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Section 4: Meeting Process

4.0 Requirements for Quorum

The conduct of official IBC business occurs at convened meetings that must include a quorum of members in order for the meeting to be held. The IBC defines a "quorum" as more than half the regular voting members. A protocol is approved only if a quorum is present, and if more than 50% of the quorum votes in favor or protocol approval. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required. Members are expected to attend the convened meetings unless they have notified the IBC Administrator in advance, that they are unable to do so. Members who fail to attend meetings on a regular basis may be removed from the committee.

4.1 Protocol Review

For the protocol to be reviewed by the IBC prior to the convened meeting and to allow ample time for Principal Investigator to respond to comments or any explicit conditions, a submission deadline (14 days) is also listed on the Research Integrity & Education IBC website: www.du.edu/orsp/research-compliance. The protocols must be submitted by the submission deadline or the protocol will be held until the next convened meeting.

4.1.1 Full Review

New protocols and approved protocols submitted with significant changes (Section 3.5) require a full committee review and will be assigned to designated reviewers. Review comments, if any, will be sent to the Principal Investigator. The Principal Investigator must respond to any queries or questions.

4.1.2 Administrative Review

Protocol amendments submitted with non-significant changes (Section 3.5) and continuing progress/annual reviews, submitted with no changes, or non-significant changes may be reviewed administratively and approved. Administrative approval may occur outside a convened IBC meeting. The IBC will be notified of all administrative approvals.

4.2 Procedures

IBC meetings are held quarterly. Rescheduling may occur due to inability to achieve a quorum of members and non-scheduled meetings may be called by the IBC Chair to discuss matters that arise and require immediate resolution. The IBC Administrator is responsible for assuring that a meeting room is located and scheduled and that all other arrangements for the meeting are made.

At the scheduled time and upon reaching a quorum, the IBC Chair will call the meeting to order and follow an agenda prepared prior to the meeting. The typical order of the agenda is as follows:

- Call to order.
- Chair's reminder to members of conflict of interest requirements.
- Approval of the previous month's meeting minutes.
- IBC related announcements.
- Educational items for discussion.
- Next meeting announcement.
- Protocol Review.
- Meeting adjournment.

When reviewing protocols for initial review or periodic review of ongoing research activities, there are several activities that the IBC must carry out on behalf of the University:

- Conduct assessment of the containment levels required by the *NIH Guidelines.*
- Assessing the facilities, procedures, practices, and training and expertise of personnel involved in research with recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents or toxins.
- Ensure compliance with the *NIH Guidelines* and the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

In reviewing proposed recombinant or synthetic nucleic acid molecules research, the *NIH Guidelines*, in Sections II and III, cite a number of matters that the IBC should consider that include:

- Agent characteristics (e.g. virulence, pathogenicity, environmental stability).
- Types of manipulations planned.
- Source(s) of nucleic acid molecules sequences (e.g., species).
- Nature or function of the gene encoded by recombinant or synthetic nucleic acid molecule sequences (e.g., structural gene, oncogene).
- Host(s) and vector(s) to be used.
- Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced.
- Change in biosafety risk for organism formed through combination of sequences from multiple sources or synergistic effect of combining transgenes resulting in new phenotype.
- Containment conditions to be implemented.
- Applicable section(s) of the *NIH Guidelines* (e.g., Section II-D-1, Section III-E-1, etc.).

4.3 Possible Review Outcomes

All non-exempt protocols are presented and discussed individually and the IBC votes on the disposition of the protocol. Possible outcomes include:

- **Approval** – When the IBC has determined that all review criteria, based on the IBC Policies and federal-mandated regulations have been adequately addressed by the Principal Investigator, the IBC may approve the research, thus providing the Principal Investigator permission to perform the research.
- **Deferred – Modifications Required** – This status is used for protocols for which all required information has not been received, required training has not been completed and/or there are remaining issues or questions regarding the safety of the protocol.
- **Tabled** – If the protocol requires clarification in order for the IBC to make judgment, certain committee members with certain expertise is not present, the IBC wishes to seek external consultation, or any of a number of other reasons prevents the IBC from conducting its review, then the IBC may wish to defer or table review.
- **Withhold Approval**- When the IBC determines that a protocol has not adequately addressed all of the requirements of the IBC Policies and regulations as applicable, the IBC may withhold approval.

4.4 Conflict of Interest

Both the *NIH Guidelines* and the IBC Policies state that no IBC member may participate in the IBC review or approval who have a conflict of interest in the project (e.g., are acting as the Principal Investigator, have financial interest in the project). All Principal Investigators and/or IBC members are required to disclose any conflicts of interest.

Should an IBC member declare involvement in any way in a research protocol under review by the IBC, or state a conflict of interest with a research protocol, then the member(s):

- Are excluded from discussion and voting except to provide information requested by the IBC.
- Will be asked to leave the meeting room for discussion and voting.
- Are not counted towards quorum.

4.5 Minutes

Review of protocols by the IBC invokes a deliberative process, and section IV-B-2-b of the *NIH Guidelines* require that the IBC meeting minutes should offer sufficient detail about the discussion of the matters that were discussed in order to document the IBC rationale for particular decisions. The IBC has some latitude in the degree of detail in these minutes.

Recorded minutes of IBC meetings are intended to reflect the substantive discussion of protocols. Minutes are intended to contain sufficient information that a reasonable person could understand the nature of the discussion. In general, the minutes should offer sufficient detail to serve as a record of major points of discussion and the Committee's rationale for particular decisions, documenting that the IBC has fulfilled its review and oversight responsibilities as outlined under Section IV-B-2-b of the *NIH Guidelines*.

Meeting minutes are not intended to provide a verbatim transcript of discussion nor to reiterate shared knowledge of the Committee such as recent discussions about a protocol in previous minutes. Historical evidence of compliance or non-compliance would

be recorded in the minutes if it were germane to the discussion. Minutes may include reference to historical discussion by the IBC from members who have served on the Committee and observed the procedures being proposed, served as reviewers for protocols involving similar procedures (where their questions were answered), or participated in past IBC discussions about the procedures.

Guidance and clarification concerning the preparation of, and the public access to, minutes of the IBC meetings has been issued by NIH/OBA:
https://osp.od.nih.gov/biotechnology/faqs-about-ibc-meetings-and-minutes/

Minutes of each IBC meeting are recorded in writing and contain:

- Date and place of meeting,
- Individuals in attendance,
- Whether and why the meeting was open or closed,
- All major motions, major points of order, and whether motions were approved,
- Protocols reviewed (identified by protocol number and protocol title), and
- The time of meeting adjournment.

In addition, in order to document the adequate fulfillment of the Committee's review and oversight responsibilities described in Section IV-B-2-b of the *NIH Guidelines*, the meeting minutes should also document the IBC's consideration of several matters described in Section II and Section III of the *NIH Guidelines* (see Section 4.2). The inclusion of this material in the meeting minutes will document the biosafety aspects of each protocol.

4.6 Principal Investigator Notification
Upon completion of the review process (**Section 3**), the Principal Investigator will receive written notification of the review decisions (approved/not approved) and whether any special conditions for approval of work is required. Included in the notification will be the IBC decision on the biocontainment/biosafety level to be used for the proposed research, any special safety considerations, applicable sections of the *NIH Guidelines*, along with the approval period (begin/end dates).

4.7 Reports to the IO
Copies of minutes and reports of laboratory incidents, accidents, spills, potential or actual exposure to infectious or biohazardous materials, and incidents of non-compliance, protocol suspensions or terminations will be forwarded to the IO, as needed and required, which could include filing a report with the Office of Biotechnology Activities or other agencies (See **Section 5**).

4.8 Meeting Frequency
Convened meetings of the IBC occur quarterly unless postponed or cancelled by the IBC Chair. Meeting schedules are typically set a year in advance and posted on the IBC website. www.du.edu/orsp/research-compliance

The Chair may call an emergency meeting of the IBC as necessary to address such issues as noncompliance or serious and/or unexpected events involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins.

4.9 Attendance of Non-Members

IBC meetings are considered open and, as such, members of the DU community and the public at large may request to attend an IBC meeting. Those who wish to attend an IBC meeting should notify the IBC Administrator in advance at (303) 871-2121 or IBCAdmin@du.edu regarding the desire to attend. While no one will be denied access to a meeting, the IBC Administrator must be made aware of additional attendees. Last minute requests may not be honored if the meeting room cannot accommodate additional attendees.