



Unpacking Consent

Professional & Regulatory Obligations for Dietetic Practice

MODULE 2: Informed Consent to Treatment

2017



Contents

Section I: Why do RDs Need Consent?

Section II: When is Informed Consent to Treatment Required?

Section III: Obtaining Informed Consent

Section IV: Express vs. Implied Consent

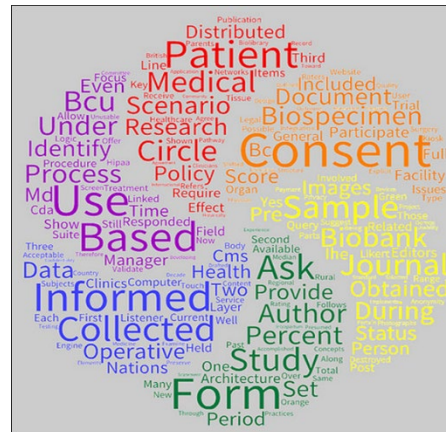
Section V: Scenarios





Section I

Why do RDs Need Consent?





It's the Law



1. *Health Care Consent Act, 1996* (HCCA)
2. Professional Misconduct Regulation under
Dietetics Act, 1991



Professional Misconduct

6. Doing anything to a client for a therapeutic, preventative, palliative, diagnostic, cosmetic, research or other health-related purpose in a situation in which a consent is required by law, **without such a consent.**





Professional Misconduct

“5. Failing to maintain a standard of practice of the profession.”

“22. Failing to keep records as required.”



Client-Centred

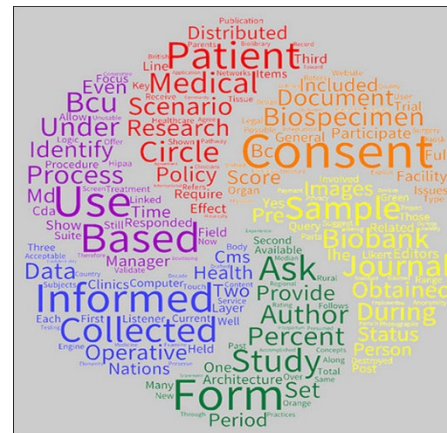


College of Dietitians of Ontario



Section II

When is Informed Consent to Treatment Required?





What is Treatment?

“Anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health-related purpose, and includes a **course of treatment, plan of treatment or community treatment plan.**”

Health Care Consent Act, 1996





Course of Treatment

Series or sequence of similar treatments administered over a period of time for a particular health problem.

Health Care Consent Act, 1996





Plan of Treatment

- Developed by one or more health practitioners
- Deals with one or more health problems currently and in the future
- Administration of treatment or course of treatment
- May include withholding or withdrawing treatment

Health Care Consent Act, 1996



Community Treatment Plan

A plan of treatment and supervision for a person who suffers from a serious mental disorder that is less restrictive than being detained in a psychiatric facility.

Mental Health Act, 1990





For a chart review or screen, RDs can rely on implied consent



College of Dietitians of Ontario





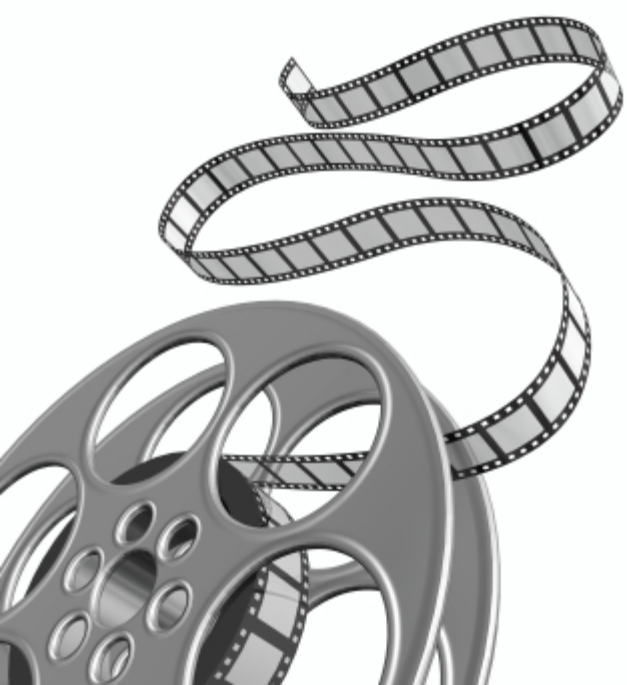
Consent to Treatment Includes...

- a. Consent to variations/adjustments in the treatment, if benefits, risks and side effects are not significantly different from original treatment; and
- b. Consent to the continuation of the same treatment in a different setting.

Health Care Consent Act, 1996



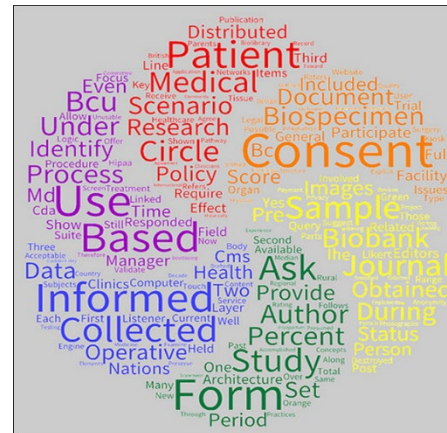
EMERGENCY





Section III

Obtaining Informed Consent





Informed Consent Process

1. Information

2. Understanding

3. Respect Client Decisions

4. Interprofessional Collaboration





1 . Information

Six Elements for Informed Consent

1. Nature of treatment must relate to the specific treatment, including the assessment being proposed.
2. The expected benefits.





1 . Information

-
-
-
-

Elements of Informed Consent

-
-
3. Material risks & side effects (what is likely to occur, even if not serious or what is less likely to occur that is serious).
4. Alternative courses of action.



1 . Information

Elements of Informed Consent

5. Likely consequences of declining the intervention.
6. Specific questions or concerns.



1 . Information

Consent must be
given voluntarily





Informed Consent Process

2. Understanding	

2. Understanding

Conversations should be
between experts

I'm an expert
on healthcare

I'm an expert on
ME and my life!

Patient

"INFORMED" CONSENT

WHAT DID I
AGREE TO?

the study groups:

combination with low dose AMG 655
combination with high dose AMG 655
combination with placebo (solution that looks like AMG 655 but with

a group by chance.
nor the researchers will
in any group. Neither

usly (IV) through a
y, you will be asked
al markers that may
product and for the in
fact of the AMG 655

Study Purpose: Treatment of Subjects with Metastatic Colorectal Cancer

- If you are pregnant, a pregnancy test will be performed before you enter the study.
- If possible, if your previously removed tumor (when available) during the study for clinical care purposes will be collected. The special markers that may help researchers develop tumor the usefulness of the investigational product in colorectal cancer.

Your eligibility for this study will be assessed within 21 days. If you will enter the treatment period.

Treatment Period

In part 1, all participants will be receiving the same treatment: AMG 655 and Bevacizumab.

In part 2, you will be "randomized" into one of the study groups:

1. mFOLFIRINOX and Bevacizumab in combination with low dose AMG 655
2. mFOLFIRINOX and Bevacizumab in combination with high dose AMG 655
3. mFOLFIRINOX and Bevacizumab in combination with placebo (solution that looks like AMG 655 but with no medicine)

Randomization means that you are put into a group by chance. It is done by a computer. Neither you nor the researchers will have a one in three chance of being placed in any group. Neither you

Trial Objectives: A Phase II/III Study of the Effect of AMG 655 in Combination with Bevacizumab and mFOLFIRINOX in Subjects with Metastatic Colorectal Cancer

- If you are pregnant, a pregnancy test will be performed before you enter the study.
- If possible, if your previously removed tumor (when available) during the study for clinical care purposes will be collected. The special markers that may help researchers develop tumor the usefulness of the investigational product in colorectal cancer.

Treatment Period

In part 1, all participants will be receiving the same treatment: AMG 655 and Bevacizumab.

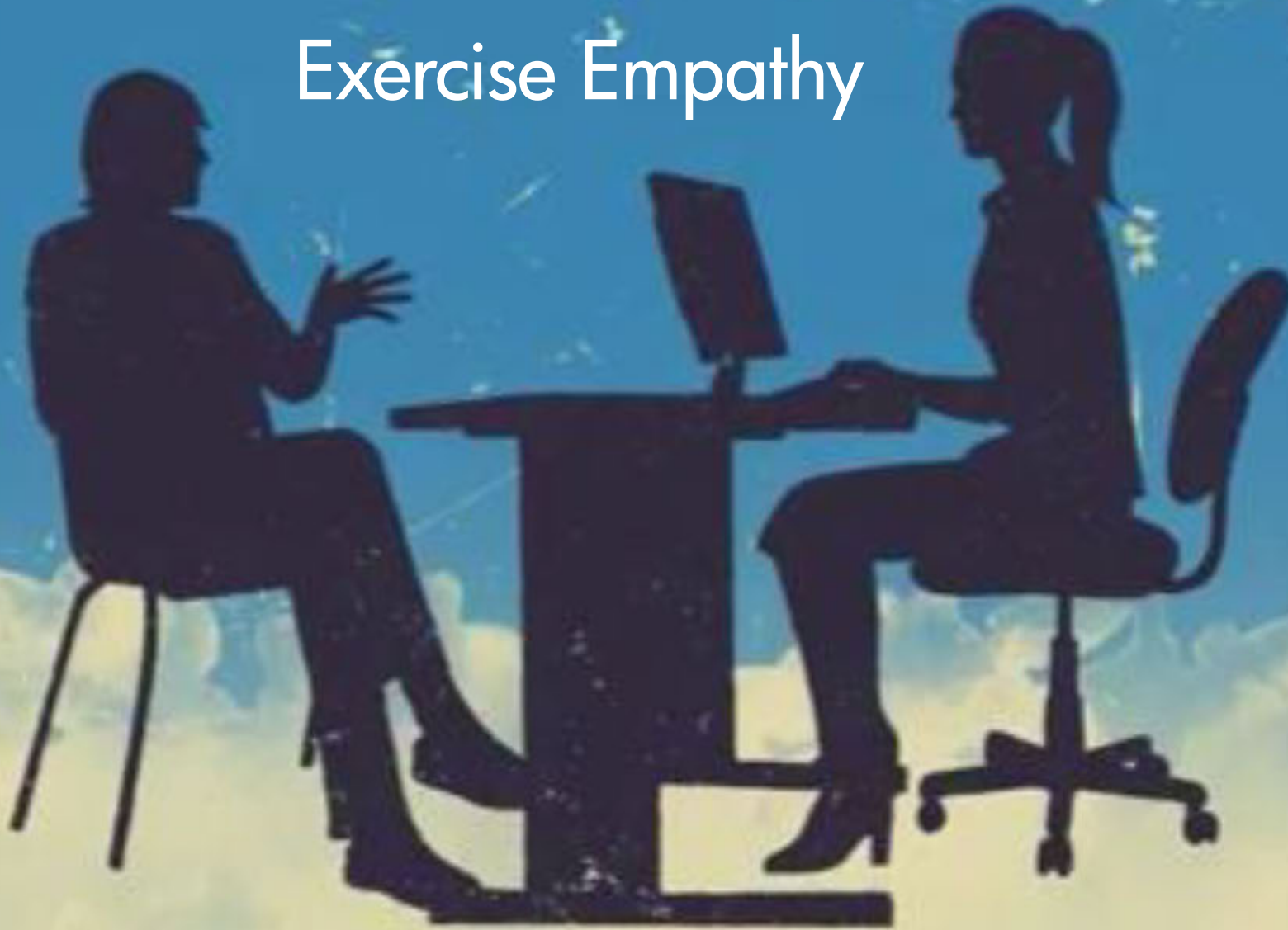
In part 2, you will be "randomized" into one of the study groups:

1. mFOLFIRINOX and Bevacizumab in combination with low dose AMG 655
2. mFOLFIRINOX and Bevacizumab in combination with high dose AMG 655
3. mFOLFIRINOX and Bevacizumab in combination with placebo (solution that looks like AMG 655 but with no medicine)

Randomization means that you are put into a group by chance. It is done by a computer. Neither you nor the researchers will have a one in three chance of being placed in any group. Neither you

(1 Cycle).

Exercise Empathy





2. Understanding

Capacity

Has
capacity

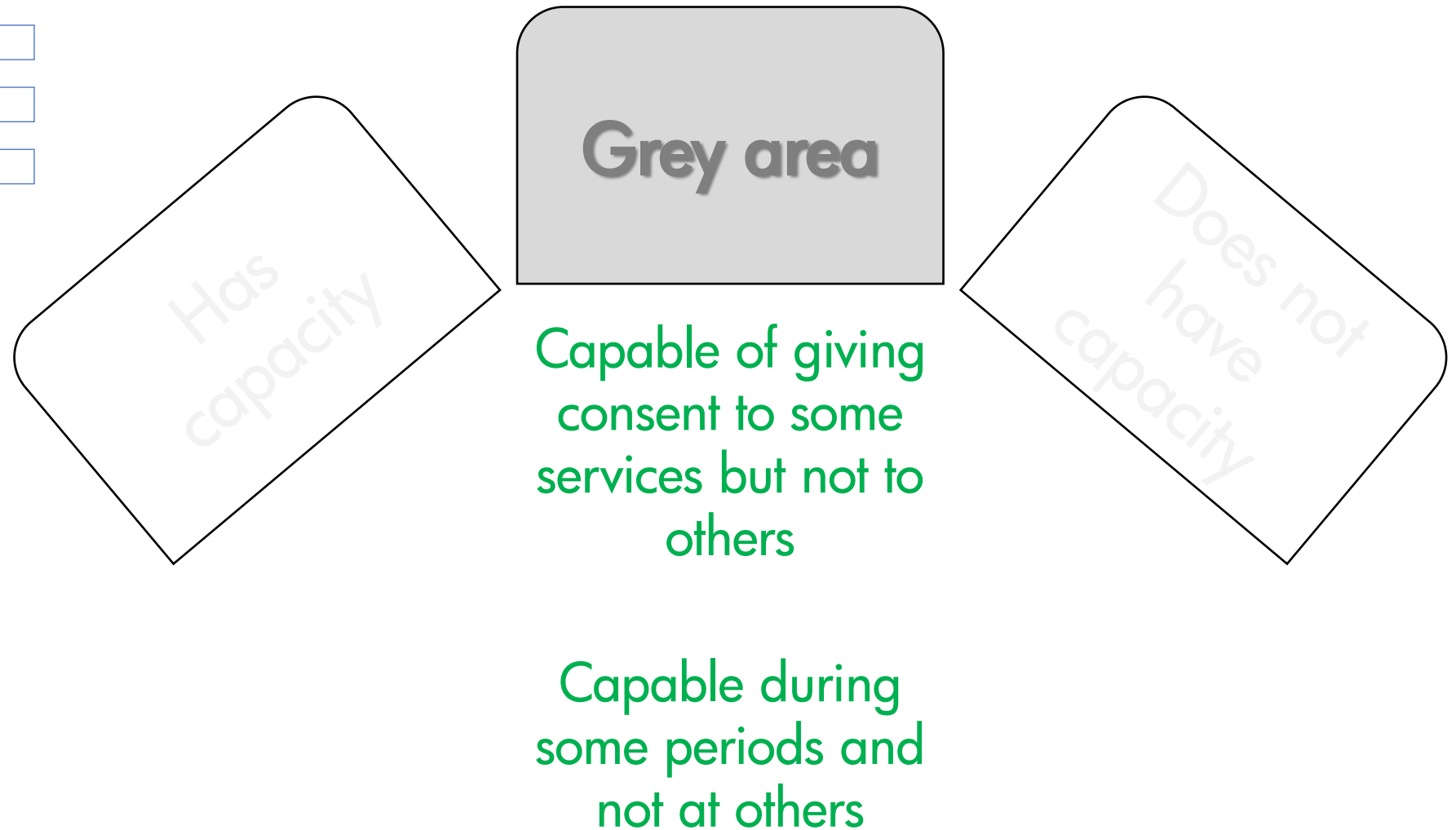
Grey area

Does not
have
capacity





2. Understanding





2. Understanding

Definition of Capacity

A person is **able to understand** the information that is relevant and **able to appreciate** the reasonably foreseeable consequences of a decision or lack of decision.

Health Care Consent Act, 1996





2. Understanding

Able to Understand

- A person has the ability to **factually grasp** and **retain information**.
- A person must **demonstrate understanding** through **communication**.

(Capacity Assessment Office,
Ministry of the Attorney General of Ontario)



2. Understanding

Able to Appreciate

- Ability to **attach personal meaning** to the facts in a given situation.
- Appreciation focuses on the **reasoning process**.

(Capacity Assessment Office,
Ministry of the Attorney General of Ontario)



2. Understanding

Consent is
based on
capacity





2. Understanding

Who Determines Capacity?

- RD are responsible for determining a client's capacity based on observations
- RDs should not proceed if they question capacity
- RDs are not responsible for assessing general capacity
- Refer to another health care provider accordingly

2. Understanding

**If a client is not capable,
a substitute decision-
maker must be identified**



Hierarchy of Individuals/Agencies





**Involve
the
Client**



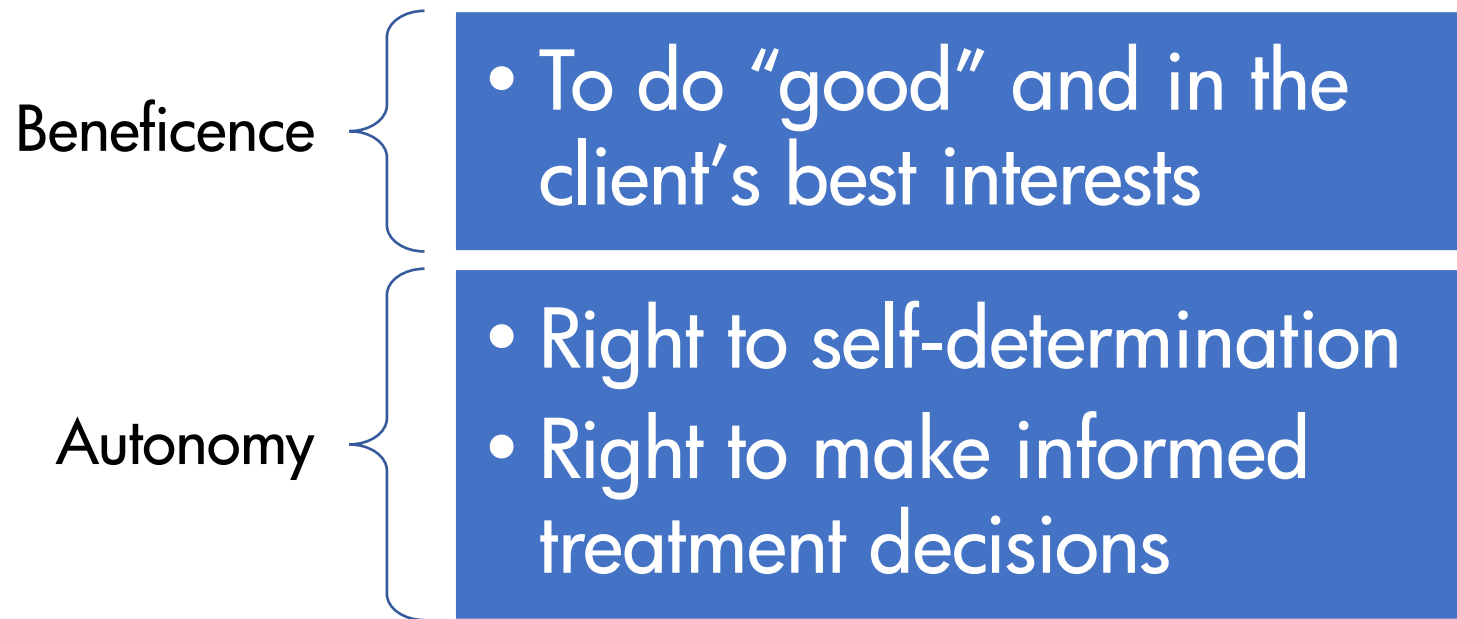


Informed Consent Process

- 1. Information
- 2. Understanding
- 3. Respect Client Decisions
- 4. Collaborative Processes



-
-
- 3. Respect Client Decisions
-



(Beauchamp & Childress, 2001)





3. Respect Client Decisions

Client's right to self-determination





3. Respect Client Decisions

Respect client refusal or
withdrawal of consent





Informed Consent Process

1. Information

2. Understanding

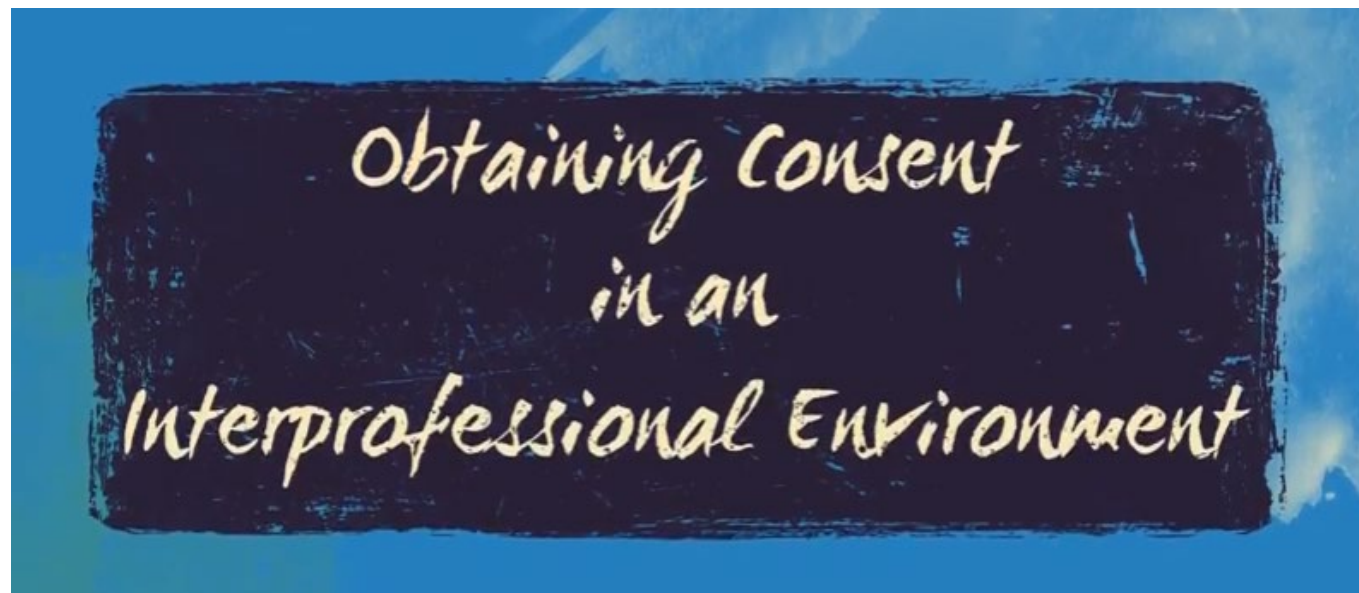
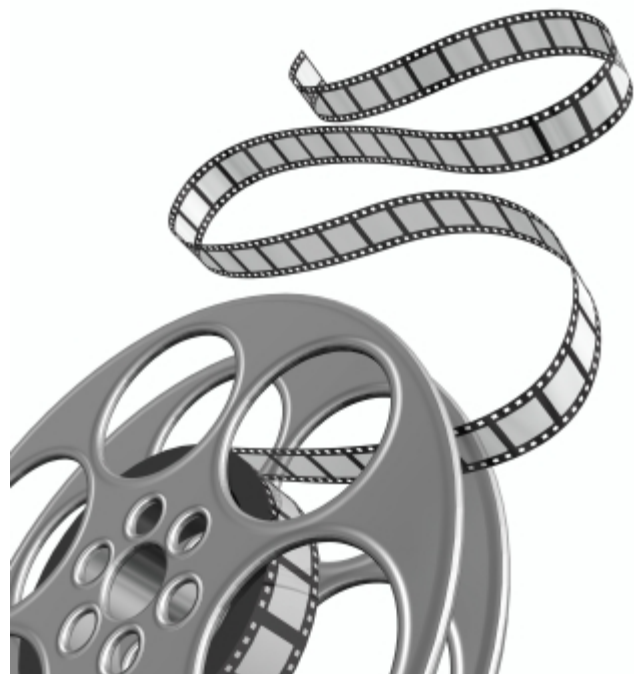
3. Respect Choice & Decision

4. Interprofessional Collaboration (IPC)





4. IPC





One health practitioner may obtain consent for the healthcare team







MD is the Treater

RD is the Proposer

RD Obtains Consent
on Behalf of MD



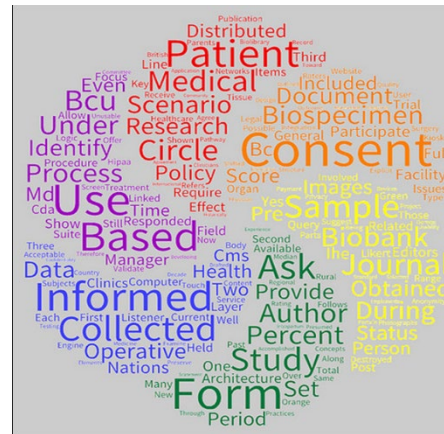
4. IPC

RDs should seek to understand their organization's processes for obtaining informed consent to treatment in a collaborative practice setting



Section IV

Express vs. Implied Consent

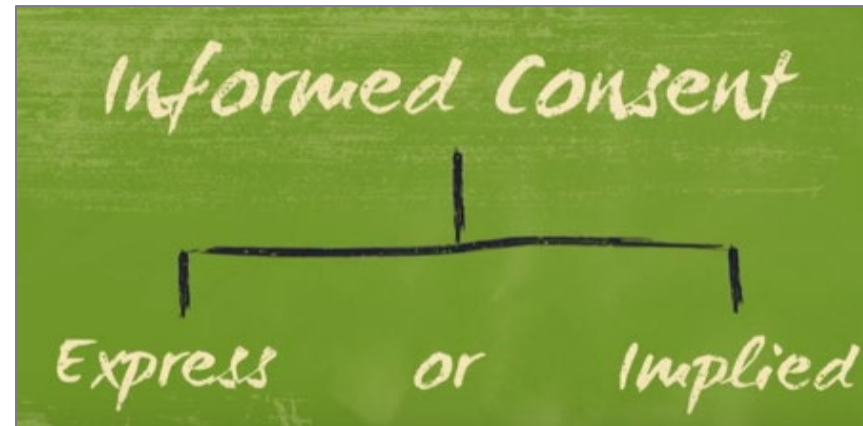




Informed Consent

Express vs Implied





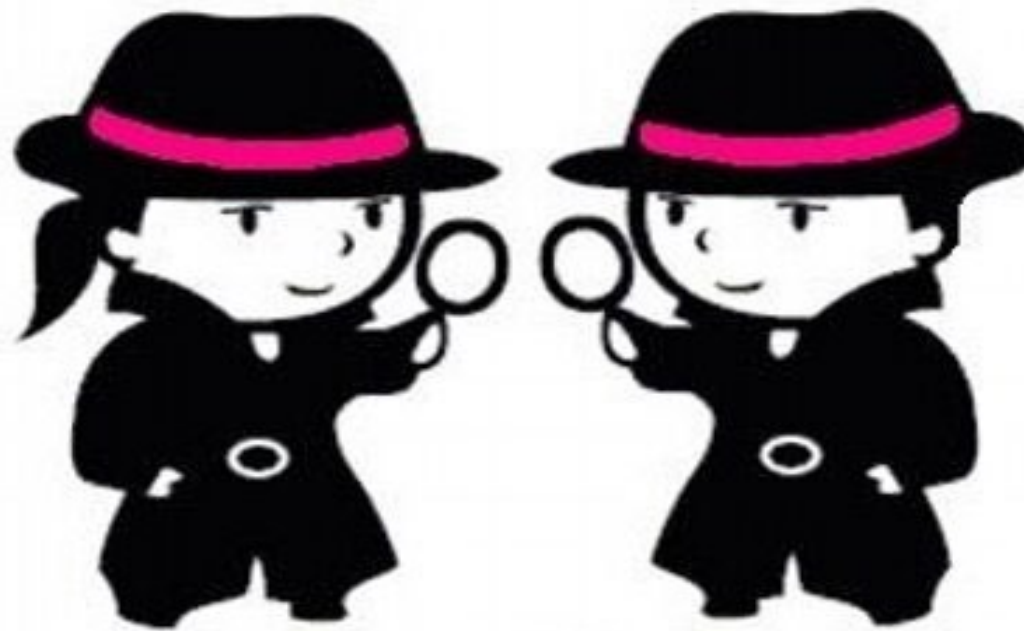


Document express consent or refusal/withdrawal of consent

Exercise professional judgment to document implied consent



Be familiar with organizational processes
for documenting consent

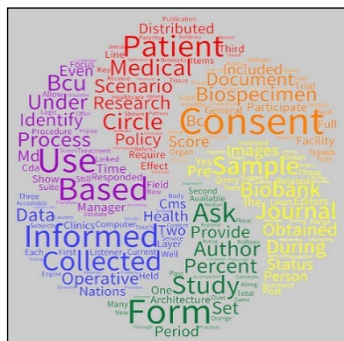


**agents_{of}
change**



Summary

- Consent is required by law:
 - *Health Care Consent Act, 1996*: Treatment, including assessments
 - Professional Misconduct Regulation, under *Dietetics Act, 1991*
- Informed consent is always required except for emergencies
- Obtaining consent is a process supporting clients to make knowledgeable and informed decisions about their treatment.
- Clients have the right to refuse or withdraw their consent to treatment at any time.
- Understand organizational processes for obtaining consent to treatment and collaborate with other healthcare providers.



Section V: Scenarios

1. [Interprofessional Collaboration](#)
2. [Custodial vs. Access Parent](#)
3. [Group Education](#)
4. [Continuation of Treatment](#)
5. [Right to Refuse](#)
6. [Questionable Capacity](#)
7. [Documenting Consent](#)





Scenario 1 – Considerations

- Is this an emergency?
- If yes, treatment can be provided without consent
- If no, consent must be obtained by baby's SDM
- Who is the proposer and implementer of treatment?
 - If physician proposes, they obtain consent or the RD obtains consent on behalf of MD
 - If RD proposes, then the RD obtains consent



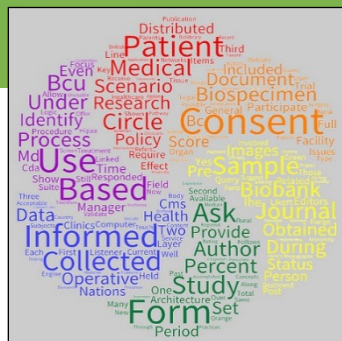
Scenario 2 – Considerations

- Who is the custodial parent?
- Custodial parent is ranked higher than access parent
- RD must obtain consent to assess and treat from Kate's mother
- Know who custodial parent is when child's parents are separated or divorced
- Consider mandatory reporting obligations



Scenario 3 – Considerations

- Is the group education considered treatment?
- If so, RDs must ensure they or another health care practitioner obtains informed consent
- If not treatment, no consent is required
- At start of class, review outline of class and conduct expectations:
 - General nature; confidentiality; no individual counselling; may freely leave session



Scenario 4 – Continuation of Treatment

A new resident has been admitted to a long-term care (LTC) home. He was transferred from hospital and the chart notes that he is on a minced diet and tolerating well. After an initial assessment, the RD agrees with the same diet order.

Is consent required to continue the diet order in the LTC home?



Scenario 4 – Considerations

- Rely on presumed consent for same treatment in different facility
- No additional consent is required



Scenario 5 - Considerations

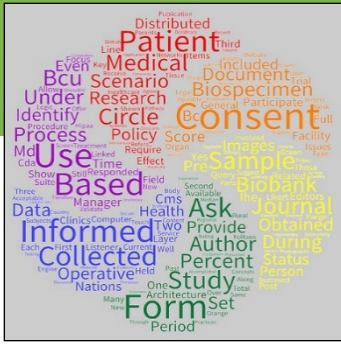
- SDM has the right to refuse treatment
- Refusal must be informed
- SDM must act in client's best interests (which can include known wishes of client when competent)
- Respect SDM decision unless reason to question
- Exception under section 37 of HCCA



Scenario 6 – Considerations

- Does the client have capacity to consent to nutrition care?
- Establish if client already has substitute decision-maker
- Suggest a friend/family member accompany client
- Refer to primary care provider for capacity assessment





Scenario 7 – Documenting Consent

During an initial assessment in a CHC, an RD needs to take a waste-hip circumference of a client. The RD explains the process and the client then moves her clothes to ensure accuracy. Measurements are taken and goals for the client's nutrition care plan are established. The client agrees to work on these goals.

What are the RD's responsibilities for documenting consent?



Scenario 7 – Considerations

- Rely on implied consent for waist-hip circumference
- Use professional judgment when documenting implied consent
- Document implied consent in sensitive situations
- Oral express consent obtained for nutrition care plan
- RDs must always document express consent



Resources

- [Jurisprudence Handbook for Dietitians in Ontario](#). (2015). Chapter 6 & 7
- [Standards of Consent](#) (2017)
- résumé newsletter articles:
 - [Changes in the Plan of Treatment & Consent](#) (2007)
 - [Documenting Consent](#) (2009)
 - [Managing Conflicts Between RDs & Substitute Decision-Makers](#) (2009)
 - [Consent to Treatment Based on Capacity, Not Age](#) (2011)
 - [Consent Basics](#) (2013)
 - [Complex Issues & Consent to Treatment](#) (2013)
 - [Cultural Competence & Informed Consent](#) (2013)





References

- *Health Care Consent Act, 1996.* <https://www.ontario.ca/laws/statute/96h02>
- *Dietetics Act, 1991, Professional Misconduct Regulation.*
<https://www.ontario.ca/laws/regulation/930680>
- College of Dietitians of Ontario. (2016). *Standards of Consent.*
<http://www.collegeofdietitians.org/Resources/Standards/NormesConsentmentFevrier2016.aspx>
- College of Dietitians of Ontario. (2017). Standards for Record Keeping.
<https://www.collegeofdietitians.org/Resources/Standards/Record-Keeping.aspx>
- Capacity Assessment Office, Ministry of the Attorney General of Ontario.
<https://www.attorneygeneral.jus.gov.on.ca/english/family/pgt/capacityoffice.php>





Please feel free to
contact the College's
Practice Advisory Service:

practiceadvisor@collegeofdietitians.org

416-598-1725; 1-800-668-4990
ext. 397