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 straight-forward 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"

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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

More information can be found in M3 "Elements of Donor Safety and Consent"

Processes Following?

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

More information can be found in M4 "Manufacturing Considerations"

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

More information can be found in M3 & M4

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.

More information can be found in M5 "Agreements & Business Considerations"

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

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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

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

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

More information can be found under M4 "Manufacturing Considerations"

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.

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