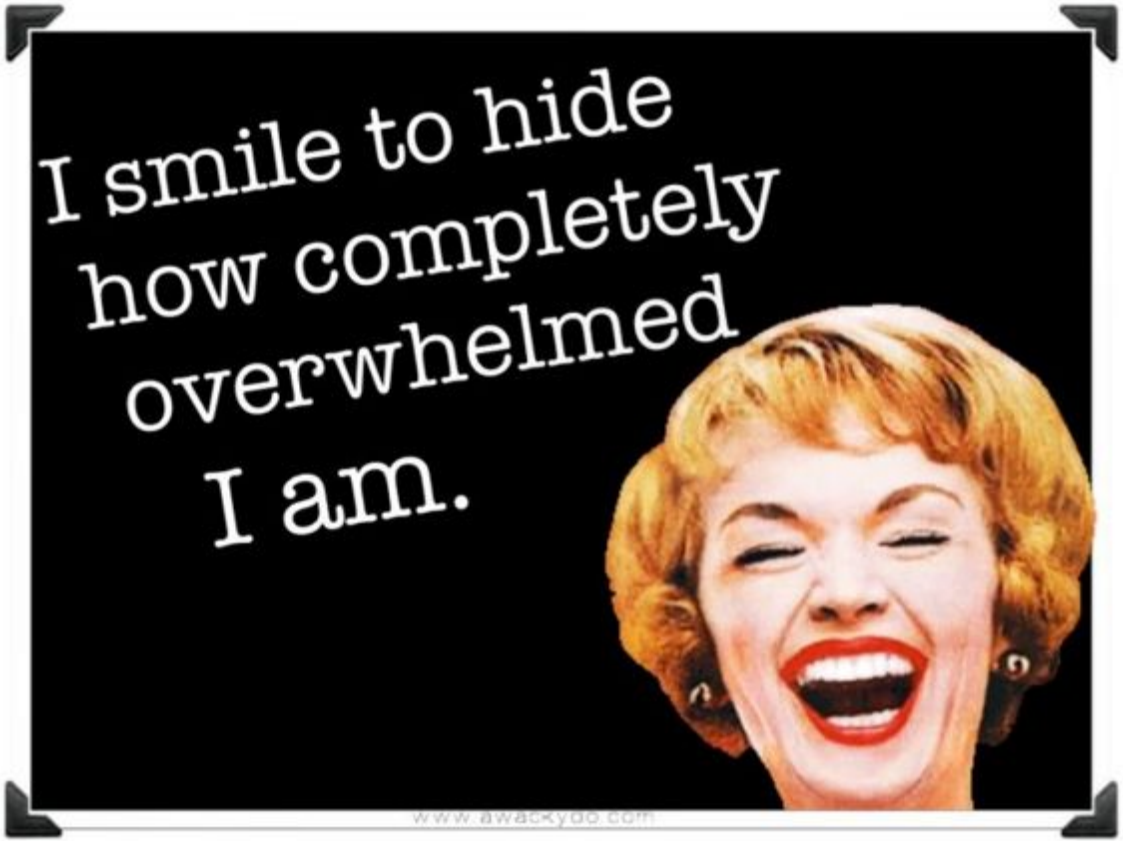
Where does one start?



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Questions?

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