Consider the entities for qualifying requests

**Qualifying requests for Clinical Trials under INDs/IDEs**

Providing cellular material for use in clinical trials and IRB-approved studies is more straightforward because much of the due diligence has been done:
- Study design, intended use, informed consent has been approved by FDA or IRB committees
- Research subjects are protected
- Important considerations include funding source and product availability

**Qualifying requests for non-clinical research**

Use of cellular material for non-clinical research (i.e., tissue culture studies, animal studies) does not put a patient at risk:
- Consider nature of associating with requesting facility, funding source, product availability

**Qualifying requests for commercial entities**

Consider the commercial entity’s use of requested product:
- Appropriate regulatory approval IDE, (IND, BLA)
- If for non-human use, consider nature of associating with requesting company, funding source, and product availability

More information can be found under M2 “Considerations for Human Research- Commercial Use”
Consider what to ask before supplying cellular source material

**Intended Use?**
- How will the cellular material be used?
- What are the studies/data supporting this use? Are data published?
  Request Non-Disclosure Agreement (NDA) to discuss supporting data, if not published

**Processes Following?**
- What processing and manufacturing guidelines will be followed?
  Should demonstrate knowledge of cGMP/cGTP practices, intention to follow

**Adverse Event Tracking?**
- How are adverse events tracked and risks mitigated when handling, manufacturing, and administering cellular material?
- How is pathogen contamination prevented and monitored?
  Lack of risk management plan could leave cell source provider liable for patient harm

**Funding Sources?**
What is the source of the funding?
- Potential cause for concern if therapy is solely patient-funded.
- Legitimate clinical trials generally have funding for patient costs.
- Corporate funded trials have investment funding or healthcare coverage for patient costs.

**Contract, Please!**
- Ask for a contract addressing the questions listed
  This will provide legal documentation of “due diligence” and reduce liability if company fails to follow the practices they claimed to follow when requesting the cellular material

**Ask yourself…**
- “Am I comfortable with this facility being associated with my organization?”
  - If not: Ask, “What else do I need to know?” or decline to supply cellular material
  - Neglect by the company to whom you provide the material could severely hurt your brand, harm patients, and lead to lawsuits

More information can be found in M3 “Elements of Donor Safety and Consent”
More information can be found in M4 “Manufacturing Considerations”
More information can be found in M3 & M4
More information can be found in M5 “Agreements & Business Considerations”
Considerations if the qualifying requests are for cell therapies that are:
- unproven
- untested
- unapproved

Source of request

- There has been a sharp rise in requests for cellular source material to treat nearly every imaginable condition from groups like:
  - Chiropractors
  - Therapists
  - Orthopedic surgeons
  - Cosmetics companies

Material requested

- The most common cellular materials requested are sources for mesenchymal stromal cells (MSCs):
  - Bone marrow
  - Umbilical cord tissue/placenta

Lack of data support

- Many current uses of MSCs are not approved by the FDA and generally unsupported by published (clinical) data
- Those requesting materials will need to have IND/IRB/FDA documentation to support a request
- Beware of false clinical trials! Though trials may be listed on the clinical trials website, www.clinicaltrials.gov, it is important to check that there is a scientific framework and funding source

Question safety

- Facilities operating outside of IND/IDE/IRB-approved studies are likely not following guidelines for good manufacturing practices, sterility testing, safety monitoring, etc.
- Check whether a regulatory body has approved a facility’s manufacturing processes

FDA warnings

- FDA warnings and lawsuits to companies administering untested/unapproved therapies indicate that the providers of cellular material to these companies may be liable for damages when patients are harmed by the treatments.

More information can be found under M2 “Considerations for Human Research-Commercial Use”

More information can be found under M4 “Manufacturing Considerations”