



## **CONSENT AND DIRECTION FOR DICHLOROACETATE TREATMENT**

I hereby confirm that I have been diagnosed with cancer. I further confirm that I have elected to have Dr. Medicor Cancer Centres Inc. ("Medicor") treat my cancer with the drug dichloroacetate sodium ("DCA").

I understand that DCA is a drug that has been found (in lab studies) to rapidly shrink human breast, lung and brain cancers (published in *Cancer Cell*, 11, 37–51, January 2007), endometrial cancer (published in *Gynecol Oncol*, Vol 109, Issue 3, June 2008) prostate cancer in combination with radiation (published in *The Prostate*, May 2008), and several other cancer types.

I understand that DCA has also been shown to effectively treat an aggressive brain cancer called glioblastoma in human research (published in *Science Translational Medicine*, Vol 2, Issue 31, May 12, 2010). Research to determine how well it will work on other cancers in humans is ongoing. I understand that high dose intravenous DCA has been studied and found to be safe (up to 100mg/kg iv in healthy volunteers and up to 80mg/kg iv in seriously ill liver transplant patients).

I am aware that the DCA treatment provided by Medicor is a promising cancer treatment, but has limited scientific proof of its effectiveness (either on its own, or combined with other treatments). I understand that the College of Physicians and Surgeons of Ontario considers DCA treatment to be unproven and not within the usual practice of medicine in this province. I confirm that no-one associated with Medicor has advised me to avoid conventional treatment for my cancer, and to take DCA instead.

I confirm that one of the following is true:

*A. I am not currently being offered medical treatment of my cancer, either because all standard medical treatments have failed, or because my oncologist (or other specialist) has determined that there are no proven treatment options for me. I understand that instead of DCA, I have a choice to receive no treatment for my cancer, and that I have the option of receiving only comfort care (palliative care).*

*B. I am currently receiving generally accepted medical treatment for my cancer which is not working optimally (or has a poor chance of success) and I would like to combine it with DCA treatment.*

*C. I have been offered generally accepted medical treatments for my cancer. After reviewing the risks and benefits of those treatments with my doctor(s), I voluntarily chose not to receive them. At this time I would like to be treated with DCA.*

### **Potential Benefits**

I understand that:

- it is hoped that DCA will cause slowing or stabilization of cancer growth, shrinking of cancer, or remission of cancer
- it is hoped that DCA will enhance the effects of my other cancer treatments (like radiation or chemotherapy) if taken according to the instructions given to me by Medicor
- it is expected that DCA may improve my heart condition (for patients with heart failure or angina)
- it is expected that DCA may improve my blood pH (if it is too acidic)

- the likelihood of these benefits is unknown
- it is expected to take 6 to 8 weeks before we can tell if the DCA is effective
- Medicor may collect information from my treatment to help doctors and patients learn more about DCA as a treatment for cancer, and that this information may be used to help future cancer patients
- my privacy will be maintained at all times in this process

### Potential Risks

I understand that:

- DCA has been used in humans to treat a rare disease called congenital lactic acidosis, and found to be safe
- DCA is likely safe to use in cancer patients, but there is not enough research yet to confirm this
- I may have side effects while receiving DCA
- I will be watched carefully for any side effects
- doctors don't know all the side effects that may happen
- side effects may be mild or serious
- I may be given medicines to help lessen side effects
- many side effects go away soon after I stop taking DCA
- DCA may interact with other medications I am taking, especially those that can cause confusion or memory problems
- DCA may interfere with other cancer medication if I do not follow the instructions given to me by Medicor

### Common Side Effects

I understand that:

- DCA can cause temporary nerve injury in the hands and feet
- this may be reduced with supplemental medication (which will be prescribed with DCA) and is treatable if it occurs, by stopping DCA and allowing the nerves to heal
- DCA can cause fatigue, sleepiness, nausea, heartburn, temporary memory loss, temporary confusion and tremors.
- DCA can cause a mild reduction in blood glucose (typically < 15%) which generally causes no symptoms

### Uncommon Side Effects

I understand that:

- DCA can rarely cause abdominal pain, abnormal increase of liver enzymes in the blood, vomiting, low blood pressure / dizziness, emotional changes, loss of balance or leg weakness
- Some animal studies show that DCA can cause liver cancer. These studies used doses which are over 100 times higher than what would be prescribed for cancer treatment
- if DCA is very effective, it can lead to rapid tumour cell death. This can cause sweats, chills, fever, tumour bleeding, life-threatening salt imbalance in the blood, low blood sugar, abnormal heart rhythm and kidney damage. This is mainly a concern when treating lymphoma or leukemia with DCA in combination with chemotherapy.
- I may have an unpredictable reaction to the infusion (for intravenous DCA only). This is because the published information on intravenous DCA is limited (even though current publications indicate it is safe).

### Unknown Side Effects

I understand that:

- DCA can cause side effects which are as yet unknown, and unpredictable
- DCA may not be effective at treating my cancer, but is unlikely to worsen my cancer

### Monitoring for Side Effects

I understand that:

- while receiving DCA I will be monitored to ensure safety, and for effectiveness of the treatment. This will consist of a various combinations of routine check-ups, lab tests, and imaging studies which may be as follows:
  - General blood tests
  - Tumour markers (if appropriate)
  - ECG (if needed)
  - Urinalysis (if needed)
  - Imaging studies (such as Ultrasound, CT scan, MRI, or PET scan)
- the frequency of tests will depend on the nature of my cancer, my age, my underlying medical conditions, my concurrent medications and other factors
- in most cases, a detailed assessment and tests will be done at the start of treatment, and monthly after that
- basic tests will generally be performed every week or every 2 weeks

### Follow-Up

I understand that while receiving DCA I will be monitored to ensure safety, and for effectiveness of the treatment. For telemedicine patients or patients who cannot attend in person regularly at the office: I confirm that I have a local doctor who will be the primary doctor monitoring my treatment according to the treatment plan I receive from Medicor.

### Reproductive Risks – for women

I understand that:

- I should not become pregnant while taking DCA, because the effects of DCA on an unborn baby are not know
- I should not breastfeed a baby while receiving DCA
- reliable birth control approved by my family doctor must be used while receiving DCA (if applicable)

### Reproductive Risks – for men

I understand that:

- I should not father a baby while taking DCA
- reliable birth control approved by my family doctor must be used while receiving DCA (if applicable)

My decision to undergo the DCA treatment is entirely voluntary. I understand that I may discontinue the DCA treatment at any time. My decision to stop DCA treatment will not affect my medical care. I understand

that the DCA treatment may be stopped if the medical staff so determine that it is in my best medical interests.

If I am to receive intravenous DCA outside of the Medicor office, I agree that it will only be infused by medical practitioner who is certified for, and experienced with intravenous medication infusion.

I understand that Medicor is owned by a family member of the Medical Director. I understand that any diagnostic tests or treatment provided by the Medical Director and/or Medicor will only be performed for my benefit, and that I have a choice of where I may obtain such diagnostic tests or treatments.

I understand that the results of the DCA treatment are not guaranteed. I acknowledge that no guarantee or assurance has been made by anyone from Medicor regarding the DCA treatment.

I have read and understand the Medicor Telemedicine / Email policy. I understand the risks associated with email communication, and I consent to the conditions outlined in the policy. I acknowledge Medicor's right to withdraw the option of communicating through email, upon the provision of notice.

I understand that after my DCA prescription medication has finished, if I choose to get my DCA prescribed elsewhere, Medicor will no longer be responsible for my assessments, blood tests or other diagnostic tests associated with this treatment. (Medicor is only responsible for the duration of the therapy prescribed by the Medical Director). I have the option to request a copy of the Medicor Drug Prescribing Policy for further information.

I have been given the opportunity to read this form and discuss it with the medical staff, and to ask any questions I may have. My questions have been answered to my satisfaction. I voluntarily consent to the DCA treatment and I accept all of the risks associated with it.

Costs

I understand that I am responsible for the cost of the DCA for my treatment, as it is not funded by Ontario Drug Benefits and generally not funded by private medical insurance. I understand that I am also responsible for the cost of any related drugs that are prescribed for my treatment, or to reduce DCA side effects (since they may not be funded by Ontario Drug Benefits or private medical insurance). I will also be responsible for the costs of any tests that may be necessary but are not covered under my health insurance.

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Patient's Signature  
(or legal substitute)

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Printed Name

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Date

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Witness' Signature

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Printed Name

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Date

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Medicor Staff Signature

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Printed Name

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