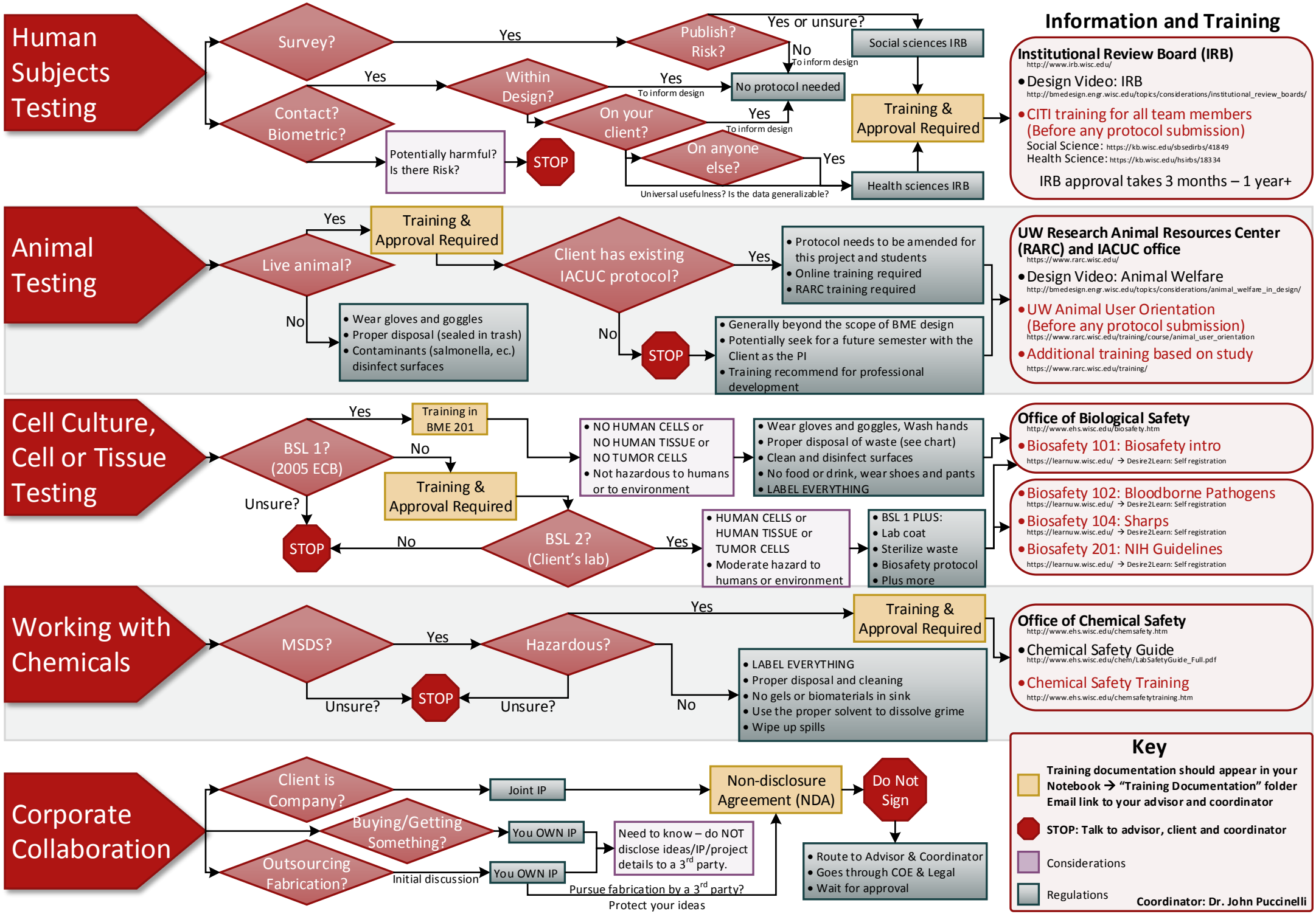
Human Subjects Testing
Survey?
Yes
Publish? Risk?
Yes or unsure?
Social sciences IRB
No
To inform design
Yes
Within Design?
Yes
To inform design
No protocol needed
Contact? Biometric?
On your client?
Yes
To inform design
Training & Approval Required
Potentially harmful? Is there Risk?
STOP
On anyone else?
Yes
Universal usefulness? Is the data generalizable?
Health sciences IRB
Information and Training
Institutional Review Board (IRB)
http://www.irb.wisc.edu/
Design Video: IRB
http://bmedesign.engr.wisc.edu/topics/considerations/institutional_review_boards/
CITI training for all team members (Before any protocol submission)
Social Science: https://kb.wisc.edu/sbsedirbs/41849
Health Science: https://kb.wisc.edu/hsirbs/18334
IRB approval takes 3 months – 1 year+
Animal Testing
Yes
Training & Approval Required
Live animal?
Client has existing IACUC protocol?
Yes
Protocol needs to be amended for this project and students
Online training required
RARC training required
No
Wear gloves and goggles
Proper disposal (sealed in trash)
Contaminants (salmonella, ec.) disinfect surfaces
No
STOP
Generally beyond the scope of BME design
Potentially seek for a future semester with the Client as the PI
Training recommend for professional development
UW Research Animal Resources Center (RARC) and IACUC office
https://www.rarc.wisc.edu/
Design Video: Animal Welfare
http://bmedesign.engr.wisc.edu/topics/considerations/animal_welfare_in_design/
UW Animal User Orientation (Before any protocol submission)
https://www.rarc.wisc.edu/training/course/animal_user_orientation
Additional training based on study
https://www.rarc.wisc.edu/training/
Cell Culture, Cell or Tissue Testing
Yes
Training in BME 201
BSL 1? (2005 ECB)
No
Training & Approval Required
Unsure?
STOP
No
BSL 2? (Client's lab)
Yes
NO HUMAN CELLS or NO HUMAN TISSUE or NO TUMOR CELLS
Not hazardous to humans or to environment
Wear gloves and goggles, Wash hands
Proper disposal of waste (see chart)
Clean and disinfect surfaces
No food or drink, wear shoes and pants
LABEL EVERYTHING
HUMAN CELLS or HUMAN TISSUE or TUMOR CELLS
Moderate hazard to humans or environment
BSL 1 PLUS:
Lab coat
Sterilize waste
Biosafety protocol
Plus more
Office of Biological Safety
http://www.ehs.wisc.edu/biosafety.htm
Biosafety 101: Biosafety intro
https://learnuw.wisc.edu/ → Desire2Learn: Self registration
Biosafety 102: Bloodborne Pathogens
https://learnuw.wisc.edu/ → Desire2Learn: Self registration
Biosafety 104: Sharps
https://learnuw.wisc.edu/ → Desire2Learn: Self registration
Biosafety 201: NIH Guidelines
https://learnuw.wisc.edu/ → Desire2Learn: Self registration
Working with Chemicals
MSDS?
Yes
Hazardous?
Yes
Training & Approval Required
Unsure?
STOP
Unsure?
No
LABEL EVERYTHING
Proper disposal and cleaning
No gels or biomaterials in sink
Use the proper solvent to dissolve grime
Wipe up spills
Office of Chemical Safety
http://www.ehs.wisc.edu/chemsafety.htm
Chemical Safety Guide
http://www.ehs.wisc.edu/chem/LabSafetyGuide_Full.pdf
Chemical Safety Training
http://www.ehs.wisc.edu/chemsafetytraining.htm
Corporate Collaboration
Client is Company?
Joint IP
Non-disclosure Agreement (NDA)
Do Not Sign
Buying/Getting Something?
You OWN IP
Need to know – do NOT disclose ideas/IP/project details to a 3rd party.
Outsourcing Fabrication?
Initial discussion
You OWN IP
Pursue fabrication by a 3rd party?
Protect your ideas
Route to Advisor & Coordinator
Goes through COE & Legal
Wait for approval
Key
Training documentation should appear in your Notebook → "Training Documentation" folder
Email link to your advisor and coordinator
STOP: Talk to advisor, client and coordinator
Considerations
Regulations
Coordinator: Dr. John Puccinelli