

		<b>Policy Title:</b>	Obtaining Informed Consent from Research Subjects
<b>Effective Date:</b>	March 3, 2017	<b>Policy Number:</b>	MHC_RP0115
<b>Review Date:</b>	March 3, 2017	<b>Section:</b>	Human Research Protections Program
<b>Revised Date:</b>	February 14, 2017	<b>Oversight Level:</b>	Corporate
<b>Administrative Responsibility:</b>		Corporate Director, HRPP Institutional Official, HRPP	

### 1. Purpose

1.1. The purpose of this policy is to define the requirements for obtaining and documenting informed consent of research subjects.

### 2. Scope

2.1. Non-exempt human subject research and clinical investigations reviewed by the McLaren Health Care Institutional Review Board (MHC IRB) at a convened meeting are subject to this policy.

### 3. Definitions

3.1. Interpreter - person who accompanies researchers to convey verbal information to another person in their native language.

3.2. Legally Authorized Representative - An individual or body authorized by a court of competent jurisdiction as the Legal Guardian of an incapacitated person, pursuant to a court order that grants the Legal Guardian the Authority to approve the ward's participation in medical research studies.

3.2.1. A Legally Authorized Representative is also a properly designated patient advocate, who has been given the authority to approve the patient's participation in medical research studies.

3.3. Short Form - a written document, in the participant's native language, stating that the elements of informed consent required by 45 CFR 46.116 and/or 21 CFR 50.25 have been presented to and are understood by the subject or the subject's legally authorized representative.

3.4. Refer to Appendix I "Definitions" for additional information.

### 4. Policy

4.1. When employees or agents of McLaren Health Care and its subsidiary hospitals conduct human subject research at McLaren and its subsidiary hospitals, informed consent will be obtained in compliance with all applicable federal and state

regulations and the requirements of McLaren's Human Research Protections Program (MHC HRPP).

4.2. No investigator conducting research under the auspices of the MHC HRPP may involve a human being as a subject in research without obtaining the legally effective informed consent of the subject or the subject's legally authorized representative unless a waiver of consent has been approved by the IRB.

4.3. A subject must have the capacity to consent to his or her own participation in a research activity if s/he demonstrates an appreciation:

4.3.1. That the activity is research.

4.3.2. Of the risks and benefits of a study.

4.3.3. Of the study procedures and requirements.

4.3.4. Of the alternatives that are available if not participating.

4.3.5. That, by choosing not to participate, this decision will be accepted without penalty.

4.4. If someone other than the investigator conducts the informed consent process and obtains informed consent from a subject or the subject's representative, the investigator must formally and prospectively designate in writing in the application for IRB approval.

4.5. The IRB will ensure, as part of its review, that the information in the consent document and process is consistent with the research plan and, when applicable, the HIPAA authorization.

4.6. The IRB will evaluate the informed consent document, the consent process, and the procedures for documenting informed consent to ensure that adequate informed consent is obtained from participants.

## 5. Procedure

5.1. The following procedures describe the requirements for obtaining consent from participants in research conducted under the auspices of MHC HRPP.

### 5.2. Basic Requirements:

5.2.1. The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided for by the Federal regulations and MHC HRPP.

5.2.2. Investigator or designee must obtain consent prior to entering a subject into a study, gathering data on a subject, and/or conducting any procedures required by the research plan, unless consent is waived by the IRB.

5.2.3. Investigator or designee are required to obtain legally effective informed consent from a subject or the subject's Legally Authorized Representative.

#### 5.2.3.1. Vulnerable Populations:

5.2.3.1.1. At the time of initial review the IRB will consider the scientific and

ethical reasons for including vulnerable subjects in research.

**5.2.3.1.2.** The IRB may determine and require that, when appropriate, additional safeguards be put into place for vulnerable subjects, such as those without decision-making capacity.

**5.2.3.1.3.** Children who are wards of the State or any other agency, institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, **only if such research is:**

**5.2.3.1.3.1.** related to their status as wards; or

**5.2.3.1.3.2.** conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

**5.2.3.1.4.** If the research meets the condition(s) above, an advocate must be appointed for each child who is a ward (one individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or in *loco parentis*.

**5.2.3.1.4.1.** The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

**5.2.4.** The IRB is allowed to waive parental permission by determining that the criteria for waivers or alterations are met.

**5.2.5.** The investigator or designee must obtain consent using a valid IRB approved informed consent document.

**5.2.6.** When informed consent is required, it must be sought prospectively and properly documented.

**5.2.7.** The investigator or designee must carry out the informed consent process by:

**5.2.7.1.** disclosing to the prospective human subject information needed to make an informed decision;

**5.2.7.2.** facilitating the understanding of what has been disclosed, i.e. ask open ended questions to validate understanding; and

**5.2.7.3.** promoting the voluntariness of the decision about whether or not to participate in the research.

**5.2.8.** Informed consent is more than just a signature on a form. It is a process of information exchange to include reading and signing the informed consent document. The informed consent process is the critical communication link between the prospective Human Subject and an Investigator or designee, beginning with the initial approach of an Investigator or designee and continuing

through the completion of the research study.

**5.2.9.** Investigator or designee must have received the appropriate training and be knowledgeable about the study Protocol in order that they may answer questions to help provide understanding to the study participant or potential study potential study participant.

**5.2.10.** The exchange of information between the Investigator or designee and study participant can occur via one or more of the following modes of communication, among others;

**5.2.10.1.** face to face interaction,

**5.2.10.2.** mail;

**5.2.10.3.** email;

**5.2.10.4.** electronic device such as eConsenting;

**5.2.10.5.** telephone; or

**5.2.10.6.** fax.

**5.2.11.** Obtaining informed consent should be obtained face to face between the Investigator or designee and the potential study participant/study participant. However, if the study design allows for obtaining informed consent via phone, fax, e-mail or any other electronic devices, this method must be approved by the IRB.

**5.2.12.** Investigator or designees must obtain consent prior to entering a subject into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB.

**5.2.13.** Sample or draft consent documents may be developed by a Sponsor or cooperative study group. However, the IRB-of-record is the final authority on the content of the consent documents that is presented to the prospective study subjects.

### **5.3. Informed Consent Process**

**5.3.1.** Only individuals approved by the IRB can obtain consent.

**5.3.2.** Informed consent must be obtained under the following circumstances:

**5.3.2.1.** The decision-making capacity of a potential research subject should be evaluated when there are reasons to believe that the subject may not be capable of making voluntary and informed decisions about research participation.

**5.3.2.2.** Informed consent may only be obtained from subjects who have the legal and mental capacity to give consent. For subjects lacking this capacity, consent must be obtained from a legal guardian or a legally authorized representative. Proof of LAR may contain:

**5.3.2.2.1.** Information related to the potential participants wishes in regards to research.

5.3.2.2.2. If no legal documentation exists (i.e. advanced directive, durable power of attorney), proof of identity and, when possible, proof of relationship to the potential participant should be obtained. This could be, but is not limited to:

5.3.2.2.2.1. Driver's License

5.3.2.2.2.2. State ID

5.3.2.2.2.3. Birth Certificate

5.3.2.2.2.4. Passport

5.3.2.2.2.5. Proof of shared residence

5.3.2.3. The informed consent process shall be sought under circumstances that provide the subject (or legally authorized representative) with sufficient opportunity to consider whether or not to participate.

5.3.2.4. The informed consent process shall be sought under circumstances that minimize the possibility of coercion or undue influence.

5.3.2.5. The informed consent information must be presented in language that is understandable to the subject (or legally authorized representative). To the extent possible, the language should be understandable by a person who is educated to 10th grade level and layman's terms shall be used in the description of the research.

5.3.2.6. For subjects whose native language is not English, informed consent must be obtained in a language that is understandable to the subject (or the subject's legally authorized representative).

5.3.2.6.1. In accordance with this policy, the IRB requires that the informed consent process include a reliable translator when the prospective subject does not understand the language of the person who is obtaining consent.

5.3.2.7. The informed consent process may not include any exculpatory language through which the subject is made to waive, or appear to waive any of the subject's legal rights or through which the investigator, the sponsor, the Organization or MHC employees or agents are released from liability for negligence or appear to be so released.

5.3.2.8. The PI is responsible for insuring that each prospective subject is adequately informed about all aspects of the research and understands the information provided.

5.3.2.9. The individual who obtained the informed consent should be the signatory for the documented process.

#### 5.4. Basic Elements of Informed Consent

5.4.1. To be valid, the consent process must provide the following basic elements of information to potential subjects:

5.4.1.1. A statement that the study involves research, an **explanation** of the **purposes** of the research and the expected duration of the subject's

participation, a description of the **procedures** to be followed, and identification of any procedures which are experimental; a description of any reasonably foreseeable risks or discomforts to the subject;

**5.4.1.2.** A description of any **benefits** to the subject or to others which may reasonably be expected from the research;

**5.4.1.3.** A disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject;

**5.4.1.4.** A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained;

**5.4.1.5.** For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available;

**5.4.1.6.** An explanation of whom to contact on the research team for answers to pertinent questions about the research or to voice concerns or complaints about the research, and whom to contact in the event of a research-related injury to the subject;

**5.4.1.7. Contact information for the IRB** to voice concerns or complaints about the research; to obtain answers to questions about their rights as a research participant; in the event the research staff could not be reached; and in the event the subject wishes to talk to someone who is unaffiliated with a specific research study.

**5.4.1.8. Contact information for the Investigator** to obtain answers to questions about the research study, such as scientific issues, how to do any part of it or to report an injury.

**5.4.1.9. A statement that participation is voluntary**, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

**5.4.1.10.** For FDA-regulated studies, the possibility that the Food and Drug Administration may inspect the records needs to be included in the statement regarding subject confidentiality.

**5.4.2. Additional elements of informed consent to be applied, as appropriate:**

**5.4.2.1.** A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable. (For example: Include when the research involves investigational test articles or other procedures in which the risks to subjects is not well known.)

**5.4.2.2.** A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. (For example: Include when the research involves pregnant women or women of childbearing potential and the risk to fetuses of the drugs, devices, or other procedures involved in the research is not well known.)

**5.4.2.3.** Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. (For example: Include when there are anticipated circumstances under which the investigator may terminate participation of a subject.)

**5.4.2.4.** Any additional costs to the subject that may result from participation in the research. (For example: Include when it is anticipated that subjects may have additional costs.)

**5.4.2.5.** The consequences of a subject's decision to withdraw from the research.

**5.4.2.6.** Procedures for orderly termination of participation by the subject. (For example: Include when the protocol describes such procedures)

**5.4.2.7.** A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

**5.4.2.8.** The approximate number of subjects involved in the study.

## **5.5. Documentation of Informed Consent**

**5.5.1.** Except as provided in Section 5.7 of this document, informed consent must be documented by the use of a written consent form approved by the IRB.

**5.5.1.1.** Informed consent is documented by the use of a written consent form approved by the IRB and signed and dated by the person performing consent discussion and by the subject or the subject's legally authorized representative at the time of consent.

**5.5.1.2.** If the investigator plans to use audio or videotapes, computer video presentations, or written materials, to promote understanding, these materials must be provided to the IRB for review. If the investigator intends to use audio or video recordings to document assent, provisions to ensure the security of the recordings should be described to the IRB. If the investigator will use an assent form to document assent, this must be submitted to the IRB for review and approval first.

**5.5.1.3.** A copy of the signed and dated consent form must be given to the subject. The investigator should retain the signed original in the research records.

**5.5.1.4.** The investigator or designee should document that the process was handled correctly via progress note or checklist. Include in the research record a contemporaneous note or checklist describing consent process and statement that subject received a copy of the signed consent.

**5.5.1.5.** The consent form may be either of the following:

**5.5.1.5.1.** A written consent document that embodies the basic and required additional elements of informed consent. The consent form may be read to the subject or the subject's legally authorized representative, but the subject or representative must be given adequate opportunity to read it before it is signed; or

5.5.1.5.2. A short form may be used if the common language of local study participants is English, but the potential exists to enroll a subject or subjects that do not speak fluent English. In order to use the short form, all of the following must be in place:

5.5.1.5.2.1. The oral presentation and the written short form document must be in a language understandable to the subject;

5.5.1.5.2.2. There must be a witness to the oral presentation;

5.5.1.5.2.3. The entire consent process must be witnessed by an individual who is fluent in both English and the language understandable to the *subject* or the *subject's legally authorized representative*. The interpreter may serve as the witness. 5.5.2.4. the IRB must approve a written summary of what is to be said to the subject (the IRB-approved English language informed consent document may serve as the summary);

5.5.1.5.2.4. The short form document is signed by the subject;

5.5.1.5.2.5. The witness must sign both the short form and a copy of the summary;

5.5.1.5.2.6. The person obtaining consent must sign a copy of the summary;

5.5.1.5.2.7. A copy of the summary and a copy of the short form must be given to the subject or representative.

5.5.1.5.2.8. The original signed summary and the original signed "short form" should be placed in the subject's research record and a copy of both placed in his/her medical record, if appropriate.

5.5.1.6 The IRB must receive all foreign language versions of the short form document as a condition of approval.

5.5.1.6.1 Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

## 5.6. Subject Withdrawal or Termination

5.6.1. For a variety of reasons, a subject enrolled in a research study may decide to withdraw from the research or an investigator may decide to terminate a subject's participation in research regardless of whether the subject wishes to continue participating.

5.6.2. In these circumstances, questions sometimes arise about:

5.6.2.1. whether the investigator may use, study, or analyze already collected data about the subject who withdraws from the research or whose participation



is terminated by the investigator; and

5.6.2.2. whether the investigator can continue to obtain data about the subject and if so, under what circumstances.

5.6.3. Investigators must plan for the possibility that subjects will withdraw from research and include a discussion of what withdrawal will mean and how it will be handled in their research protocols and informed consent documents.

5.6.4. Regulatory requirements regarding the retention and use of data after subject withdrawal or termination differ between research subject to FDA regulations and that not subject to FDA regulations.

5.6.4.1. Under applicable FDA law and regulations, data collected on human subjects enrolled in an FDA-regulated clinical trial up to the time of subject withdrawal must remain in the trial database in order for the study to be scientifically valid.

5.6.4.2. For research not subject to FDA regulations, investigators, in consultation with the funding agency, can choose to honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis.

5.6.5. When seeking informed consent from subjects, the following information regarding data retention and use must be included:

5.6.5.1. For FDA-regulated clinical trials, when a subject withdraws from a study, the data collected on the subject to the point of withdrawal remain part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.

5.6.5.2. For research not subject to FDA regulations, the investigator should inform subjects whether the investigator intends to either:

5.6.5.2.1. retain and analyze already collected data relating to the subject up to the time of subject withdrawal; or

5.6.5.2.2. honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis.

5.6.6. Sometimes, a subject wants to withdraw from the primary interventional component of a study, but is willing to allow the investigator to continue other research activities described in the IRB-approved protocol and informed consent document that involve participation of the subject, such as:

5.6.6.1. obtaining data about the subject through interaction with the subject (e.g., through follow-up interviews, physical exams, blood tests, or radiographic imaging); or

5.6.6.2. obtaining identifiable private information from the subject's medical, educational, or social services agency records or from the subject's healthcare providers, teachers, or social worker.

5.6.7. When a subject's withdrawal request is limited to discontinuation of the primary interventional component of a research study, research activities

involving other types of participation for which the subject previously gave consent may continue.

**5.6.7.1.** Investigator should ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study.

**5.6.7.2.** Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through noninvasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.

**5.6.8.** If a subject withdraws from the interventional portion of the study, but agrees to continue follow-up of associated clinical outcome information as described in the previous paragraph, the investigator must obtain the subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents would be required.

**5.6.9.** If a subject a) withdraws from the interventional portion of a study, (b) does not consent to continued follow-up of associated clinical outcome information, and (c) does not request removal of their data, the investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent.

**5.6.10.** An investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status

## **5.7. Waiver of Informed Consent**

**5.7.1.** The IRB is allowed to waive or alter the consent process by determining that the regulatory criteria for waivers or alterations of the consent process are met and that the research is not regulated by the FDA.

**5.7.2.** An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above; or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

**5.7.2.1.** The research involves no more than minimal tangible or intangible risk to the subjects;

**5.7.2.2.** The waiver or alteration will not adversely affect the rights and welfare of the subjects;

**5.7.2.3.** The research could not practicably be carried out without the waiver or alteration; and

**5.7.2.4.** Whenever appropriate, the subjects must be provided with additional pertinent information after participation.

**5.7.3.** An IRB may approve a consent procedure that does not include, or that

alters, some or all of the elements of informed consent; or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

**5.7.3.1.** The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

**5.7.3.1.1.** Public benefit or service programs.

**5.7.3.1.2.** Procedures for obtaining benefits or services under those program.

**5.7.3.1.3.** Possible changes in or alternatives to those programs or procedures; or

**5.7.3.1.4.** Possible changes in methods or levels of payment for benefits or services under those programs.

**5.7.3.2.** The research could not practicably be carried out without the waiver or alteration.

**5.7.4.** FDA regulations do not provide for waivers of informed consent except in emergency situations.

## **5.8. Waiver of Documentation of Informed Consent**

**5.8.1.** The IRB is allowed to waive or alter the consent process by determining that the regulatory criteria for waivers or alterations of the consent process are met and that the research is not regulated by the FDA.

**5.8.1.1.** When the IRB considers waiving the requirement to obtain written documentation of the consent process, the IRB reviews a written description of the information that will be provided to participants.

**5.8.1.2.** When granting waivers of the requirement to obtain written documentation of the consent process, the IRB considers requiring the researcher to provide participants with a written statement regarding the research.

**5.8.2.** The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either that the:

**5.8.2.1.** Only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality; or

**Note 1:** Subjects must be asked whether they want documentation linking them with the research, and their wishes must govern. (Example: domestic violence research where the primary risk is discovery by the abuser that the subject is talking to researchers.)

**Note 2:** In order to waive written documentation of consent where the only record linking the participant and the research would be the consent document, the IRB has to determine that the research was not FDA-regulated.

**5.8.2.2.** The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required

outside of the research context. Procedures such as non-sensitive surveys, questionnaires and interviews generally do not require written consent when conducted by non-researchers.

**5.8.3.** In cases in which the documentation requirement is waived, the IRB requires the investigator to provide in the application materials a written summary of the information to be communicated to the subject, and the IRB will consider whether to require the investigator to provide subjects with a written statement regarding the research.

## **5.9. Consent Monitoring**

**5.9.1.** In reviewing the adequacy of informed consent procedures for proposed research, the IRB may on occasion determine that special monitoring of the consent process by an impartial observer (consent monitor) is required in order to reduce the possibility of coercion and undue influence, ensure that the approved consent process is being followed, or ensure that subjects are truly giving informed consent.

**5.9.2.** Such monitoring may be particularly warranted for:

**5.9.2.1.** High risk studies.

**5.9.2.2.** Studies that involve particularly complicated procedures or interventions.

**5.9.2.3.** Studies involving highly vulnerable populations (e.g., ICU patients, children).

**5.9.2.4.** Studies involving study staff with minimal experience in administering consent to potential study participants, or

**5.9.2.5.** Other situations when the IRB has concerns that consent process is not being conducted appropriately.

**5.9.3.** Monitoring may also be appropriate as a corrective action where the IRB has identified problems associated with a particular investigator or a research project.

**5.9.4.** If the IRB determines that consent monitoring is required, the IRB Chair and the Corporate Director of HRPP will develop a monitoring plan and submit it to the IRB for approval.

**5.9.5.** The consent monitoring may be conducted by IRB staff, IRB members or another party, either affiliated or not with the institution. The PI will be notified of the IRB's determination and the reasons for the determination.

**5.9.6.** Arrangements will be made with the PI for the monitoring of the consent process for a specified number of subjects. When observing the consent process, the monitor will determine:

**5.9.6.1.** Whether the informed consent process was appropriately completed and documented,

**5.9.6.2.** Whether the participant had sufficient time to consider study participation,

5.9.6.3. Whether the consent process involved coercion or undue influence,

5.9.6.4. Whether the information was accurate and conveyed in understandable language, and

5.9.7. Whether the subject appeared to understand the information and gave their voluntary consent.

5.9.8. Following the monitoring, a report of the findings will be submitted to the IRB, which will determine the appropriate action to be taken.

## 6. Responsibilities

### 6.1. IRB:

6.1.1. The IRB will evaluate whether the proposed plan to assess capacity to consent is adequate including consideration of state and local law and organizational policy.

6.1.2. The IRB will evaluate the informed consent document, the consent process, and the procedures for documenting informed consent to ensure that adequate informed consent is obtained from participants.

### 6.2. Investigator

6.2.1. The investigator and research staff must have adequate procedures in place for assessing and ensuring subjects' capacity, understanding, and informed consent or assent.

6.2.2. The investigator must obtain the legally effective informed consent of the subject or the subject's legally authorized representative prior to procedures unless (1) the research is exempt under 45 CFR 46.101(b); (2) the IRB finds and documents that informed consent can be waived (45 CFR 46.116(c) or (d)); or (3) the IRB finds and documents that the research meets the requirements of the HHS Secretarial waiver under 45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings.

6.2.3. The investigator will obtain consent from all eligible subjects ensuring equal access for potential participants.

## 7. References:

7.1. 21 CFR 56

7.2. 21 CFR 50

7.3. 45 CFR 46

7.4. Appendix I "*Definitions*"

8. Previous Revisions: March 25, 2013, November 20, 2015

9. Supersedes Policy: None

10. Approvals:

MHC Institutional Review Board initial approval: January 18, 2013

MHC Institutional Review Board acknowledgment: December 4, 2015, March 3, 2017

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Institutional Official of Research

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Date