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# Advancing Healthcare through Education & Research in BioTherapy



#### DISCLAIMERS AND LEGAL NOTICES

**This template** for Informed Consent to leech therapy (hirudotherapy) is provided by the BioTherapeutics, Education and Research Foundation, without warranties concerning the applicability of this draft at any specific facility. Please modify the document as needed to fit the specific policy, procedure, formulary, or logistic demands of your institution. Be sure to read and follow all warnings and labeling information associated with products used in the application and removal of leeches, and inform your patients of the true risks, benefits and options, as this is only a sample of the document that you should use.

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The BioTherapeutics, Education and Research (BTER) Foundation is a public charity whose mission is to support patient care, education, and research in treatment and diagnostic modalities that use live animals. More information about our services can be found at the address below, or on the internet at: <u>www.BTERFoundaiton.org</u>.

I, (Patient Name:) \_\_\_\_\_\_, acknowledge that I have been informed about the procedure of leech therapy, the reasons for its use, reasonable goals of therapy, likely risks, and appropriate alternatives, as outlined below. Furthermore, I acknowledge that I have had the opportunity to ask questions and have had those questions answered to my satisfaction.

# Description of the leech therapy procedure (check those that apply):

□ Placement of live leeches on the body (part of body: \_\_\_\_\_\_). The leeches will attach, bite, and suck approximately 10 ml (two teaspoons) of blood over the course of about 1 hour. During the process, they will introduce some natural chemicals from their saliva into the incision – chemicals that prevent the blood from clotting, take away pain, and decrease inflammation. The leeches will stop sucking blood and naturally drop off in about 45 – 90 minutes, but blood will probably continue to ooze from the bite site for many hours.

Photographs may be taken for the purposes of (delete all those not applicable) monitoring efficacy of the treatment, documentation in the medical record, teaching or publication.

Other aspects of treatment:

# Persons who will be involved in the procedure

]	

# Indications (reasons) for using maggot therapy (check those that apply):

- Remove excess blood
- Decrease pain
- Decrease inflammation:
- Other:

# Risks, Warnings Possible Complications

# The following risks are most common:

- Mild pain during treatment
- Prolonged after bleeding (bleeding from the leech bite)
- Itching and reddening of skin around the leech bite (allergy-like reaction)

# The following are examples of risks that are not very common:

- Infection at the bite site, or spreading from the bite site
- Temporary enlargement of lymph nodes
- Pigmentation changes/scarring at site of leech bite
- Temporary swelling of treated part of the body, arm, or leg

**Some side effects require treatment** (for example, compression bandages for bleeding, antihistamines for allergies, antibiotics for infection, etc.).

If serious or unexpected side effects should develop, please contact us by phone or come in to the medical practice/clinic for assessment.

#### **Contraindications and Warnings:**

Leech therapy should not be performed if (be sure to tell the doctor if you have any of these conditions):

- You are taking anticoagulant medications (e.g., Coumadin, Marcumar);
- You have hemophilia or other hematological diseases;
- You have acute gastric ulcers or erosive gastritis;
- You have significant anemia;
- You have immune deficiency, due to AIDS, cancer, chemotherapy, etc.;
- You have severe chronic diseases (advanced-stage cancer, dialysis, heart disease, liver disease, bleeding disorder, etc.);
- You have history of poor wound healing (often associated with poorly controlled diabetes mellitus, obesity, and long-term cortisone treatment);
- You have an allergy to any of the active substances in leech saliva;
- You have a tendency to develop keloids or scarring.

#### Alternative treatment options (check those that apply):

- Surgery:
- Medication: \_\_\_\_\_\_
- Phlebotomy with needles
- Other:

# Pre-procedure requirements (check those that apply):

- Answer all of the doctor's questions completely and honestly, including all underlying medical and surgical problems, medications, allergies, etc. Inform the doctor of any medical problems listed above, or which you believe might affect the efficacy and/or safety of this treatment.
- Study all of the information given: reading materials, videos, etc.
- Stop any medication or wound treatments so recommended by your health care provider, such as:
- Begin any medication or wound treatments so recommended by your health care provider, such as:

# Requirements during therapy (check those that apply):

U Wear comfortable clothing for the procedure, because you may need to sit still for over an hour.

Other:

# Post-therapy requirements (check those that apply):

- □ Keep all required appointments.
- □ Inform your therapist immediately if you or your wound develops symptoms that are unusual or problematic (fever, confusion, etc).
- Come in for a dressing change on the day after treatment.
- Come in for a check-up three to seven days after treatment, or sooner if complications arise.
- Other:

# Additional requirements (check those that apply):

#### **Consent and Signatures:**

Of my own free will and without coercion, I agree to undergo leech therapy and promise to adhere to the treatment and post-treatment activities stipulated above and described by my therapist, as these are intended to make the treatment most successful.

Potential risks, benefits, and alternative options have been explained to me, and all of my questions have been answered.

Patient / Client				
Name:	Signature:	Date:		
Physician / Therapist				
Name:	Signature:	Date:		
Person administering consent (if not the therapist):				
Name:	Signature:	Date:		
Witness				
Name:	Signature:	Date:		