If an informed consent form is used, what information should appear on the report?

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Acknowledgment:

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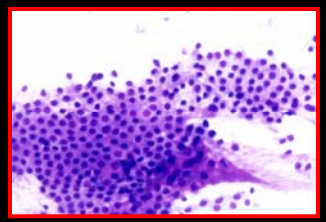

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Informed consent is the communication process between a patient and physician that results in the patient's agreement to undergo a particular procedure or treatment.

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- Regulations governing informed consent vary greatly between states.
- Therefore providers performing FNA need to design informed consent forms based upon individual state regulations.
- Failure to obtain adequate informed consent renders a physician liable for negligence or battery and constitutes medical malpractice.

If an informed consent form is used, what information should appear on the report?

- The form should be written clearly without unnecessary “medical terms” so that the patient fully understands the procedure.
- Providing written information (e.g. brochure) may increase patient comprehension.

If an informed consent form is used, what information should appear on the report?

- The form should explain:
  - The thyroid FNA procedure
  - Potential risks and complications
    - Especially the most common complications, hematoma and site infection.
  - Mentioning the possibility of a non-diagnostic sample, and the possibility of false negative and false positive results is discretionary.

If an informed consent form is used, what information should appear on the report?

- Controversies:
  - None for round 1
  - Round 2:
    - "It is a great idea to put *false-negative rates* and *false-positive rates* on the informed consent, so that patients will not expect 100% accuracy in thyroid FNA. They can refuse biopsy if they demand 100% accuracy. These rates are much better to put in the informed consent with patient's signature prior to biopsy than put on the pathology reports after the biopsy in my opinion."

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Conclusions:

- The form should be user friendly and explain:
  - The thyroid FNA procedure
  - Potential risks and complications
    - Especially the most common complications, hematoma and site infection.
  - Mentioning the possibility of a non-diagnostic sample, and the possibility of false negative and false positive results is discretionary.

Discussion